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Speakers:

-Melissa Farrell, RN, BSN, CCRC, *Director of Research, Planned Parenthood Gulf Coast* ("**PP**")

-Tram Nguyen, *Ambulatory Surgery Center Director, Planned Parenthood Gulf Coast* (**"PP Tram**")

-Anitra Beasley, MD, Physician, Planned Parenthood Gulf Coast ("PP Beasley")

-Medical Assistant, Planned Parenthood Gulf Coast ("PP Nurse")

-Two actors posing as Fetal Tissue Procurement Company ("Buyer")

frame counts are approximate

036000

Buyer: Hello, [Name]. Nice to meet you, finally.

PP: Nice to meet you.

Buyer: [Name].

PP: Nice to meet you [Name]. Come on around, I see you got to enjoy some of our traffic.

Buyer: And learning about your weather and your allergies.

PP: Are y'all miserable?

Buyer: I forgot to take my allergy medication this morning-

PP: I can offer you some Benadryl but I don't have-

Buyer: I was about to say, is there a doctor in the house?

PP: Yea, we've got allergy medicine everywhere, everyone is pretty much affected right now. That's you, no. It's not, come around, this is my office.

Buyer: Wonderful.

PP: Have a seat.

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Buyer: Do you want the door shut or?

PP: Which ever, shut, open. I don't think we're going over anything too confidential just yet. Alright, so where did you come in from?

Buyer: California, originally.

PP: Oh, California.

Buyer: In just days, we've been so many places, which state is this?

PP: We have monitors that do that. Especially some of the monitors who do our clinical trials, that are not regional. They just go everywhere, study is rolling heavily, quickly, they go from state to state to state, and they're like where am I?

Buyer: So I apologize if I'm asking- [Name] was catching me up- was there someone where on site that knows how to go through and find what we need? And Tram? Right. Tram is who I met the national meeting when we were exhibiting there, a few weeks ago.

PP: Maybe ya'll- let me give you my business cards. Maybe you can tell me a little bit more about what your needs are and what-

Buyer: Can I just go through a checklist with you-

PP: Sure.

Buyer: -before my allergies strike?

PP: Where did I put those meds? One second. Hello, do you have any allergy meds that are non-drowsy? Like Zyrtec or Allegra D or Allegra or anything like that? That's kind of funny actually. They've added some medication over in the workroom, ibuprofen, and naproxen, and all that other good stuff, would you id checking that because our guests are suffering. Ok. Allegra has got some allegra, I love it. Ok, thanks. Bye. We have a staff member named Allegra and she said: "I gave my last allegra to Allegra." That's kind of funny actually. But, go ahead, she's going to run something up for us.

Buyer: I just want to go through- try to get an idea of the process and all that. And just to back up-

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Buyer: We understand that your affiliate has done tissue collection for quite a long time.

PP: Tissue collection.

Buyer: So you have a system and everything-

PP: -from residual specimens to discarded specimens, through urine, blood, you probably know fetal tissue doesn't fall under the same category. It does but it doesn't,-

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PP: -because of the nature of fetal tissue we also have some of our policies regarding it.

Buyer: Affiliate specific, yea.

PP: That are specific, well specific to any Planned Parenthood in the United States, in terms of fetal tissue donations. So, Planned Parenthood that you would work with for fetal tissue, we all follow the same procedure. So, additional documentation-

Buyer: It's just because we've found a lot of different variation so far and Deb Nucatola is kind of our contact on the national level -

PP: Right.

Buyer: And so actually it's not really a national part, it's kind of influx right now.

PP: The paperwork piece of it, the documentation to have in place is consistent, how that's implemented facility to facility is different, because of state laws.

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PP: Texas has some of the strictest laws in the country.

Buyer: Really?

PP: Oh, yea.

Buyer: I mean abortion care in general, we all know exactly what's going on.

PP: Yes, so and with fetal tissue all the way up to in vitro diagnostics, where we collect additional specimens, drug studies, generally we don't deal with anything phase one, most phase two we don't, mostly because of the risks to our patients-most of our subjects are our patients. Phase two, it depends on the product.

Phase three. Phase four, we've done those studies post market. So, we've done vaccine trials and some, ugh the term is escaping me, coffee hasn't kicked in. It's the type of clinical trial, it's highest risk, it's drug, it's biologic category, an IRB and a bio safety monitoring committee a B.S.-I'll think about it.

Buyer: It'll come to you.

PP: It'll come to me in a minute. The whole range falls under the scope of what we do, in the research department. we even have some sponsors working indiagnostic device companies, where they're developing a new instrument or whatever. And, we have high complexity clearance we do our own gonorrhea and chlamydia testing here. I'll show you when I give you a tour. The left over tubes, i don't have the exact one,but hey look something like this, this is another brand. After they ran out of the instrument, they had some people buy these. It's one of the leftover tubes, I was like ok. So, yea that's basically the scope of what we do. I'd say about ninety percent of business right now is in vitro diagnostics, we collect additional specimens for people at the time of their visit. Vaginal specimens, cervical lesions- a bump, urine, we had a request recently, for nasopharyngeal swabs. That's the scope of what we do, but yea, go right ahead.

Buyer: So, the consent, how do you handle that, what do you do?

PP: Well, we obviously would have to have a written protocol and submit it to the IRB for developed informed consent. Generally specific- now I say generally specific, because we have two different protocols that are just umbrella protocols. I was thinking about this with Tram's email, it's been rattling around in my head for a couple of years. We need to do this with fetal tissue, we have an umbrella protocol, it isn't specific to a certain- it's for specimen donation or specimen procurement. It isn't specific to- the protocol itself is for procurement but there's not a specific study that it's for. We're not going to do any data analysis on it, we're doing this for use in the future or whatever.

Buyer: Is it not for a specific type of specimen either? It could be for cervical biopsies or-

PP: We have two that exist currently for two different diagnostic device companies for their R and D needs. Although, the protocol is for general specimen acquisition. then we have a consent form underneath it that specifies why you're here for your visit, we have studies going on, you may be eligible for participation in this study, collection- Oh yea. Allegra has Zyrtec.

Nurse: I don't have Allegra, I have zyrtec.

Buyer: This is so kind of you. Thank you.

Nurse: We live here, are you not from Texas?

Buyer: No.

Nurse: This is just kind of our life.

Buyer: Yea, it's becoming my life, thank you so much.

Nurse: You're welcome. Welcome to Houston.

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Buyer: So, this is like Allegra? If I pop this, is it all the same thing?

PP: Allegra, I think is a histamine one blocker, that's a histamine two. You should be fine.

Buyer: Ok.

PP: Because if you did Allegra and you're still feeling bad, this will help, and it won't make you drowsy. Not knowing anything else about your medical history, and being a nurse, this is just it.

Buyer: I'm not going to pass out?

PP: Oh, you shouldn't have mixed Allegra and Zyrtec. It's like mixing Vodka and beer you shouldn't have done it. The general specimen acquisition protocols have been really great in the past seven or eight years because we have this general protocol, we have this general consent.

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PP: And we have an a la carte budget. On the front end, we develop everything in advance and as our sponsor has R and D needs, they shoot me a work order that says "Missy, I need two-hundred vaginal swabs, patients that are symptomatic." And they give me criteria like this, and we use the same consent from over and over and over, we use the same budget over and over. If we have any weirdness, like right now I'm being asked for nasopharyngeal swabs, and we had that covered in one part, we said nasal swabs, but it didn't actually click and put it in our budget. I think we had it in there like, we'll figure it out when it happens, so now we have to go back and redo that. That's kind of the general scope of that-

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PP: We get requests a lot for fetal tissue. We would look at something like that maybe for fetal tissue as well.

Buyer: Okay. It sounds like maybe some language would have to be drafted and—

PP: I could send you, I've got a deidentified protocol that lists all different specimen types and can easily share that.

Buyer: Do you have a copy of that? I would like just to see, how much we might have to add—

Buyer: But your consent form is not fetal tissue specific right now?

PP: No.

Buyer: And how that fits with like CFR regulations and some of the NIH requirements—because most researchers who are using that material, unless it's a privately funded company like Neuralstem or somebody like that, they are relying on NIH grant money and so it's—

PP: Right.

Buyer: There's certain boxes to check, and—

PP: Yes, well, and that brings up a certain, you know, horse of a different color as well because the regulations have changed lately and with grants that if you guys or we are listed as like a subcontractor on this grant for collection, used to be we're not subject to audits from NIH or anything. That has changed. So, as a subcontractor you have to be aware of the same regulations you would if you were the grant-holder, and comply with them. Even though may not apply whatsoever, so. We're very strategic in the grants that we accept being involved with. I can tell you, there are very few that our organization- I can count them on one hand and have fingers left.

Buyer: Oh wow.

PP: Just because we get audited all the time because we're Planned Parenthood for everything else, so we're very risk averse, but strategic. So, we'll take on grants where we have a lot of mission type support. Something we're really behind. But otherwise, we really focus on our industry sponsored studies.

Buyer: So, you get audited by the NIH under this administration.

PP: Oh yea. Mhm. Yup.

Buyer: So, this will tie into patient volume which is why we wanted to meet with you. In the past, promising something to our research clients and then not being

able to deliver because our contacts- the volume wasn't there for specific requests that are there. Do we have data on what kind of volume you have?

PP: We do. Let me make myself a note of things I'm going to send to you. I'll send you a blank ICA, a blank protocol, I can get you some visit information, you're lucky because it just came out for two thousand fourteen so in terms of like, males and females that we see, age groups, I can give you visits, you know, people that come into our clinic. This affiliate here in the Houston area, is made up of nine family planning health centers, including this building. Two in Louisiana, seven in the Houston area, then in this building there's our surgical services area, where Tram works, there's our abortion services area, and then our family planning clinic and our research clinic is all encompassed in this building. So, I can get you some figures.

Buyer: So, gestational age, if that could be included in that- because obviously, we're most interested in second trimester specimens and most of the requests tend to be from sixteen weeks and up. That's probably your experience already if you've had a lot of people requesting-

PP: It depends, most of our contacts are academic over in the Texas medical center and depending on what they're researching they may not want second trimester. They may want just first trimester sometimes they're very prescribed in what they want. they want first trimester, this many weeks, blah, blah, blah. It's very specific as to what they want.

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Buyer: The quality of the specimen, and then, depending on the age-

PP: Sorry to interrupt, could you speak more about the quality?

Buyer: So, for example, most of the clients that we see and that we would service are people who are in the regenerative medicine field, they're doing stem cell studies specifically. My experience is mostly with humanized mouse models, I think I mentioned the liver-thymus pairs that are really important.

PP: Mhm.

Buyer: And when you're doing those, especially if you're gonna do a cell isolation, people think of cells, "Well, the tissue has a bunch of them, right?" Well, the stem cell population is only a specific ratio to the total number of cells that are in there.

PP: Mhm.

Buyer: And they also tend to be more fragile than the other cells you're dealing with. So if you're wanting to get a good yield when you're doing that isolation, the integrity of that tissue sample 7itself, the physical integrity is pretty important.

PP: Okay. So just to clarify, one thing that is a disadvantage, in terms of utilizing our site, is the recent regulations have made it almost impossible for us to use abortion pills. So yeah, it's kind of complicated. If you want to do the research, it's Texas House Bill 2.

Buyer: Yeah, we don't want stuff from medical abortions. I think the only medical abortion we would want would be like an induction from later.

PP: Yeah, but, well, so for earlier trimester, anything that's from an abortion pill, medication abortion, there's more of a possibility of having everything intact. Versus a surgical abortion that, you know, the products of conception are not intact.

Buyer: But are your patients during medication abortion here at the clinic—that's all at home, right?

PP: It's basically at home, but depending on when they come back, because they would have to come back for a series of pills or what have you, so yeah, they could potentially be here, or be given a sterile cup to take home with them.

Buyer: Has that ever been done before? Have you collected-

PP: No.

Buyer: Okay, so-

PP: Off-topic. But-

Buyer: I just, I like thinking outside the box, but I'm just thinking, could we do that? The thing is, what also becomes very critical is just the timing from the completion of the procedure, to actually packaging and shipping the material.

PP: Mhm. Correct.

Buyer: When we're talking about isolating stem cells, and the cell viability and all that, you know, the timing is really really critical.

PP: Mhm. Right.

Buyer: And so, to me, I don't know if it's, if someone is laboring out a first trimester pregnancy for, I imagine it takes quite a while, certainly longer than a surgical procedure, and then we're relying on the patient to—

PP: It just really depends. That's the big piece, right. In terms of quality, I had to get with Tram, asking her just, you know, their general process. So for POC, products of conception that are less than 16 weeks, it's evacuated either in a syringe, when it's very very small, or in a non-sterile glass jar, via the vacuum pump as part of the procedure. It's processed in the lab, it's a non-sterile process, it's done unless it's evidence collection, that's why I asked you about that, because we actually do quite a bit of evidence collection in terms of rape patients and stuff like that where everything has to be sterile, because it's gonna go on to be analyzed outside of here. So this is still less than 16 weeks. Tissue is washed through a strainer and placed in a glass tray, the tray sis on top of an xray box and it's floated with water. The transparency makes identification of all the parts easier. After the physician has confirmed the tissue correlates with gestational age, tissue is placed in a biohazard container and gets discarded into a single container and then is placed in the freezer. Anything after 16 weeks is immediately placed in the freezer after the procedure. And it is all sent away once a week for incineration. So that's kind of the scope.

Buyer: Okay, so this is kind of an avenue off but I think in our business, probably that I saw, and I don't know much about this area, this is probably more [Name]'s, but I, we're asking for intact specimen.

PP: Mhm.

Buyer: And the technician took a hose and was just full force, spraying, and [Name] said you know, could you be losing things? And not only just losing things, there's basically two considerations when we're trying to get the particular organ types or tissue types requested. One factor is the nature of the procedure itself, are you doing an IPAS, are you doing electrical suction, are you doing a D&E, is it breech presentation—

PP: That, right.

Buyer: Stuff like that. And then, what we're realizing, as we're observing some of the processes, is there's kind of another component too, when they're doing the regular P.O.C. check, and they're blasting it with the hose, you could have a lot of stuff still sitting in the body cavity, but you're blasting it with the "fire hose," and then you put all of it in the light dish, and you've got to play, "Find The Liver," for an hour, and—

PP: Yeah. Yeah. And under the scope of where we probably have an edge over other organizations, is our organization has been doing research for many many years. And we've had studies in which the company or the investigator has a specific need, for certain portion of the products of conception.

Buyer: Mhm.

PP: And we bake that into our contract, and our protocol, that we follow this. And we deviate from our standard in order to do that. So, you know, we can do it in a way that we're still verifying that everything is there for the safety of the patient, but then we maintain the integrity of that sample. So yeah, that's definitely something we can do. So as far as, this is our standard process, telling you then we can get creative about when and where and under what conditions can we interject something that is specific to the tissue needs.

Buyer: So that goes to my next, can you get creative, can you alter-

PP: Mhm.

Buyer: If we say, that we need a liver.

Buyer: Or not just liver-thymus, but also neural tissue—

PP: Right, the neural tissue is what we've done specifically in the past.

Buyer: Could you adjust the procedure, if you knew—

PP: Mhm.

Buyer: Okay, they need high volume of this—

PP: Mhm.

Buyer: Could you match that, and—

Buyer: You know, 18 to 22 week neural specimens, both hemispheres intact. So that it's intact—

PP: Yeah, I think we could do that. Some of it is really outside, some of it will be happenstance, because you know sometimes as the procedure's happening, you know the procedure itself, for the removal, is generally standardized. And so just depending on the patient's anatomy, how many weeks, where it's placed in the uterus, we're going to potentially have some that we're going to be able to do more or less intact, and some that will not be.

Buyer: Right.

PP: But it's something that we can look at and explore how we can make that happen, so we can have a higher chance. It will probably require a little bit of input from the doctors. Because the doctors are the ones asking to, really be doing that, you know, when it matters, and the cases where it's mattered and the physicians have needed an intact specimen—

Buyer: Right.

PP: So, we can make it happen. We just need to figure out how that we can do this under our project needs.

Buyer: Right. How many providers practice in the 2nd trimester? Specifically, the later than 16 week cases.

PP: I mean, everybody here does. I want to say we have 6.

Buyer: Six providers that go beyond sixteen weeks. Wow.

PP: I'm pretty sure they're all under the same credential. Even before the laws changed that require an ambulatory surgical center in Texas to be- you know, it's in the supreme court right now, not sure if you're aware of that- mandates that abortions have to be at an ASE. When we moved into this building, in 2010 we went from an outpatient clinic and converted it to ASE, so were already there. So, in the event the laws go through, you know, become enacted, we will be one of only six or eight facilities in the entire state.

Buyer: Which means your volume will go through the roof.

PP: Yea, um, yea.

Buyer: It sound like you are very proactive about seeing where things are going. You're ready to-

PP: Yea, I think it was accident, I don't think it was anyones radar. We knew that we wanted to do abortions at sixteen weeks and past, and knowing that in a lot of those cases an ASE is required, we went ahead and just bumped it up. Just because business wise we wanted to be able to offer that to the community. Because there are so many- even though we have several academic institutions here, the way abortion is going in the United States, it's even being taught in some of the very large academic institutions that would do second trimester abortions, even for fetal anomalies, they're not even doing it anymore. So all of those patients are being sent here. yea, it's actually pretty sad that patients in that situation with a fetal anomaly, going through everything still have to jump through additional hoops, hardship-

Buyer: The stigma.

PP: Yea, that's another whole topic. Yea.

Buyer: Certainly is.

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Buyer: So it sounds like you have physicians that would be able to change the procedure, that if they're knowing—

PP: Yeah.

Buyer: That okay, this patient could provide certain specimens, and we want 'em intact, so that physician has the knowledge and the ability to change the procedure a bit just to make sure we can get—

PP: Right. And it will depend, obviously the change in the procedure will have to be where it's not gonna put the patient at more risk, prolong the procedure and put her at more risk. And alter the procedure so we leave things in the patient—

Buyer: We want all of it! I don't know why we would leave any-[laughter]

PP: Right. And that's something we'll have to discuss with our doctors and see how they could do it. Because some of our doctors have projects and they're collecting the specimens, so they do it in a way they can get the best specimens. So I know it can happen—

Buyer: The doctors were doing research?

PP: Yeah, mhm.

Buyer: Oh wow. Now can they, for example, convert to breech under ultrasound guidance and then—

PP: I guess it's just gonna depend.

Buyer: On their skills?

PP: Yeah, on their skills and everything and, I mean, we can be flexible to do whatever, but you know, I don't know, we'll have to have further discussions with them about—

Buyer: That's really their area of expertise.

PP: Yeah, yeah. So.

Buyer: Does Amna Dermish practice here, ever? Or is she only at the greater Texas affiliate?

PP: I think Greater Texas, I don't recognize her name at all. We do have some doctors that drive in from other locations, but her name is not one that I recognize.

Buyer: Ok, should we talk about dissection methods? No, I guess that would be Tram's- who actually does the tissue procurement if it's a request that you guys are processing?

PP: Yes, Tram's group does, and any kind of physicians that we work with in the med center- no physicians here that we have a contract to collect specimens with. That they want the actual specimen differently, put in a different media, or whatever. So yea, I sit with Tram and we go over what the needs are, how it can be fit in. How we can integrate it in a way that everyone's needs are met. And then discuss logistics about how that's going to look. you know, how many patients, strategically, which patients should we approach, so it's less administrative burden on everyone. Yea, we can look at all of those details when we have more specifics.

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Buyer: So, I want to talk about the burden that I imagine- I know from other clients that we have- the burden that is put on you and our compensation to you to make sure that this is working on both ends. You're happy, we're happy it's beneficial for you, it's beneficial for us. Do you have- I have an idea for what burden- in the past people have been very happy and then oh my goodness, I didn't know that we'd have to do this, or store this, or you'd be in the way or all sorts of things.

PP: It really, you know gets specific to what your needs are. We do have again, an edge because we've done so much research, a lot of their staff already has CITI training, I don't know if you know what that is, it's a level of research training. That they know how to consent the patient, they-

Buyer: What is CITI?

PP: It's Collaborative Institute Training Initiative. It's where people get research specific training, in how to protect human subjects. And so they know how to consent the patient, they know how to do everything and doing to where, we're kind of aware of the burden on the administrative side and actually in the pop room, there's a little area, a little space. that would be training that's specific to those folks. So, as far as the administrative burden it's working out the logistics on our end as we're having a research department like ours. Again, we have that edge because even though we don't do that as frequently as all the other projects I was telling you about, it something that we have done in the past working closely with Tram's group. Our department is five here in research some (inaudible) staff members that have training and what have you but we're able to integrate that and so I'm not saying it's necessarily easy but one of the thing that we really work to do is integration. Seamless integration, the best that we can, taking into consideration what the standards are and why these standards are

here and the needs of the client and getting the samples, in the time, in the manner, in the condition that you need them. Not compromising patient safety, and we're not compromising clinic flow. it's a juggle and initially there's hiccups, always. There's always hiccups, I'm not going to say we're going to come out of the shoot being perfect but we do that. And you said something about wanting to be on site?

Buyer: Well, if you've got someone, that's great because when we have to be on site we kind of get in the way.

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Buyer: What I have found is making compensation for certain specimen types higher, just to keep customers happy.

PP: Right, and we would definitely have to work that out in terms of budgeting. Especially because of the current situation with the regulations, they're extremely busy up there. And they're excited about it. And we have patients that come in all the time asking if they can donate the fetal tissue. A, because they hear about it in the media or whatever. And B because we've done these projects in the past. And I don't know how it got out there, because people don't talk about their abortions, so how they got, how they talk about the fact they donated fetal tissue—

Buyer: I'm glad that's happening though, because the fact that people can talk about it, the stigma can just be-

PP: Yeah, and gosh, I wish we were further along there. Because they, most of the time when folks come in and they've made that decision already, they're there, there's no boohoo, and grief, and things that are often portrayed. But to see some benefit to the situation, a lot of women ask to be able to donate the fetal tissue somehow. so, and I'll show you when we go towards our storage we already have contracts with dry ice companies. We have two minus twenty-two refrigerators. two incubators, so we do a lot of research because we have capacity that maybe other facilities that only do clinical don't have. We get what we need to do to alter our standard of care so that we're still maintaining patient safety, still maintaining efficiency in clinic operations, but we integrate research into it.

Buyer: Okay. So it sounds like as far as your cost, it's not going to be, it'll just be, you're already set up.

PP: We're already set up, we will definitely need to work out something as far as covering additional cost for additional things related to it—

Buyer: Exactly, exactly.

PP: I'm very particular about working with the language of the budgeted contract to where the language is specific to covering the administrative costs and not necessarily the per-specimen, because that borders on some language in the federal regs that's a little touchy.

Buyer: Mhm.

PP: And of course, we don't offer the patient any compensation at all, and of course you know that.

Buyer: Right, right.

PP: Expressly prohibited. But yeah, we can definitely work that out. And realizing that most of the clients that we have had are academic institutions. We've had some industry sponsors as well, and it, we had a collection that was going on when I got here that had been multi-year. It had been collecting specimens of a certain gestational age in a certain way, those actually worked really really well, because our staff, they really like to get on auto-pilot. They want to do their job, they want to do it well, and if we have a long-term project, where we're getting lots and lots and lots of specimens, they can get on auto-pilot after the initial training pretty quickly. So everyone likes monotony, to an extent you know.

Buyer: It's efficiency, I see it is.

PP: So, if you do things the same way everytime and you don't have to engage that part of your brain, this is new, I'm figuring it out- that kind of uncomfortable feeling- once you get into that pattern that feels good, and staff really like that. That's one of the areas where I work with Tram and the other clinics to get there there very, very quickly. That means being a little pushy, that term has been applied to me from the beginning, because I realize it's a band-aid approach. Get it done and get in incorporated into your operations really quickly, get everybody on board and get that efficiency.

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Buyer: In those cases when, and [Name] can speak to this again, but I'm more on the business end of it.

PP: Yeah.

Buyer: I know that going with the history of what's happened, and wanting to not have that happen again, we have, for specific specimens, the compensation would be higher.

PP: Mhm. Mhm. Right.

Buyer: Because we know, there's gonna be problems. How do we frame that so that that's, we're not saying we're giving a higher—

PP: Yeah, we can work it out in the context of—obviously, the procedure is more complicated. So that anything that we integrate into that procedure, without having you cover the procedural cost, is going to be higher. So anything of a higher gestational age, there's more opportunity for complication, there's more administrative time involved,

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PP: Sometimes the procedures are longer. So then, anything that we piggy-back onto that for collection purposes, obviously, would have to, that additional time, cost, administrative burden.

Buyer: Right. So our compensation to you, our specific specimen, intact, could be built into that.

PP: Yeah. And that's something that, getting more information about it, as intact as you need, how we're going to do that, then from there, getting, when I'm working with our clinical trials and all of our additional specimen collection needs, I'm pretty bullish about getting as much information as I can prior to budgeting. Because I can't budget effectively, correctly, if I don't have all the information. And otherwise I'm budgeting blindly. And I have an expression, you can't budget for crazy. I need to know everything that's involved, have it in writing so that I can sit down with the parties involved actually doing the work, so I can say okay guys, let's work this out now. And we even will go as far as to have timed trials where we go up there with a stopwatch and time how much, so we can at least know what our cost is. Because I think, in terms of budgeting, if you don't even know your cost, how can you develop a budget to cover that. So—

Buyer: Okay, so I want to say this to, that this might prevent some of your crazy. That, if you run into crazy, I want to you come back, feel free to come back to me and say, you know, for that request, to match those requests, we need a little more for that. Come back to me and say what you're compensating for that, we want to raise it. Because I don't want to be crazy. Feel free.

PP: Yeah. And I mean crazy, comes when you, from my experience, when we have sponsors who aren't aware of the clinical component. So their preconceived idea of how we're going to collect and how we're going to process are not in line with what we actually do, and for whatever reason they've got ear muffs on when I'm trying to explain what we actually do, and that's where crazy comes in when we don't really have good lines of communication. But it sounds like you guys are really really familiar with the process so—

Buyer: Exactly. And I think what can kind of make us different is we can be very attuned to the practice environment that you guys have. And I'm just, thinking of Cate [Dyer from StemExpress] and someone who's not very attuned to the practice environment and some of their collection sites, and there've been problems because of that, and that's not sustainable for anybody, and it's really not profitable or beneficial for anybody, and so—

PP: Right. And that's the thing that it's, a lot of folks I get this mainly from academic institutions, they see Planned Parenthood and think, "Oh, you're non-profit. That means you're non-budget." And they will come to us with budgets that are, quite frankly, insulting. I mean, really? Where in the United States can you, an 8-page consent form for this amount of money? It takes 30 minutes to administer that to a patient. So, you know, again, with the understanding that just because we're non-profit, doesn't mean that we're fiscally unstable. If anything, we serve the community and we have to provide services to the community at a very very low cost, and we can't underwrite anyone's research project.

006500

Buyer: No, and what I've found is, what's been very positive for me, this little start-up, just the rewards that I have gotten from it personally, emotionally, that we can come in to an organization that is non-profit, like Planned Parenthood, and with partnering, we can make it very fiscally rewarding to you, for both of us.

PP: Mhm. Yeah. Yep.

Buyer: But I understand, I don't ever want to insult you, and I want it to be fiscally rewarding to you, and no crazy.

PP: Mhm. Yeah. And we can definitely work on that. I try to do as much as I can on the front end having conversations like this, getting as much documentation as I can, and working out all the logistics ahead of time, and as you can probably see, Tram immediately got me involved, knowing what it takes. We already have done this, so we have some expertise here, that I think maybe in other situations that you may have experienced not knowing what's involved and how to make this work in a facility, they couldn't account for the crazy, and the crazy was self-imposed.

Buyer: Right. And some of them can't see the fiscal growth for their own clinic.

PP: Mhm. Yeah.

Buyer: Just by thinking outside the box and making sure everything's in place, and it's framed the right way. But this can be very beneficial for their clinics.

PP: Mhm. Mhm. Yeah. And you know, we definitely want to get as much information as we can. Because I'm hearing you talk about maintaining the integrity of the specimen, and you know, clinically, obviously, when they're doing their follow-up with specimens, it's just to ensure everything is there, nothing is left in the patient, and [snapping fingers] moving along as guickly as possible. because we've got so many people we have to serve in the community. When we have a research need, or we have a procurement need, they recognize, okay, gotta slow it down a little bit, they will bake that in, we can even take it so far as to bake it into scheduling. Because we have had some situations where everyone who is coming in today is going to be approached about a study. And we've had days where we've had to collect, you know, 6, 8, 10 specimens, that we get in one day. And that, you know, to recognize that everything had to change in order to enroll. That's another thing that we do strategically as well. because understanding that 2nd trimesters are only done on certain days. Knowing that okay, we have a need, and they're only done on certain days, by certain physicians, and certain staff, and they already scale back the schedule, working that in. So, I think just, I think we already have a lot of the infrastructure that will make this very successful.

Buyer: Mhm. Excellent.

PP: So as soon as y'all can start throwing paper at me, that would be great.

Buyer: And so, maybe, and we can't get as specific as we would both need obviously right now, but I'm wondering if we can maybe play out a little bit what the process would look like, for specifically, let's say, for paired liver-thymus, we have, there's a new client in Oklahoma, medical research foundation, that's doing a lot of really interesting immunology work and expanding in that area, and so if we can provide them with intact liver-thymus pairs, paired from the same donor, you know, 18 to 22 weeks gestation—

PP: Mhm.

Buyer: And obviously, you know, at least one a week would be good, if we could get 4 or 5 a week, even better.

PP: Yeah.

Buyer: And this is for humanized mouse models. What is that gonna look like from start to finish if we're using your process, imagining that we're not even sending one of our, maybe we send one of our techs initially, just to go over the protocol with Tram and everything.

PP: Yeah.

Buyer: And then after that, what does that-

PP: So, ordinarily, we're a little bit different, because generally, the protocol comes to me, we have our meetings internally, how does this work, what is this gonna look like. How are we going to make this work? In order for me to move forward with budgeting. So we do that all on the front-end. And look at our schedule, how does this fit into our schedule, is this even possible? We do a feasibility assessment on the front-end. Again, getting as much information as we can to sit down and write out a plan, and then I can budget, I can come back with a budget on it. I'm very much the person, when we look at something like this, under promise, over deliver. So, I need to go with Tram and get specific information about how can we make this happen. Is this something we can actually deliver on? I know- last I heard, and things change a lot upstairs- we had one or two, I'm sorry we're right next to the freight elevator here. I think it's two days a week that a certain part of the schedule is dedicated to second trimester.

Buyer: Two days a week?

PP: Yea. Now, that may have changed, but that was the last I've heard. I need to verify-

017100

Buyer: Here's something we've also run into, let's say there's a specimen that's collected later in the day, and we need to ship it to- Oklahoma

PP: Yeah.

Buyer: Well Oklahoma's close, California, New York—is that doable?

PP: Yeah. Yep. We do that right now on a daily basis right now for research. there are five FedEx hubs in Houston that are open until 8pm, and my staff and I all have cars.

Buyer: Awesome.

018000

PP: So, we drop off specimens all the time.

Buyer: All out of state?

PP: There's nothing in-state that we ship. Everything goes-

Buyer: Is that courrier or is it?

PP: We will go out to our offices and collect our specimens. We're all trained and credentialed so we know how to ship biologics. We ship dry ice, flammables, even U337 diagnostics so we're doing-

Buyer: I don't think we need to be talking about packaging-

PP: When we get to do the lab piece, it'll make a little more sense.

Buyer: And you ship fetal specimens to other states-

PP: We have not shipped any fetal specimens-

Buyer: Ok.

PP: Everyone that has come in and collected specimens has been local. So-

Buyer: Is that a possibility?

PP: Oh yea. It's really just a matter of what category does it fit into according to (inaudible) and shipping according to that category. It's also going to depend on the media. If your media is ethanol/methanol based then that puts into category six, that's flammables. And we're limited to how many we can fit in a box, we can still do it, we just have to spread it out into different boxes. You can't have more than fifty cc's in a box-

Buyer: Not to interrupt, fetal tissue will never be in media like that because the cells need to viable. It needs to be RPMI or something like that.- What's the cost, I'm not familiar with that? Is there a higher cost with that?

PP: Typically, our sponsors set up a FedEx account for us, and we just use that account. We go online, we have it set up in our FedEx world account, put everything in, print up the air bill, slap it on, put it on dry ice, put it in the freezer, bricks, whatever we need to do and either drop it off- whatever we need to dowe have FedEx pick up here about three or four pm. Then anything that is late, something that was collected late, we drop it off at FedEx. It's literally on the way home for me, so yea.

Buyer: Ok so we could make it a cross country-

PP: Yea.

Buyer: Yea, because with the fetal specimens, it's kind of taking it to the next level because the timing is that critical for the cell viability in time for culture from procedure-

PP: Most of our other additional specimens, because they're investigational use only IUO, maybe you'll hear about that from some future clients of yours. Their viability hasn't even been established so we have to get them out of here as quickly as possible and they're there either at the seven am delivery or the ten thirty delivery.

Buyer: Oh, excellent.

PP: Right now is a good time, most of the time we don't have any weather issues but winter time is outside of my control.

Buyer: Ok, that's good.

PP: So, we ship and it goes wherever, so anything that goes to the east coast generally has to go through Indiana, if Indiana's having issues- Indiana and Kentucky are the big FedEx hubs for anything going to the Northeast. Oddly enough we generally don't have any issues with stuff that goes to California. It's east coast that we have a lot of issues-

Buyer: It's difficult.

PP: Now, if anything needs to go to Louisiana then we need to have a whole separate discussion because Louisiana is- we've got clinics in Louisiana- there is some sort of bad mojo when it comes to FedEx and Louisiana, I mean we routinely have things not delivered on time. We don't have any abortion clinics in Louisiana so we're not even on the topic of discussion but we have some issues with Louisiana shipping.

Buyer: Louisiana might be currier distance, how far is New Orleans from here?

PP: Eight hours. We just use FedEx or UPS. We have damaged boxes, we have things that don't arrive on time. When there's freezes that are well North of them, that's their excuse not to deliver that day in New Orleans, so I don't understand it. We have so many issues in Louisiana, it's maddening. When I go over there and train clinics for additional specimen studies, I don't ship anything in advance anymore. I just bring it with me. I rent a Ford Explorer or something, I pack everything in the back because it's the only way I know, for sure, it's going to get there. No, Louisiana is, unique. It's very unique, at some point, we hope- we're building a new facility in Louisiana, we have a clinic in New Orleans right now for family planning services. We're trying to expand and have abortion services there so go ahead and look online at the Louisiana (inaudible) which is the name of the- it's in the newspaper all the time.

Buyer: It's kind of depressing.

PP: It is extremely frustrating, yea because there is a need there. It's just the nature of politics in the south.

027100

PP: Right now you hear about it almost everyday even in Congress and the state level. Just the roll backs in reproductive health care dynamics in this country are amazing. I mean, we're even attacking birth control.

Buyer: Right, right. What's your take on that? Do you have any-American Taliban? What do you think? Is it changing or?

PP: I think, unfortunately, our society is becoming too complacent, where some of this radicalizing has been able to flourish. I think part of it is an education thing, people make statements abortion causing breast cancer, or birth control causing autism or things like that and out general public is so ill educated-

Buyer: Scientifically uneducated.

PP: Exactly. They don't understand- if they say "emergency contraception is an abortifacient because it doesn't allow the fetus to implant" And not understand-

Buyer: What fetus? There's no fetus.

PP: They mix up terminology and it sounds good, it looks good, people- "Oh yea, that sounds right." And in some cases some politicians that are actually OB GYN's come out and say these things, they're credible. Yea, so I thinks it's multipronged, there's a lot of reasons for it. We can just kind of-

Buyer: How do you fight that though? What kind of plan, well education is one. What-

PP: Education, one. Just keep providing the best services that we have because one in there women have attended Planned Parenthood for free services in their life. So when you have media spin about "Oh Planned Parenthoods goal are this." Whatever, you have people who have been here "I didn't get that. I got services, I got treated nice, I wasn't judged, I got to participate in these studies, I got a stipend, I got free testing. What more can I ask?" We have patients say that all the time. So, all we can do is counteract it.

Buyer: Ok. Sounds nice, so don't be too depressed.

PP: Don't be too depressed. Its just one of those things, you know? Every once in a while we step into a time travel machine and go back to the nineteen fifties, politically.

Buyer: It comes in waves.

PP: Yea, it comes in waves. All we have to do is keep researching, keep science out there, keep valid information out there, so.

Buyer: Very good. Excellent.

PP: So, I need to talk to Tram about ways- with this little bit of information- visit with her about feasibility, in general before we make any commitments. How is this possible, let's think about this. Let's think about that. And then the shipping, but that's a non issue.

033000

Buyer: What is your exact upper gestational limit?

PP: That's something, I'm glad you said that because with the laws that changed, the terminology is different. We still use gestational weeks, but it's calculated differently, estimated date of conception against LMP. So, I need to make sure I'm speaking the same language. I think we go up to twenty, I don't think we go past twenty, pretty sure about it.

034000

Buyer: Do any of your providers use Dig?

PP: I don't know about that.

Buyer: Because digoxin kills the stem cells, nukes the tissues. No feticide can be used.

PP: I don't think we do. I've not heard of that. And I'm- we all get together for certain meetings within the organization, there's operational discussions. I never heard of digoxin.

Buyer: I think I heard Tram say you didn't, but I just wanted to confirm because that's a pretty important base line.

PP: It would impact your tissue samples.

Buyer: They would be unusable. I had a colleague who tried to do, you know, just for kicks and giggles-tried to do a cell isolation on a liver from a digoxin case. Nothing. Didn't get anything out of it. Yea, it's a feticide, it destroys everything. It can't be used.

036500

Buyer: The later procedures are those two day, one day? What's the cervical prep like for those?

PP: Cervical prep. You're saying for alter-

Buyer: Sixteen plus.

PP: Again, that is state specific. The patients are required to come in on- for instance, on a Monday, have their ultrasounds, do a lot of the documentation, etc, etc, come back on Wednesday for their actual procedure. So, depending, there may be some activity at home, medication or whatever on Tuesday, in between. So yea, I have to get those details. That again, as the laws have changed, we've had to change our procedures. We're kind of in a weird place right now, we've changed a lot assuming that house bill two is going to be upheld by the supreme court. So we're kind of in this limbo right now, this is how we're changing it, just assuming worst case scenario. But no, I have to get updated on that personally because I'm not aware of the changes. So, what is the cervical prep for sixteen weeks plus, any other prep that you're aware of that happens elsewhere-

Buyer: I mean it used to be the case that second trimester was always at least a two day procedure. You know, whether LAMs or Dilapan the first day, inserted for overnight cervical dilation, and the next day is the actual procedure. Lots of affiliates are starting to use Misoprostol now, either alone or in addition to some kind of mechanical dilator. Sometimes they're doing that over night, more and more places are moving to same day prep even up to eightteen, twenty weeks.

PP: I think we're doing, because of the regulations, it's all same day. I think-when you're saying this, it sounds familiar to what I've heard recently.

Buyer: Would it be helpful for you to see- I don't know if you have this- a client list, just today's to see what's going today. What's the volume, would that be helpful to you. I don't know if you can provide that.

PP: I can't. I can't in terms of a client list. I can see if Tram has something.

Buyer: Is there anyone in surgical today who is around when we do the tour?

PP: I can look, as soon as we finish this here. Yes, it will depend on when we wrap up. There are basically two clinics. The ultrasound clinic, because ultrasound has to occur twenty four hours before. And the other half, where they actually do the procedure. It varies day to day which is first and which is second.

041500

PP: Let me shoot her an email real quick, and see if we can pop up there. She had asked and I said: I don't know if we will need to see your facility, I will let you know.

Buyer: Tram? Is that Tram you're talking about? Oh, she's here.

PP: Yea.

Buyer: Oh, it'd be great to see her again.

PP: She is awesome.

Buyer: Yea, I can tell that she is very passionate about it. Is she the only procurement technician that they use- no. So, she's got a team of people.

PP: She's got a very large department.

Buyer: Oh. [Name], I was thinking about the conference call-

PP: Do ya'll need time for a phone call?

Buyer: No, maybe we need to talk about this with you. The sickle cells anemia

043400

PP: Uhuh.

Buyer: And is looking for specimens, he needs kind of everything from the hematopoietic system. So we're talking liver, long bones, and cardiac, so heart specimens. From—

PP: Intact also?

Buyer: Yeah, all intact. From African-American donors only.

PP: [nods affirmatively]

Buyer: Because we're looking—and I was playing this out in my head the other night, thinking about it. You know, in theory there are prenatal screening tests for sickle-cell anemia, it's probably too complicated to try to insert that—

PP: Typically at this gestational age they haven't, you have to do family history.

Buyer: Do you guys take family history for that?

PP: Again, that falls under the research part of it. If we're doing this under a research protocol and we have a need for that information it's something we can integrate into what we do. So, I don't think that is asses initially, different types of anemia are. Obviously because we're doing a procedure. So, sickle cell anemia may be included in that, I don't- one second, I can ask. Hi, quick question, you know, upstairs do you remember if any of the intake involved sickle cell anemia in any of the history questions or anything? Ok. So you've seen it. Ok. Thanks. There's an anemia question in there, it's an other so if it's sickle cell, it's usually a write in.

Buyer: Interesting. The other thing is too, I think the prevalence of the carrier gene among the African-American population is like 1 in 12.

PP: Mhm.

Buyer: So if you have 12 patients, 12 termination patients of African-American descent during the week.

PP: Mhm. Mhm.

Buyer: And that means, statistically, at least one of them is likely to be a carrier, so at least one of those fetuses will have, will be appropriate for inclusion.

PP: Mhm. Mhm.

Buyer: And I imagine that he would want controls as well.

PP: I was about to suggest that.

Buyer: So it might just be a matter of, if there's 12, collect—

PP: Select everything from African-Americans. And you're going to have your controls, you're going to, just by numbers, you're gonna see it.

Buyer: Exactly. Exactly.

PP: So, instead of trying to find out, because you know, sometimes people just don't know their- they just don't know. It's a little (inaudible) hold on, she may have a follow up. Yes. Ma'am? Oh, ok thank you. Bye. She just sent me the intake for so I can look at it and see what's on there. Let me print this out for us, and again, whenever we have a need for additional information- for family planning, cervical samples, pap samples, what have you. We have electronic medical record so our research questions, we build what's called "templates." We get the information from our study sponsors on what data they need, that is not our standard of care. And we build a template so as a patient is seen- this issue

is coming in for the well woman exam, so there's a template, like back in school when we had the projectors with the transparency-

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PP: With one question then another question. So you put the transparency up and all the questions get asked. f she wants a depo then we have another template for that. When it's reseach specific, once patient gives consent, the procedure is to merge the template and ask all those questions that are specific for research. Anything we would need to do, in terms of the data behind the sample, we can integrate that too. So I- Tram's department has not moved over to electronic medical record yet, but that is something that we can still integrate in there. Let me go grab that off the printer real quick, be right back.

Buyer: Ok. Excellent. While you're doing that, is there a restroom I could use?

PP: Yea, very close by.

Buyer: (Inaudible) Yea, I've just been drinking the green tea the whole time. Don't discuss anything important without me.

PP: Were you up there when they were doing the second trimester procedures? Do you know if it's- like, I know they have an ultrasound one day and two days later they have the actual procedure. Do they do anything in between or is the entire procedure including cervical prep done on the second day, second visit I should say. Ok. Yea, I just wasn't sure if that's what you got out on the front end. Alright. Just curious. Alright, thanks.

Buyer: Were they doing second tri cases today?

PP: Not sure, that was one of my staff who works up there, but she works in kind of a specific area. Uh, I don't have access to the calendar to see what's on the schedule. I was going to check that out. Ok, we'll wait for Tram. This is an example-

Buyer: Is she coming down here or she calling?

PP: Yea. I sent her an email, we already had a dialogue back and fourth. I told her you may or may not want to go up there, we already talked-

Buyer: Yea, we would love to go take a look up there, mainly just the path lab to see if any specimens are there, kinda to get a baseline of what-

PP: What is today? Today is Thursday.

Buyer: It's Thursday already. Almost Friday.

PP: Yea, I think it was Wednesday.

Buyer: TGIF tomorrow.

012000

PP: Exactly. I can't remember what they are doing in the morning versus, because if they're in the middle of procedures right now we can't, but if it's ultrasound time, they're not even using the procedure rooms, it would be a perfect time. the only hitch is it's an ASC, it's an Ambulatory Surgery Center. So, it's like a surgical suite in a hospital and you have to be in scrubs, booties, everything, to go back there.

Buyer: Even if there aren't procedures going on?

PP: Mhm.

Buyer: Wow.

PP: Oh yea. Sterile environment. I'm sure- we have a scrub service so we have scrubs you can change into. I mean, I'm in scrubs but I'm outside, you have to be in those scrubs. But yea I can check with them.

Buyer: Do you need both of us, or are you ok? I thought you might want to see it but if you trust my judgement. I do just your judgement, it's your area of expertise but the whole scrubs thing.

PP: (Inaudible)

Buyer: See? She gets it, it's the hair.

PP: Mine generally- this is my god given gift, my hair- my curly hair. It does get out of place when you're changing frequently. Things are like-

Buyer: So what- I'd really like to see it but is it something I could slip over or do I have to take off?

PP: I really don't know what they would require. I've yet to take anyone up there. Most of my research stuff, they want to see the ultrasound suite because we do ultra sound for our contraceptive studies. Which is not part of the actual surgical suite itself.

Buyer: I mean, it's really just the path lab, or the specimen lab. I don't know what your term is for it here.

PP: Yea, I think they call it the POC lab. In our- they might call it the procedure area too. So yea, I'm not going to bore you trying to describe it. You'll see it, it's nice.

Buyer: And you don't have to be in scrubs for that area?

PP: Oh yea. It's attached to the procedure area, so yea.

Buyer: We'll see what Tram says about that.

PP: I sent her an email. She's really good about getting back to me. So yea, just glancing on here and seeing if anything- it's pretty thorough. "Hemetic disorders leading to blood won't clot properly leading to too much bleeding. Blood clot disorders, protein disorders, blood clot disorders" so-

Buyer: They have anemia mentioned twice, one on each of these forms.

018500

PP: So yea I'm pretty sure it comes up in discussion, if it's an issue. How about while we're waiting for Tram to see the email and respond, I give you a tour of our space, our lab- lab will probably more pertinent for where we actually ship from. Any specimen that is collected upstairs, processed upstairs, generally we work out something with the staff, where one of my folks runs up, grabs it, does whatever we need to with it- in terms of maintaining temperature putting it on dry ice, whatever. Then we bring it and ship from our area, so we can take a little tour of our area and my lab, just so you have an idea for future reference of what else we have.

019100

PP: If you don't mind taking a walk for a little bit.

Buyer: Yea.

PP: And I've got my iPhone so I can see when she's replied.

Buyer: Oh good. We'll come back, so we can get these later.

PP: Oh yea. So you saw where you came in, you check in with security. Directly across the hall is our family planning, dysplasia and vasectomy clinic. On the other side we have about nine exam rooms and really about twenty staff that work in that area. The majority of patients that come in are from family planning services but again we do get a lot of our research activities over there in term of enrollment. This area right here, as you come in is primarily the research wing. We have a couple of offices over here, they're for our HIV outreach counselors, as the name implies, they're outreach and they're out of the building most of the

time. They're here often when they're doing results and counseling patients. Conference room, from a research perspective, we have a lot of meetings, that's why we have a conference room built right into the space.

Buyer: Good.

PP: Training meeting, you now, constant. Storage closet. For additional specimens as you can see we have barcode access. Additional specimens we have a lot of extra product that comes in that we utilize in terms of collecting those specimens. So we have to be a little bit diligent about making sure all of our product that is for one study, stays with that study. Because often times we have similar approved products as a comparator- I don't know if you've been exposed to that yet. We have- (inaudible) developing a new test for herpes, and you want to demonstrate to the FDA that it works, you have to compare it to an already approved test. So if multiple people, multiple companies are doing studies on herpes, they're comparing to all those test that already approved, we have to keep all those approved products that we're going to use separate, and no commingle them. Anyway.

Buyer: Are you guys working with Lisa David with Medicines 360? The new IUD they're developing?

PP: (Inaudible) This whole hallway is the research space and all of our drug studies. We have patients come in to vitals, we have to get blood, we have to collect urine. So this is sort of the mini lab. This is Christina, she works in our department. She helps move budgets and contracts-

Buyer: She helps directions too.

PP: This is Lashaunda she is our research nurse and she also handles employee health, employee health and family research.

Buyer: And guest health.

PP: I'm sorry?

Buyer: I said, and guest health.

PP: This is Erica's office, she just walked down the hall. And if you want to go in here- hey did you notice I fixed the sign? It's gone, I don't know where it is. I swapped them. We have our own exam room, again, because we do trial, drug trials, patients have to come in more frequently that standard. We make sure they're safe so that happens in here. We have done, in the past a lot of phlebotomy collection for the new HIV test, the new hepatitis test. The patients come in and they donate three or four tubes of blood, we have lots of phlebotomy chairs around here. So we're all checked off to cart blood. This is our

investigational product storage area, it's temperature maintained. So our study drugs that have to have restricted access, or any types of products that have to have restricted access and this swipey- only five people, us and our security manager can get in the room. This is Joanna's office.

Joanna: Hi.

PP: Joanna, I stole from out family planning clinic across the hall. She comes to us from a varied background, family planning, and dysplasia, and she works in our surgical services area. This is who I called earlier.

Buyer: It's a good feel.

PP: Access, I got access. So, we ship a lot and we ship often and all of these different types of shipping containers are what we use to ship different types of biological specimens. From dry ice to refrigerated to class six flammables, so it's organized though you may not be able to see it, and different volumes as well. Depending on what studies are going on, all these boxes will get turned over at least once. They just go out and come back, go out and come back. So we also have some projects where we are doing the investigational testing for a product, and other facilities that are collecting, are sending that samples here. Our loading dock is right here. When we bought this building (inaudible) Strategically we put the research area here because we do so much shipping and receiving. It makes it easy for shipping and receiving because then they're not taking things all over the rest of the building we're just right here, so yea. It works out really, really well. It's a full size loading dock, we can take pallets.

Buyer: Who handles your medical waste disposal? Is it Stericycle?

PP: You know, no. It's somebody else, I can't remember the name, it's a recent change. I'd have to ask. This is our lab, the lab is split into two pieces. This part is our clinical lab, gonorrhea and chlamydia testing. We do our point of care testing, controls are generated here and sent out. This instrument diagnosis gonorrhea, chlamydia, herpes and trichomonas. And then this is the research side. We have a dry ice container here, we have another dry ice container on the other side of the freezer. We have another dry ice container in about half of our family planning clinics. A lot of the specimens that we have, as I mentioned are not stable for very long, so we gotta get them on dry ice real quick. Computer set up right over here. it's one of those things that's neat to see in action, when we're handling all the specimens. We have, as I mentioned, two incubators, one freezer that locks, the big, big tall one is a freezer, and then the two refrigerators. Lots and lots of space for the stuff we have to do in the lab. All of them CLEA compliant we maintain temperature logs and everything.

Buyer: (inaudible) so I can take a look in it.

PP: Sure.

Buyer: Oh excellent.

PP: We have all of our studies broken up into little baskets. I don't have any studies right now that are using dry ice. So there's nothing in the dry ice box.

Buyer: This reminds me of a (inaudible) do you guys use those for fetal collection?

PP: We did have a study many, many, many years ago that did use a hood, I can't remember exactly what it was for. Turned out it wasn't even actually a hood, it just blew air down which might be counterintuitive to what you want to do.

Buyer: And just boxes for storage back there.

PP: The instrument goes through a lot of products (inaudible) there's a lab tech, but she's on lunch right now. This is the area where the courriers that bring the samples from family planning- our gonorrhea and chlamydia samples from our family planning clinics. They pick up empty boxes, the clinics send their samples back in boxes, these are extra boxes for that. This is the research side, so when we've got- we're functioning as a central lab and other facilities are sending us their research specimens, that's here. So shipping and receiving, I usually give them a list. These are all the facilities shipping to us, to our lab. They're going to have this code on it, those go here. Instead of taking them to my box room, they go here. yea we have a system in place. This is my favorite part of the whole building. I think I was a lab tech or something in a previous life.

037000

PP: Let' see if Tram has replied back yet.

Buyer: What time is it?

PP: It is 11:03

Buyer: Do you remember the range of that conference call- they were supposed to send me a text between twelve and one.

PP: No, she hasn't replied yet. Hello. It's Thursday, do you know if they're doing ultrasounds first or clinic first, you know what they're schedule is up there today? I don't either. I know what it is on Monday's and Wednesday's because of Dr. FIne. I sent Tram an email, I don't wanna- I went into ECU but apparently I don't have access. Yes, there was nothing? They're not doing that ITT training today, are they? I thought that was just Southwest. Ok. I see Tram is in a meeting. Ok. Yea, when I click on it, I get nothing. Maybe it's because you have different

access, not that, that should mean anything in terms of patients. Ok, because we're going to need to go over to the area where they process the POC. And that would be ideal to do during lunch at the clinic. Are they running the clinic simultaneously? I was under the impression they were not. Yea, that was my understanding too. So it sounds like it is. (Inaudible) clinics, oh ok. Ok, outlook shows she's in a meeting. No, I'm seeing items, ok thanks for your help. Bye. Today is a concurrent day, so they're doing ultrasound and procedures today. Tram is in a meeting right now but she's only in a meeting until noon. So, did you guys have to get on a teleconference call.

Buyer: Not sure yet, they're going to text us-

PP: Because I can step out into the conference room next door.

Buyer: If you need to, we're just waiting for a text. we're in limbo, it might not come through.

PP: Yea, I'm waiting for Tram. I wanna take you up there and have you see the space, but if they're doing concurrent clinics but if they have people on one half doing ultrasounds and people on the other half doing procedures and she's in a meeting so. We'll just wait for her, and tread water for about forty five minutes or so.

Buyer: When do you think she'll be done?

PP: The schedule says she's in a meeting from eleven to noon. So she's in a meeting for just an hour. I don't know if she's in the meeting talking and she can't see on her phone that I emailed or if she's in a meeting, you know, attendance check and she can look at her phone.

049100

Buyer: So you said that you have been able to provide neural tissue to multiple researchers-

PP: I'm trying to remember specifically the company that did the procurement. When I got here, it was a little bit after, I've been here for nine years. I'm positive there's (inaudible) for neural.

Buyer: When you got here it was an outside company that was doing procurement? It wasn't internal? Oh wow, Ok.

PP: It was a company that- they were doing stem cell research. I don't know what happened to them. I never followed up to see, you know, what became of them. I think I heard their name mentioned in reference to- you know governor Perry has some sort of stem cell procedure.

Buyer: Oh really?

PP: Yea.

Buyer: How ironic.

PP: Yea, he's a little more relaxed about the whole stem cell- adult stem cell topic, you know, tha maybe some other folks (inaudible)

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Buyer: You know when I go to stem cell conferences- regenerative medicine meeting, they have whole sessions about how do we talk about what we do publicly, how do we educate the public, or how do we frame this publicly, similar to some of the discussions you'll have at NAF, then plenary. So it's really interesting how there's a lot of crossover in some of these worlds. Although the levels of intensity may not always be the same, so it's just been a, a real neat-

PP: I think there's a lot of areas again, where the public is so uneducated on the topics that you know, even we I talk about research, drug research and what have you, there's this weird faction of society where anything that comes from a drug company is bad. The conspiracy theory is that people are trying to manipulate you through the drugs. They have a cure for cancer- that's my favorite, but they won't make any money off of it so they won't use it. Yea, it exists in lots of areas of medicine not just specific to abortion of fetal tissue or stem cell. Even though it is a little more rabid in those groups.

002600

PP: Now tell me again, you said- her name is escaping me- up at the national office.

Buyer: Deb Nucatola.

PP: Deb Nucatola. Are you guys working with the national office.

Buyer: We've been coordinating with them as much as we can. Deb has been really helpful in terms of which affiliates to kind of hit up first, and which providers are going-

PP: Yea, usually they try to centralize this around the research department, are they not doing that.

Buyer: What Deb has told us is that they used to try do things under research but it but they decided, because it's just collecting tissue- unless an affiliate is

directly partnered with an academic, which you guys have been for the most part, it's different for a third party collection agency like us. So just simple procurement and collection, they said research is just kind of overkill for that, and in some ways it is. I guess that the national office there's discussion on exactly how involved they want to be at all in this issue, and legal is saying no, we don't want to get too involved with it, let them deal with an affiliate by affiliate basis. Yea, there's a whole- I don't know if you were at the national meeting, no you weren't at the national meeting because we would have met you with Tram otherwise.

005000

Buyer: There was a whole panel on there was a whole panel on tissue procurement in terms of tissue disposition. I guess they may be thinking of drafting a national policy or memo or something. It's kind of all in the air- when we started talking with her, really in depth over the summer. I decided it would really be great to get some kind of national clearance with PPFA national so we could go into any affiliate that has the volume and apparently one of our competitors had approached national about that a few years ago with exactly the same request and that generated a lot of discussion. And legal said that at this time we don't feel like the supreme court- we don't feel it would be a wise move.

PP: Especially state to state the regulations are so different in terms of how abortions are performed. I think that's the biggest underlying factor there, because historically anything research related in the last five years the national office really wants to centralize anything that's research related. Ideally, the way I see it, any ongoing procurement type of system, we're going to need a general sample acquisition protocol, we're going to need a consent form that can be utilized, even though it's not absolutely required for regulations, it makes the most sense to have an informed consent-like document that the patient signs that says: "I am giving this up, I'm not being a paid for it." blah, blah, blah, has all that language in it. To me, that would make the most sense to do at a national level and ask affiliates who wants to be involved and submit that to an ethics board on a central level- that makes the most sense to me but, the reason that sounds like it's not- that has been the deal with research for the last five years. They really, really, would like things centralized and affiliates like mine, we've had a long standing research department for twenty something years. We're a little resistant to having everything centralized because we've been doing our own thing for a long time.

Buyer: Right.

PP: So, that's kind of surprising to me that they are in that position with fetal tissue.

Buyer: It sounds like the positions are all in flux right now- because I don't know if you know Deb Van Derhei with PPCAPS. I guess she's only been there for

about two months or something. She- that's one of her first tasks now is to get a handle on who all is doing tissue collection, they don't even know at the national level, how many affiliates are doing it. which is unfortunate for us because we were hoping that CAPS could provide the master list of who's going to which gestation, what the volume is, and it sounds all-

PP: I'm so surprised.

Buyer: Yea. The researchers- we would have our own spreadsheet already figured out.

010000

PP: I'm very surprised by that part of being related to Planned Parenthood is being like a franchise and there is annual information that we have to submit about our populations, there are policies that are called out standards and guidelines you know, of how we conduct our business. Every affiliate is a separate and distinct corporate entity. We still function under all the same guidelines and principles. When it comes whether or not they have the data, I know they have the data. I know they have the data, I know they another question.

Buyer: Maybe it exists in five hundred different emails (inaudible)

PP: I just have a hard time.

Buyer: I know, several people from CAPS said the same thing "I don't know"- do you see it as an easy thing to have and produce? I'm sure you have a very efficient system in there-

PP: Tram- because they don't have electronic medical record yet, the numbers are kept but they're not kept where I can get my hands on them, they're not in any medical record. If you asked me how many paps we did this year, I could pull everything up and look it up. But because they're not in ECW yet I can't I have to go to Tram, but that number is kept because it has to be reported to the national office.

Buyer: Right.

PP: That's why I'm confused that no one is able to get you that information. I know that their are reports out- that get sent out every year. How many family planning services we provide, how many STI checks, how many HIV, how many positive HIV tests we detect, how many abortion procedures. I know that exists, because I've seen it. So if we have to compile it in order to report to the national office, they should have the ability to compile it and report it. Now does it come to a breakdown of per trimester or week- gestational week, I don't know if it goes to

that level of detail. I know that definitely exists on our level, up to the national office, I don't know.

015400

Buyer: Do you guys have required reporting for your fetal tissue collection? Is your program something that, because they do want to centralize research, are you guys providing that?

PP: Mhm. So in terms of reporting, any study has to be registered with the national office, and the legal department reviews the contracts mainly for indemnification language, to make sure there's mutual indemnification language.

Buyer: And they do that now, legal does that for all your research contracts, including for like Baylor researchers using fetal specimens.

PP: Mhm. They review all of that. So, now as far as record-keeping, how they retain that information up there, every single study that we submit gets assigned an ID number, I don't know if it's in any kind of data base where they can search and see that there are this many studies going on in Planned Parenthood world for fetal tissue. I don't know how it's maintained up there.

Buyer: And then on the flip side, is there a national Standards and Guidelines for fetal tissue collection that you guys follow?

PP: Mhm. Mhm.

Buyer: Really. Because that's what we were asking for, because then we would be able to tailor what we're offering to—

PP: That's why I was very confused by what you were saying because, it's there! That's going to take me a minute to find because I don't access it that often.

Buyer: You haven't (inaudible)

PP: Yea, if it's for fetal tissue I need to- unless it's new this year. It's been the same, there's a form that we have to use with the national office that the physician that is performing the collection is not involved in the dating. That's going to change because that's a state requirement now. Who ever is doing the dating has to be the one doing the procedure. So-

Buyer: What do you mean by dating?

PP: Gestational age. Yea. Then there's another form where we have to attest that the patient is not being paid for the sample, just a lot of little check boxes-

this comes directly from the national office. Give me a second, we just went through an overhaul of all of our network drives in an effort to clear things up.

020000

PP: I need to figure out where the standards and guidelines have been moved to. Let me see. Anything that falls under the umbrella of studies either for sample collection, additional sample collection, I guess there's a vague definition of-I mean, I even go as far to submit it for our residual or waste specimens, like if someone wants to collect urine, and we have urine-left over urine in the cups,we've done that and we've registered that. they've never pushed it back and said no, this does not meet the definition, we don't need to do this. The general policy, that all research, anything involving additional specimens, anything like that gets routed through me, in this department. There actually used to be an entire section on abortion services section and tissue donation. I just remember when I first started here, there was this project going on- ok I need to, (inaudible) brush up on this.

Buyer: It was under the abortion section but now its not there?

PP: I'm not seeing it, but it doesn't' mean it wasn't combined with something else or renamed. The renaming of things is something that happens.

Buyer: Can you search the document for fetal tissue.

PP: The way they have this broken up, I can't just search fetal tissue.

Buyer: I'm just imagining, if we would, like NAF for example- we could say that we have constructed a plug in solution that tracks with the PPFA standards and guidelines. Maybe StemEx couldn't say that, we could.

PP: Ideally I would just go to the national website and look there. Ya'lls timing is not that good. The recently changed vendors who handle all the remote access and stuff. Most of us here at PPGC can't access the national website at the moment. It's kind of a pain though, because we have new employees, new employees have to log in and do training online.

Buyer: They can't do that.

PP: They can't comply because no one can log in. So yea. I wonder if I went ahead and downloaded it already, let's see. Hello, do you remember where we end up archiving all the old amphioxus stuff? Not all the boxes, the online stuff. I mean, we didn't keep much online at the time, I need to get with IT and figure out a way to tie it down, so it doesn't move like that. Do you remember the different check off lists that PPFa required, in terms of this person performed the abortion but did not perform the dating, blah, blah, there we two forms we had. Where

were those- do you know where those were tied to? I know they weren't tied to SOP's they came out of the standards and guidelines right?

Buyer: (inaudible)

PP: Yea, that's- yea, no. That's not- I'm just looking for that form. But it's- we're having a discussion about- PPFA was saying that they don't standardize fetal collection. Yea. Right. Yea. I'm just not seeing it there. I found it, I found it. It was under pending studies, all the flies moved again, under historical. Historical studies, and then there's a tab under it. But this is from 2005 so it might not exist in our standards and guidelines anymore. So yea, ok. It existed, I'm not hallucinating. Ok, alright. Bye.

038000

PP: I know I'm not hallucinating, this is from PPFA -

Buyer: Is there any way to get a hard copy of that?

PP: This may not- if they're telling you this doesn't exist anymore, it may not exist anymore.

Buyer: (inaudible) this is good. I like that, why would they get rid of that.

PP: If it's just becoming more complicated in a state by state basis, I think that this is hard to implement. And you really don't want to enact a policy or guideline that everybody can't follow. "Affiliate fetal tissue donation programs will be monitored upon the affiliate recertification process." That's why I was saying-

Buyer: Has that ever happened?

PP: Yea, because it falls under research. They lump it in and as far as the "monitoring" goes, that's our registration and stuff. Counciling. "The following must be involved in protocol" So here's information about what we have to say, in the protocol itself. The consent. Forms that we have to use. "The clinician has to sign a form that says the tissue was donated, the consent was obtained prior to collecting the tissue, and no alteration in the timing of the termination of the pregnancy, or the method used was made for obtaining the tissue." That's why I said we can do it in terms of this, but we can't delay an abortion in order to get a later gestation. Of course, that's unethical or anything that's going to put her at risk in terms of " no alteration was made in terms of the timing of the termination or the method used." So if we're going to be doing a surgical procedure, the surgical procedure is going to be the same. We're not going to say hey, let's experiment with giving you, you know, whatever medication-

Buyer: Prostaglandin-

PP: Exactly. Yea, we're not going to do that.

042300

Buyer: Right, but a D&E is a D&E and the order that you do things in is-

PP: Right. See, that's the thing is sometimes they change the titles so I need to find- here's another consent form that we had approved by the IRB. I'm (inaudible) about keep thing those, because I don't like to be creative and make up my own names and my own language, I like to steal language from previous ones.

Buyer: I'd like to see for us too, in creating language. I'd be nice to have a copy of that.

PP: The other things is- I have to grab this off the printer- I think, how long are ya'll planning to stay.

Buyer: We just got the text, they pushed it back to three. So we're- we don't have to stay until three.

PP: No,you're welcome- I booked the whole day, I don't have any plans one way or another to cancel, that's why I said you're timing is good because so things got moved around in my schedule, so I was going to be free all day. Tram's responding-

Buyer: Yea, if she's responding, I think it would be good to loop her into the conversation. And just to get like a baseline visual of what the POC's are looking like, specially in second tri. Like if there's still stuff in the freezer form, you know, or if there's stuff from today.

044500

Buyer: Yea, and also you said in the POC lab they have a separate station for actually doing tissue procurement and dissection- something set aside-

PP: It depends, if they are going to have, if the procedure is for evidence then everything changes, it's got to be sterile, it's got to be this. It's the same space, just set up differently. We do the same thing in the lab, we have a study that is for a certain thing and there's a potential of contamination and it's just a matter of saying it's this space instead of this space. It's just a matter of space allocation, so. She's going to see what she can do and let me know. Same thing, it's a dual clinic. I think with the increase in volume that we've seen. Because so many of the abortion providers that we've seen, with this law in limbo, they can't really operate like this and they've already gone out of business. We've already seen

an increase in volume- a huge increase in volume, so they probably now, where they used to have an abortion clinic is now an ultrasound clinic, and they're having to do them simultaneously and it can be a little hectic. She said the front, if we wanted to tour that, which is intake area, waiting room, ultrasound area, the counselor's office where they consent the patient but the back, the actual surgical area- they're running really late, is what she said. If just the front is ok, after one pm. But the back is pretty late, and I replied to her and said: " they really want to see the POC lab."

Buyer: Probably the only visitors you will ever have.

PP: So worse case scenario, all of us are armed with iphones, I'll go up there and take little video snippets, photos, whatever we need to so that you guys can see what you need to see. I totally understand that, so many of our study sponsors have to physically see our space. Especially in the clinics, do you have exam rooms, do you have lab space, do you have refrigerators, show me the tem logs for the refrigerators. We have to do this all the time.

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PP: --thing. So.

Buyer: Yeah.

PP: It's just, I wish I had carved out time on her day. I feel a little guilty that I didn't click to that, so.

Buyer: No, I think if you just go up with your iPhone and we can get a visual that way. Would that be helpful to you?

Buyer: Yeah, definitely. Probably email is better than text because for stuff like that, the bandwith is--

PP: Mhm. So. Let me go grab that SOP off the printer. I'm notorious for leaving stuff on the printer.

Buyer: It's just too bad we weren't in there while the procedure is going on like we were the other day. I'd just like to be able to--

Buyer: Mhm. But pictures are great. Would it be helpful seeing pictures, actually seeing some of the specimens?

Buyer: Oh yeah, that's the only picture that really matters.

Buyer: Okay, would that be possible for you to capture that, if they're so busy that--

PP: I can ask. All I can do is ask.

Buyer: Okay.

PP: I don't know if they will shoot it down, and say it's way outside the confidentiality agreement. I don't know. [laughter] They might, I don't know.

Buyer: No, we were in there picking around in the dish with one of the other affiliates just recently, so. We are low, low stigma here.

PP: Oh, I understand. This is called now--See, it says Medical Affairs doesn't need to approve specific affiliate protocols if they're in compliance with our Standards and Guidelines. But oftentimes there's changes you know, changes in how it's processed, changes in you know, it's not just, okay, here it is, it's usually something involved, and every time we make a change, it has to go through Medical Standards and Guidelines, and if it's done through a research protocol, then that has to get submitted to the same group, it's just the Research Division, so I don't know--you hearing something about registration with the Research Division. Specific here: "aborted tissue donation programs will be monitored as part of the affiliate recertification process." No minors by the way. No, we won't be collecting any tissue from minors. It's pretty complicated, I mean for minors obviously we have to have parental consent, they're--

Buyer: Oh, in the state of Texas.

PP: Yeah, state of Texas, we have to have parental consent, and then for research it would be different. So if they're donating the fetal tissue, is it falling under the umbrella of research, is it not, we're just not even gonna go there because--

Buyer: Yeah it sounds like it could be complicated.

PP: I think it's gonna be too tenuous in terms of maintaining compliance with regulations, and with the regulations possibly changing, I'd just rather not go there. We have enough patients who are non-minors.

Buyer: Yeah.

PP: So, "affiliate protocols must include provisions to ensure compliance with federal, state, and local laws regarding minors, documentation, retention of records, and storage and transfer of aborted pregnancy tissue." Are you aware of any specific shipping and transportation regulations specific to fetal tissue? I've never seen anything specific to fetal tissue.

Buyer: No. Just what's standard and customary for every other biospecimen collection agency out there. I mean, my feeling and what we've discussed with our legal team before is much of this ought to just fall under the standard Uniform Anatomic Gift Act and yeah. Leave it at that.

PP: So how do you ship it, do you usually ship it to like the person or the organization in Oklahoma, dry ice, you ship it in a speci-cup?

Buyer: Yeah, uh, specimen tubes is what we like to use for most materials, just the 25 to 50 mils. Similar to the vacu-tubes you would normally use for blood draws and things like that. And I mean depending on the researcher and their protocol, and the distance, some people want it on wet ice, some people want it on dry ice, it's always variable just depending on--

PP: Okay. I just asked one of my team to look up in IATA and see what category it falls under. Just because I'm curious, we've not shipped any before, so I'm curious, I mean all of our other researchers that were local, even the company, they sent a courier to pick it up.

Buyer: Were they all even local to Houston?

PP: Mhm. Yeah. And so much of the research is done, like, one of the researchers that I can think about, she was performing the procedures, and would look at the schedule and pick which ones, and let staff know, "Okay, can we try to enroll these?"

Buyer: Mhm.

PP: Because she wanted certain gestational age, and she--

Buyer: Is she still a provider here?

PP: Mm. No. She's actually, um, now the Medical Director at another Planned Parenthood and it's escaping me. Dr. Regan Theiler? Have you met her? T-H-E-I-L-E-R.

Buyer: Not in Texas. You know, that name sounds kinda familiar, but you don't know what state that would be in?

PP: Um, northeast.

Buyer: Oh, northeast.

PP: Northeast somewhere. I want to say she went to Southern New England, which that's not true--

Buyer: Yeah, I know Dr. Burkett at Northern New England, so that's not--

PP: Yeah, Southern New England has got Timothy Spurell, so it's not that either. It might be Southeastern Pennsylvania.

Buyer: Okay.

PP: Let me put that note to look up Dr. Theiler. Because she would be a good reference for you too.

Buyer: Mhm.

PP: She does a lot of research, so--

Buyer: And Pennsylvania is a big research hub.

PP: She knows what's involved in modifying what we need to do to get you the specimens that are intact. Because, she's done it. So I'm surprised I didn't think about her a minute ago. Yeah, Dr. Theiler would be a good one. And she was doing those here. And you had asked another question, and then I got off on that topic, I don't know--

Buyer: Oh, I was just going to ask about the researchers that you've supplied in Texas before, what kind of studies they were doing. What it primarily stem cell stuff, or--?

PP: The company was doing stem cell stuff, the other researchers, Dr. Theiler's was specific to a marker, and that marker--she was actually mainly looking for the placenta tissue, and looking for markers in the placenta that would have to do with implantation. Specifically because implantation could have huge impact on other kinds of abortifacients, contraceptives, and infertility medication for people who may have some sort of issue with that marker that doesn't allow the placenta to implant, so they abort. So yeah, that was her area of focus and there was a specific chemical she had identified and was doing a lot of research on that. So, and she was actually doing the research and had the lab, so week to week what her needs were changed, and she would just, "K, I need these ones this week now." So because she was doing the research and she was here, she would collect on the days when she was here so that worked out perfectly.

Buyer: And the ones who needed neural tissue, do you remember what they were working on?

PP: No idea.

Buyer: Yeah.

PP: No idea. They were not very specific in terms of the integrity of the sample either. So as long as they got everything, which were the instructions, they were happy with it.

Buyer: Oh, interesting.

PP: So, yeah. I don't have any detail about that. I think they had, a lot of different needs in terms of what they were doing with it. And they were mainly, I do remember a discussion specifically about neural tissue, but then a lot of work in stem cell. The company was just known for stem cell work.

Buyer: That was Amphioxus, was the other one?

PP: Mhm. Mhm. Yeah, yeah. So.

Buyer: Yeah, I've never heard of them.

PP: They're local. I don't even know if they're still in business. I would think that they are. I remember hearing about them. Oops, I just misspelled it. The Amphioxus Song, okay.

Buyer: Song?

PP: It's what it said. They appear to be still in business. Amphioxus Cell Technologies. Amphioxus.com. Why didn't that come up? That will be funny if they're blocked. Okay. Our IT blocks some of the strangest--mm mmm. It doesn't appear their website's live anymore. They may not be around anymore. This was 2006? 2005, 2006. I don't see anything about them. And I know I've looked them up in the past, I've seen a lot of media stuff about research and what have you that they were doing. But you know with the way things were with cell, stem cell research, they may not have been able to prosper.

Buyer: Yeah, and in the state of Texas.

PP: Well Tram's gonna let me know about--oh my goodness. Yeah I'd be curious if they were still in business, but I don't see, I'm not seeing any evidence that they are. Well here's the president, he's--okay, maybe not. Really? Yeah, their website's not even live anymore. Dang it! I hate when it does that. Yeah, apparently they don't even exist. So. Yeah, but that was, we finished up sample collection with them in 2008. So, and they started right before I got here, so 3 years. I can't remember, I'd have to look up the parameters. Back then we didn't keep things in electronic format. But it was collection Monday through Friday, they would send a courier over, and I don't remember if it was any specific gestational ages. I think at the time we were not doing 2nd trimester abortions, so it had to have only have been 1st trimester. But it was basically everybody and anybody who agreed to donate. So like I said, some days we'd have as many as

6 or 10 in a day. So, but, yeah, I'm very curious what we can deliver in terms of 2nd trimester. I mean I have no knowledge of our volume. I know it was enough that we had dedicated days that we were doing it, so Tram can tell you that easily, probably just off the top of her head. So.

Buyer: Yeah. Off the top of your do you happen to remember, or I don't know if we can talk about this, the, like, per-specimen what compensation was like from Amphioxus, just so we have kind of a ballpark idea.

PP: I don't. That one, would definitely be different.

Buyer: Right, because they are pretty different. I'm just thinking in terms of, like a paired liver-thymus from a single donor, what we might be looking at for that.

PP: Yeah. Because we had two levels of invoicing for them, we've had it worded as "per consent," because the consent process was the administrative part that we had to do, and then we had an overall administrative fee for basically working it into the clinics themselves. And at the time, "per consent" was \$25. And that also covered if a patient consented to be in the study and then for whatever reason, we didn't get a sample, or she changed her mind, because I see, I didn't do that budget. It was, existed when I got here. So there's probably some situations where somebody would consent and then just not, we didn't get a sample or she changed her mind or something happened to the specimen or I can't think of it off the top of my head. But we technically can't, ethically I don't think they were, based on what I'm reading here, I think it's paying for the specimen itself, that language that we--

Buyer: Right. On paper, it has to be massaged a little.

PP: Yes. Yeah. Yes. So, the consent process is what is unique to the visit, is consenting the patient.

Buyer: Right. Now obviously, we don't want to end up paying for material that we can't use--

PP: Obviously.

Buyer: And that might be, so if there's a certain, like, consent fee and then something else that represents the specimens--

PP: Mhm. Yep. Yeah. I think definitely a, a-la-carte approach would be the best. Because if there's, say for instance your project with the sickle cell. If there's a level of screening that has to happen so there's not everyone that comes in needs to be approached, that involves time and so something for the screening. And then any paperwork that has to be done that's unique to donating the tissue. And then anything that is unique in the processing. So anything that is standard

of care, that's going to be standard, stays the same and is not billable. Anything that is going to be specific to acquiring the specimens, then that would be--

Buyer: Yeah.

Buyer: And so then that's what we would want to make sure is your compensation would be higher for that specimen, and then how we say that, how we--

PP: Yes. How we frame it, I think is important too. I think that we're not altering anything, and that it's clear that we're not altering anything, even if the procedure itself there's a modification in how they do it, it's still the same procedure, but we're doing it in a way that we preserve the integrity of the specimen, I think is, yeah. Something that we can definitely discuss that with Tram.

Buyer: It sounds like what can probably happen is we can kind of give you our needs--

PP: Mhm.

Buyer: And sort of how in our, according to our budgeting and our practical use kind of how we look at everything--

PP: Mhm.

Buyer: And then you guys can kind of translate that--

PP: Yes.

Buyer: You know, translate that into something that looks good on paper. [laughter]

PP: Yep. Yeah. And you know, again, knowing that I think the biggest thing is staff and management want to see that costs are covered.

Buyer: Mhm.

PP: You know? And obviously, from our model, and ideally, in my context of budgeting for crazy, budgeting for crazy also includes making sure we budget for some things that we just can't predict for. Okay, we think that this thing is gonna take this time, and we'll take the, go through the steps of starting to time it, but then maybe when we actually start implementing, then like you had suggested, "Hey, come back to me," because we find that this particular step, when we're using that actual product, or the actual instrument, we have to do this, this, and this to get it instead of it just being one step. And we definitely take that into

consideration. We try to do everything we can on this end to role play it and time it and--

Buyer: Mhm, mhm. I just don't want it to turn into a situation where it's not financially beneficial for you.

PP: Yeah, yeah. And we'll, I'll take you up on that. I'll take you up on that. We definitely want to do that. Because that's what staff and management need to see. Is that we're not underwriting anybody's project. And I go to great efforts to demonstrate what the cost, actual cost is to us--to whomever asks--and then, this is what is budgeted. So they know, okay, you're covering costs, there's margin, that's covering overhead, or whatever we need, just to make sure everything is covered.

Buyer: Right, and so then when we're coming in and making it beneficial to you financially--

PP: Mhm.

Buyer: You can frame it so that that's--

PP: Mhm. Yes.

Buyer: Okay.

PP: Yeah.

Buyer: Because that's how we're going to keep you happy, right?

PP: Yes. Yes.

Buyer: To make sure that financially--

PP: Yes.

Buyer: You're growing your clinic---

PP: Mhm.

Buyer: And however you need to say that, framing that on the other end.

PP: Mhm. Yes. Okay.

Buyer: And then we also just need to know, you know, what our outlays are gonna be too so that we can watch our margins.

PP: Well, and we also, too, one thing that is extremely helpful, and it makes sense, but sometimes a lot of our investigators and sponsors don't think about this, when we're involved in studies, oddly enough we like to know about the outcome. Because we are into research, we all have that little Curious George mentality, and we get information or discoveries are made, or products go to market, or whatever, we love that feedback. And when we had the physician who was here, that was doing her own research, in these staff meetings, she would tell the staff, "I realized this, and I found this, what this may mean in the future, is this," oh my gosh, everyone was so engaged. And that's the main thing, the engagement is to keep people engaged. And the budget is great for our bean counters, the engagement with the staff actually doing the procedures is what is key. And maybe from time to time, if you guys are able to travel down and meet at a staff meeting and just talk about what's involved, and where the tissues are going, what kind of research is being done, what we hope in the future this will lead to, that goes a long way.

Buyer: That's how you really sell people.

PP: And that's, that's something that's not anything that's a financial benefit to the organization or anything, but keeping the staff engaged, that is--especially with long-term projects. That's something that's very important, is keeping people engaged. And knowing about what is happening in advances, that's the main point. Because that gives them a sense that what they're doing is valuable beyond the money.

Buyer: Right. Yeah.

PP: Because I mean it's not, quite frankly, the people who are actually doing the procedures and doing whatever are going to see no financial benefit. This is just part of their job. [laughter]

Buyer: Mhm.

PP: So there's gotta be a, something else there that keeps them engaged. So, and usually that's information. It's just that, is information about the project.

Buyer: I wonder if since they don't know the financial benefit--

PP: Mhm.

Buyer: I wonder if giving them some incentive financially so that they know there's both benefits down the road, this is the research and that's excellent for that emotional,

PP: Mhm.

Buyer: but financially is there any way to--

PP: Internally with like bonuses or anything?

Buyer: No way at all?

PP: PPFA actually has from like the sponsors, not pay us enrollment or finder's fees, we have regulations about that for our conflict of interest policies. And then internally, it is something, it's kind of a sore subject because I would really like to be able to, but it's just really really hard to administer because we have some studies where there is room, we could potentially have a bonus, we have some studies where there's not, and operationally each of our health centers are different where some of them, it's just easier to do our studies there, then should some people get something that's really just because their clinic flow is better because their building is built differently? And you know, so it just makes the whole thing--we used to, we used to back in the day, but.

Buyer: You used to be able to give the--

PP: Oh yeah, we used to be able to, bonuses and, yeah, yeah. Out of my department, we used to be doing the beginning of each month, bonus reports for the prior month, but I mean it's even spread that the changes have changed, it has changed even that drug companies can't give us pens anymore.

Buyer: What!

PP: Yeah, no, I mean drug companies used to be able to come in and provide lunches and--nope. No. With all of the, again with the perception that drug companies are bad, and they're going out to manipulate these doctors, and they're prescribing drugs that are not necessary, and ba-ba-ba-bah, there's been such a pushback in Congress on that with you know anti-kickback laws, and the sunshine act, and all of these things that they've implemented in terms of regulations, because there's the perception that this unethical type of relationship exists. So. I know. I know. So, maybe a lunch from time to time, maybe a breakfast if they have morning meetings and just some information about the projects will be good.

Buyer: Mhm. And just, no way to write it in so that you know, okay, this is--

PP: We could totally write it in, I mean, we could cover it under "meeting costs." That's how we cover lunches in my department. "Meeting costs." Yes, yes.

Buyer: Uhuh. Okay.

PP: We're providing information and updates about the study. We feed 'em. People love food.

Buyer: Mhm. Okay. That's good to know.

PP: Yeah. And I can bake that into the budget too.

Buyer: So just a way to, thank you.

PP: Mhm. Just acknowledge the effort. That's the big thing is just acknowledging the effort. Giving them the information that they need to stay engaged.

Buyer: And there are ways it sounds like to do it both financially and just the feedback of what happens with--okay.

PP: Mhm, mhm. And like I said, staff really like to know what they're doing is valued, and valuable, and there's various ways you can do that and still keep them engaged.

Buyer: Okay. Excellent. Speaking of lunch, I'm getting a little hungry, I don't know about the rest of you, is there any news from Tram?

PP: There's not.

Buyer: I'm wondering if maybe just, if we can't get in, if we could impose upon you to go ahead and take those--

PP: Okay. I'm gonna, what I'm gonna do is, I don't want to traipse up there myself until she's given me the go-ahead, because they're really busy and she's just getting out of that meeting, um, let me wait for her to circle back around because that one email that said, "Clinic running behind," whatever whatever, let's give her till one o'clock, and then, I'll peck at her again. And see if I can go up there and either take pictures or steal you in.

Buyer: Okay. Yeah. So then I'm wondering if maybe we should like break for lunch, and then--

PP: Okay, if you want to. What are you hungry for?

Buyer: I--I'm here to please, I'm happy to--

PP: Oh my gosh, we've got--it's weird. Our building, it's, there's nothing in walking distance. Everything we have to travel. But we have lots of good places.

Buyer: What's your favorite?

PP: Obviously, I'm--not opposed to food. There are good Mexican places around. There are good Vietnamese places around. There's great seafood around.

There's a Chinese/Vietnamese place that's really good that's not too far. I'm just trying to keep us close by in case you get your text about your meeting, and in case--

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PP: Come up now. We can come back quick.

Buyer: It all sounds good, why don't we make it the closest one?

PP: Yea. They're two seafood places that are relatively close, the chinese food place that's relatively close. The chinese place usually gets pretty hairy after twelve o'clock, in terms of a long wait. Trying to think outside the box- obviously because we don't have a lot of places around here, we don't have any places that are walking distance. For us, my group, typically we all bring our food. Or we all plan to go out on a day we're going to take a long lunch. Sometimes it takes a minute to get my brain engaged when we haven't been going out.

Buyer: Or delivery? Yea, is there anywhere that delivers.

PP: We do, all of our house accounts require a three hour window, because of the travel time. We can pop in the car and go down 45 with a couple exits down, where their are a lot of options. Then we can just decide.

Buyer: Yea, sounds good. Is this my copy?

PP: There's the research piece. This is obsolete, this is from 2005.

Buyer: That would be good to see the language though. I know it's obsolete, but still having the language.

PP: And then you got this one.

Buyer: Do we get that or? Yea this is the one with the, this is the intake form with all the-

PP: And those are always subject to change.

Buyer: Do you feel comfortable with my driving?

PP: Yes.

Buyer: Ok.

PP: I didn't give you anything that causes drowsiness, should not operate machinery so we're good.

Buyer: Alright. These are-

PP: Where in California?

Buyer: Southern California.

PP: San Diego area, maybe?

Buyer: Los Angeles. Do you know that area?

PP: I have family at one time in San Diego. I love san Diego it's gorgeous. My uncle, was a police officer for thirty years in L.A. As a kid, we went to visit my uncle pretty often and um. Disneyland, whatever, I have very fond memories of L.A. I've been to as far North as San Jose, but I've never been to Northern California.

Buyer: So were you born here-

PP: Houston. Born here, raised here, haven't left here. Yea, probably won't. I like to travel a little bit from time to time. Like, I could totally be a Canadian. I've been up to Canada several times, oh Canada. Yea, Houston is my home. What about you guys, you both originally from California?

Buyer: Yea. Yea.

PP: Cool, cool. So, in California, I noticed they have a lot of fish tacos.

Buyer: Yes.

PP: That is odd. Here in Texas, we're right on the Gulf Coast, we have a lot of seafood, fish tacos are not real common. Not like they are in California. that was the thing, when I went to San Diego to visit former in-laws. Oh, Missy you have to come try this fish taco place, and they were also native Texans, but they moved. And I could not wrap my head or tastebuds around these fish tacos.

Buyer: Ok, first time I had them, my girlfriend ordered. She's Korean, so I just let her order, and I thought they were really good.

PP: I like chicken, pork, beef tacos, lamb, goat, I've had other types of meat. The fish tacos I just-

Buyer: Try it sometime.

PP: I have. I tried it several times.

Buyer: Oh, you did try it. I thought you said you didn't try it.

PP: I tried it, and I didn't- let me let my folks know I'm taking off. I cannot type today. So, other than fetal tissue, what else?

Buyer: Adipose tissue is a big one actually, we have-

PP: Oh I'd be happy to donate. So you probably work with a Liposuction facilities?

Buyer: Yea, we have relationships with several cosmetic surgery centers in the Southern California area. There's plenty-

PP: I'm sure you get plenty.

Buyer: Yea, we actually just got a really interesting-

PP: It's actually really popular down here.

Buyer: Oh really?

PP: Yes.

Buyer: You know what's really interesting trying to pop up in some places is clinics that are lip and stem cell clinics. Believe it or not. Where they will lipo out a small amount of your adipose tissue, they take it out, isolate some of your own stem cells and re-inject it back into you. There's some places like that popping up in L.A., there's one in Colorado-

PP: I thought there were regulations inhibiting stem cells, being, even your own from being re-introduced back into your own body.

Buyer: I think it depends on who's paying for it and how's it's marketed. There's some talk in California among the research community, there's clearly such a demand for services like that some of the more forward thinking researchers in California, who are part of the California Institute for regenerative Medicine and all of that. That are maybe wanting to establish a chain of trial clinics for procedures like that, that are considered lower risk and more promising. So that if people are going to do it safely and with full informed consent and all that.

Buyer: Is this wind normal?

PP: No. More normal during the spring time. Usually during the summer time, we call it sea-breeze, you have the same thing in California, where you have a gentle breeze. This is a front that's moving in (inaudible)

Buyer: Could you get me my driving glasses?

PP: My daughter just got her driver's license-

Buyer: I forget, are these the driving ones?

PP: My daughter recently got her driver's license and we went to and auto show and she really liked this Chevy Cruze.

Buyer: The rental person liked it too. This one has a- I won't mention it, it has a little humorous sound to it. wait a sec, I gotta show you.

PP: It's leather on leather. Not that I'm that tall, but the whole motion sickness thing, if I'm not the actual driver-

Buyer: Am I going to right, left?

PP: You're going to go left then right where this truck is at the light, not the light, I mean the stop sign. Then you're going to turn left here again. Was the GPS really off for you, did you have to?

Buyer: No, the GPS was ok, it's just pour understanding of the way that exits work, with the freeways, it was off.

PP: I mean being in a strange a car, that's why if you were uncomfortable with that I would totally understand it. And then we're going to go left here.

Buyer: Left here. (inaudible)

PP: It's very strange.

Buyer: There's a welcoming committee at this clinic too huh? Right or left?

PP: You're gonna go left, and then you're going to jump on the access road there. You may have to floor it, event though the speed limit on the access road is forty-five miles an hour, people routinely go fifty-five, sixty and above.

Buyer: When I get on it, should I be in the left lane or the right lane?

PP: You're going to want to get over to the left lane as quickly as you can, so you can get on the entrance ramp to the freeway. You drive in L.A. and this is challenging?

Buyer: It's just that it's new.

PP: It's new, yea.

Buyer: It's new and it's a new car and I don't have visibility like I used to.

PP: What do you drive at home? I'm going to fix your collar.

Buyer: Thank you. So you're saying to go-

PP: Just it hit, if you look out here on the right, you see where the entrance ramp is?

Buyer: That's where my destination is?

PP: Yea. Have you talked to any of the Planned Parenthoods is California yet? Mar Monte or-

Buyer: Yea, so our problem is, all the affiliates in California are already partnered with a tissue procurement organization. So, its real tough to get in when someone is already there and so we've had to cast our gaze further afield to untapped locations.

PP: Yea. Well good, I was actually hoping that we would meet up with someone, I went up to AACC two years ago, which is a big lab conference. There were several tissue procurement companies there, they were not looking for fetal tissue though, the most bites I got out of those contacts, they wanted urine from women of various gestational ages for whatever type of project they were working on. There was a lot of communication issues you know they want urine alone, if it's discarded urine. If it's discarded urine and a bunch of patient information, then it gets complicated because I need consent forms for that. There are federal and discarded tissue regulations for discarded waste. (Inaudible) Have you guys ever been to Houston before? Is this your first time in Houston?

Buyer: I may have been ten years ago, on a family vacation, but I don't think I remember what part of Texas it was.

PP: A family vacation in Houston?

Buyer: Yea, there was some stopover in Texas but I- it was a long time ago, I don't remember what part of the state it was.

PP: (Inaudible)

Buyer: No.

PP: So [Name], it sounds like you have a very science-y background.

Buyer: I do, my background is in molecular bio, so.

PP: Ok.

Buyer: So, I make a right-

PP: Stay in this lane, when you get to the light, we're going to u-turn, look over on the other side where it says: Pappas Seafood House. I think ya'll would like that, it's pretty tame in terms of spiciness because a lot of our sea food restaurants out here have a lot of Lousiana cajun influence, quite frankly they're both hot. A lot of red peppers, so I don't want to give you acute indigestion on your way home, so we're going to Papa's.

Buyer: Should we take off our nametags before we go in?

PP: Certainly. (Inaudible)

Buyer: So I wanna stay in the right lane?

PP: You can actually, it's not protected so you will need to yield, but you'll want to jump over to the right hand lane. You've got it, and once we get over to Papa's you can just (inaudible) So adipose tissue, what was the other thing you were talking about?

Buyer: Adipose tissue, we actually just got a contract with a researcher that focusing on regenerating the telomeres.

PP: Telomeres?

Buyer: Telomeres are basically on the ends of the chromosomes and the shorter those get, they degenerate over time with aging and that's causing senescence after aging, is that the DNA and the chromosomes degrade, it has to do with the telomere length at the end of the chromosomes. There is something about stem cells, there telomere's don't degrade as quickly or are more preserved or are auto regenerative, which is why there is such a regenerative capacity to the stem cells. This project is looking at- don't crush my legs. So his project is looking at adipose stem cells from older populations, so the inclusion criteria is- uh, where did I put it.

PP; Oh, go ahead, I was going to put my head-

Buyer: Did I lock it? It's locked, yea.

PP: Thank you.

Buyer: Yea, go ahead. So, the inclusion criteria is age fifty-five and up. So, it's kind of interesting coordinating with those centers when they have those patients.

So, it's their adipose tissue that we're collecting and sending to that study. And we've done some cancer biopsies before, and there's an oncology clinic about twenty miles away from our office.

PP: I'm very chatty, so every once in a while, just throw and elbow and say check your email. I told her to text me but depending on what she's doing, she might just reply to my email.

Buyer: Look at that Texas red fish, that looks good.

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PP: I should have asked first if either of you has seafood allergies or anything.

Buyer: No, I would have said something. So, what do you like here?

PP: It'd probably be easier to say what I don't like. I love seafood, I love to fish.

Buyer: Do you?

PP: I love to fish.

Buyer: What kind of fishing do you like?

PP: Mainly saltwater fishing. Flounder, Redfish, which is another kind of fish that's pretty common. Speckled Trout. I have a little, small cabin in far Northeast Texas, and we-

Buyer: Do you have a little boat?

PP: we have a little catfish pond.

Buyer: So, you have a little boat?

PP: I don't have a boat at the moment.

Buyer: How do you go out?

PP: My uncle has a boat. My uncle from California that's yea- he's the one that we go out and fish with. How is that light reflecting on your face like that? Must be the little spot light thing.

Buyer: Is it on my face?

PP: It's moved now. But yea, it was a real-

Buyer: Is it this?

PP: It was something. It was reflecting, I was like: "How is that happening?" Now, I don't feel bad, I felt bad about leaving my staff because we all eat together. They're having an email discussion about what's for lunch, and what are we going to do, and apparently no one's having lunch today, so I don't feel bad now. Did you get your text about the-

Buyer: Yea, it got pushed back until three.

PP: And feel free, if you need to group and want to meet into our conference room, you are more than welcome to.

Buyer: Thank you.

PP: Because I don't know, by the time we wrap up and with traffic and everything, I don't know if you'll make it back to the hotel in time for three.

Buyer: Yea. Yea. Did you decide- I think I did, yea. I think I'm going to get the Rainbow trout that they do over here.

PP: Sounds like a good choice, rainbow trout and shrimp.

Buyer: where are you seeing that- it's over here.

Waitress: Hi. (Inaudible)

PP: Can I have water, no lemon?

Waitress: No lemon? Anything for you?

Buyer: Water.

Waitress: No lemon?

Buyer: Lemon is fine.

Waitress: For you?

Buyer: Water with lemon.

Waitress: Anybody want to start with an appetizer today? Some calamari or-

PP: Not me.

Waitress: Ready to order or need a couple more minutes.

PP: Do you want an appetizer?

Buyer: I think I'm ready to start the main course, yea.

PP: The bread. (Inaudible) I think we know what we want.

Buyer: rainbow trout for the both of us.

Waitress: Ok, do you want it with the shrimp or just the naked. We have it with shrimp, or with no meat, just the trout.

Buyer: Just the trout. Just the naked trout with the herb olive oil and all that. Yea, yea, yea.

PP: And for me, the blackened cat fish. That was easy.

Buyer: Yes, so tell me about your fishing, have you been doing it since you were a little girl or-

PP: Yea, I was supposed to be Brian. Yea, I was supposed to be Brian, the doctor told my dad: "Hey you're going to have a little boy" This was back before ultrasounds were really good and my mom never had one, so I don't know how he knew that. But my dad always loved to fish and I loved to do things outdoors and my dad always fished and so I just went with him.

Buyer: You don't have brothers?

PP: An older sister. Girls. No brothers.

Buyer: (Inaudible)

PP: I love to be outdoors, it's unfortunate that I got my dad's irish freckly skin so I have just bathe in sunscreen when I'm outside because I burn so easily but I love being outdoors. the little place that we've got in East Texas is on thirty-six acres. Lots to do outside, hiking and just recently we've cut through to make trails, so we've got a little more than two miles of trails (inaudible) lots of pine trees, lots of oak trees, the whole are has some timber to come in and cut, the previous owners were my brother-in-law's grandparents. They just turned eighty-nine, we got the property from them last year, they just could not maintain it anymore because they've gotten older so (inaudible) the whole timber part.

Buyer: How do they maintain (inaudible)

PP: With a tractor. I've had to learn how to drive a tractor.

Buyer: And so they couldn't do that.

PP: They had about ten acres of it that was partially cleared. It had cattle in the pasture, you know, part of it was cleared in the pasture area. We don't have cattle, I know it's against the grain of a lot of Texas stereotypes but we have no cattle. I have no cattle, I have no intention of having cattle.

Buyer: What would happen if it wasn't maintained? Why can't you just let it be wild.

PP: Most of it is. It's just the pasture area of it, because the weeds get so tall. The wooded areas that are like twenty something acres we leave that- we cut through trails, so we find areas with not a lot of trees, w clear mainly just weeds and brush that obscure us from walking but we try to cut back as few trees as possible.

Buyer: (inaudible)

PP: Yea we did.

Buyer: See I told you.

PP: Most of the area- I don't know why but for whatever the reason, we just don't have scorpions in Austin. Austin, yes, definitely. Central Texas, yea. Up in my area, piney woods, Northeast, we haven't seen any, doesn't mean they're not there. Do you have a thing about scorpions?

Buyer: No, I have a thing about earthquakes.

Waitress: (Inaudible)

PP: Better safe than sorry. So, scorpions and earthquakes, are they related?

Buyer: No, not at all. (inaudible)

PP: They do have earthquakes, small ones. And of course, (inaudible) the drilling process, North Texas (inaudible) small ones, like a three on the richter scale.

Buyer: So, that's not even (inaudible)

PP: That's a rumbly stomach in some cases.

Buyer: (Inaudible)

PP: That you've been through? No, I never have.

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Buyer: (Inaudible)

PP: So, can I talk more business? Tell more about specimens, I'm very curious about what people are doing. Sorry. I love my personal stuff and talking about fishing but-

Buyer: Do you ever go to regenerative medicine conferences? That- I think you would find that fascinating because it's like any kind of industry conference but it's all about stem cell work. There's World Stem Cell Summit, I think it's every December. There's several meetings in California, because we really are the leaders in that industry, here in California, Wisconsin, North Carolina, some places in Texas too. (inaudible)

PP: With stem cells, I've heard about it in adipose tissue, I've heard about obviously marrow regenerative (inaudible) where else are stem cells prolific, where you could easily acquire tissue.

Buyer: Adipose is like the major site or mesenchymal stem cells, that give rise to a lot of your internal organs, the hematopoietic system, which is the blood producing system. Prenatal, that's the liver and postnatal (inaudible)

PP: (inaudible) before I went into research. So, at the time there was a big boom for people to preserve the placenta and cord blood for stem cells. Just banking protocols that we have.

Buyer: Exactly. Exactly. So, yea that's-

PP: Is that still popular?

Buyer: Yea, that's big in California, many hospitals are starting to institute protocols for banking and all of that. What is still difficult is neural stem cells, and neural progenitors. It's hard to get a good source of that apart from fetal tissue, but even that is difficult because getting a calvaria out intact is kind of tricky and even then it's even mashed for transplantation, it's kind of this whole other ball game. There is some really interesting work being done, and this sounds like science fiction, but it's real. It's called direct lineage programming, where they can actually take- they take cord blood or peripheral blood, or cord blood even and they apply a certain antibody or factor to that culture and it will actually change that cell lineage of stem cell from hematopoietic to neural.

PP: I didn't know that was possible.

Buyer: I know. It sounds like science fiction, it's been done, the study has been published.

PP: There's stem cells that does this and-

Buyer: And it goes through a certain lineage and that's why it's called direct lineage reprogramming, where they actually change the lineage that the stem cells are in. It sounds like magic, it's incredible. Which people that ten years ago when the IPS cells, induced pluripotent stem cells came on the scene, people thought it was science fiction as well. It's a big thing now- it's largely replaced embryonic stem cells in terms of what investigators are looking at- IPS has largely replaced that. The production of IPS cells is difficult and personally I don't think that's where the future is in terms of clinical applications. I think that for translational research, I think we're looking at fetal stem cells, and autologous-bone marrow, adipose- I think that's what holds the most potential for going from the lab to the clinic.

PP: So, how would you, if you don't mind my asking. How did you start with procurement, processing, how did you get into that.?

Buyer: (inaudible) So many, many years ago, when I was in Southern California I was actually working in clinics. I was working with(inaudible)

PP: That's long enough were I don't recognize the area code, so please continue.

Buyer: So working in clinics and working with women who are struggling emotionally, that was really my function. It got a little scary in California, so I moved out of state (inaudible) stigma, whatever they were struggling with. Fast forward, my niece was in college and telling about this need for tissue, so just listening to her talk about it. (Inaudible) what a way to (inaudible) where is the positive. Knowing that there's this huge need (inaudible) what a waste, what a goldmine. What a goldmine, not only financially but for the stigma (inaudible) the staff. You could probably tell me about the staff. (Inaudible) just hearing my niece talk about it. I knew I needed science, that's not my field. (Inaudible) there's a need and people who have it, and how do I bring them together? That's where [Name] came in (inaudible)

012500

PP: There's definitely opportunity, I don't know about the other Texas affiliates, at our affiliate, I mean we don't have any ongoing fetal donation and the only potential competing project would be from a Rice University physician who wanted, in total he needed fifteen specimens.

013500

PP:Very small project, he went through all the hoops of getting it approved through his IRB and everything. And then, I've seen this a lot, which is why early on I said we don't get involved in grants. A lot of academic studies, unfortunately

the physician or you know, researcher writes the grant and then as an after thought, "hmm where am I going to get this." They know they want to come to Planned Parenthood to get it but they don't bring us enough money. Then there's mentality where "you're no profit, you should just give us the stuff." I wasn't joking when I said insulting budgets, I mean they're wanting us to do all of these things consent the patient, collect the specimens, and do this, and do that and for nothing, literally, literally, zero.

Buyer: Do they not understand the process? How could they expect you to do that for zero? Financially, that just wouldn't be- how could they do that? Do they not understand?

PP: I don't know what they don't understand. You're doing this anyway, just these few extra things, like it's no big deal. There's a lack of connecting to the things you're asking us to do more than what we are and we have to because of what it is. We had the one physician I was talking about, that I had been working with for about a year to get his protocol approved with his academic IRB. And I told him we have to set up a contract for this, we have to set up a budget, this and that. I sent him a contract for another academic study with the physician who used to work here. I redacted everything and I said: "I'm going to leave the budget numbers in here, just as a reference, obviously we will need to discuss it." Never heard back from him. We went through all that work to get your protocol approved with the ethics board and-

Buyer: This is a provider?

PP: This is a student doctor M.D. P.H.D. at an academic institution in town. in terms of academia, doing anything in academic makes my hair grey. There's just, I don't know what it is-

Buyer: Is it an attitude or just a disconnect?

PP: A disconnect. What we do in an academia bubble, and then what we do in a corporate world, in a clinical world, it's very corporate.

Buyer: The hairs are split between academics and applied science. **PP:** Just because this works in academia doesn't necessarily mean it works in or can be reproduced anywhere else.

019200

Buyer: I think what you're saying (inaudible) non profitable. I know that maybe your costs are going to be extremely high, but how do we help you maintain and financially grow and oh my goodness show a little profit here and there. What's wrong with that?

PP: That's- I don't know what that issue was and quite frankly because it's an academic project, I'm not real aggressive about trying to get back in touch. I'm not looking forward to working with it anyway. We take on very few academic projects, and I know what have patients come in all the time asking about donating tissue. Every time I have one, even there is some cost for my time in getting them started or whatever, I do it because I know it benefits our patients. I really, really enjoy that.

021100

PP: We have- I make it a point to have very healthy budgets on all of our industry sponsored studies, so there is room in my day for me to underwrite some projects for local academic studies, especially because we don't have it come around that often, because we're in Texas.

Buyer: Do you find, if you can a patient about what we've doing, would that help her in her decision?

PP: I think for the most part, when patients come in, they've made their decision.

Buyer: Yea, you said that. I just wonder if there is a percentage there, that would help.

PP: Maybe some, not so much with the decision itself, but the stages- what was that? Catfish here. Oh, that was quick.

Buyer: Yea, I was talking about. I'm used to working with clinics (inaudible)

PP: I think it's with the stages of grief (inaudible) what have you. Even though the decision is made, just the next steps (inaudible) and make that who you are without rejecting it. (inaudible) My staff consented the patient, baby sat the older child while she was having the procedure. We asked her about past pregnancy, she didn't even acknowledge it, it was gone from her mind. "She said I thought I was pregnant but I wasn't." My nurse was like "I scheduled the procedure, I saw you up there, and make your appointment." It's because of the stigma.

Buyer: Right.

PP: She just completely blocked it from here mind.

Buyer: That is sad, but it was still there.

PP: Still here.

Buyer: What kind of samples was the academic researcher requesting, that you mentioned? Do you remember?

PP: He needed fetal tissue, but i don't remember what specifically it was for. I have to look.

Buyer: Sounds like you haven't provided things for humanized mouse models before.

PP: At Baylor, I worked with a doctor that did.

027000

PP: I forgot where he got his. At the facility I worked at we didn't provide abortions. We performed abortions in the IVF department, we did reductions, we had (inaudible) They have to agree to that.

Buyer: They have to what?

PP: They have to agree to reductions. Some people say no.

Buyer: What happens if they say no? They already agreed to it right?

PP: They can agree not to, but we don't know until they become pregnant and have however many. They so no, and the the doctors council them. A lot of them pay thousand of dollars for IVF and then they lose all the fetuses

Buyer: Because they don't do induction?

PP: (inaudible) because they body is not meant to have a litter.

Buyer: Right. My feeling is that they're just not understanding (Inaudible)

PP: We try. But you know, whatever their religious beliefs are, it's ok to have IVF, and everything that's involved with the evasiveness of that but when it comes to preserving the lives you just created-

Buyer: They're not willing to eliminate in order to save- I'm really not familiar with that patient population, but if they knew an excess fetus could be donated to research could that make those conversations easier?

PP: Usually the mindset of the folks who are against it is for any reason. It will not be removed for any reason scientific, genetic, nothing. You could say all six fetuses are going to have (inaudible) it doesn't matter. If that is the mindset, that is the mindset. How's the fish?

Buyer: It's excellent. So, I'm very impressed with the facility.

PP: Oh, thank you.

Buyer: I've heard that the Gulf Coast affiliate is the largest in the country.

PP: Behind Mar Monte, mhm.

Buyer: Is it the product of many mergers or acquisition.

PP: Oddly enough, no. The only merger we've had recently, is a Louisiana affiliate that we merged with (inaudible) Which is unusual because they're having a lot of different mergers nationwide of a lot of Planned Parenthoods.

Buyer: What's interesting about, I don't know if you'd call it the administrative structure of Planned Parenthood, is it puts you guys in a much better position, compared to the independent providers as these different laws roll out.

PP: Another part of this, sadly is as these come out, I get it from my family "Oh, what do you think about this law? What do you think about this in the media?" I'm like oh I love it.

035000

PP: So much of what we do- so much of what happens impacts our donor base. Any of this will push our donors to write that check. So you know the whole big blow up about the Susan Komen thing? Planned Parenthood only received about three hundred thousand dollars. Susan Komen does breast cancer screenings (inaudible) and I'm not meaning to trivialize it but, in the grand scheme of things, that's not a lot of money coming from Komen. So when that happens, we got multiple times that back in donations. Specifically for breast cancer screenings so everytime the craziness goes out-

Buyer: your donations go up. Yea.

PP: So there is a positive to it, as sad as it is.

Buyer: I wonder, why do the providers seem so stressed out. It's kind of a different story when we meet them at some of-

PP: At the conferences.

Buyer: Yea, like at NAF. The camaraderie is wonderful. But for example, one of the providers in Texas, several of the providers in Texas were telling us not to long ago- we didn't hear from them or several weeks, and I started to wonder, what's going on. finally, one told us the reason we hadn't heard from them was because they were hit with surprise inspections from the health department, just on a rolling basis. You guys have them too, in Texas.

PP: Oh yea. Oh yea, we have them.

Buyer: Just surprise inspections, they just drop bye because they're looking for something to do.

PP: We're just audited for organizations, financials, we get audited. All of our family planning clinics, get audited. Pharmacy, audited. We were involved in the clinical trials to get plan B over the counter, we got an audit out of that. It's ok, it's a badge of honor, when you come out of and FDA audit with no findings, it means you know your stuff.

Buyer: Yup.

PP: Yea, that's the thing, we get the audit, but there's never any findings.

Buyer: It's just a fishing expeditions. Pardon.

PP: Unfortunately the number of providers is about to drop. (inaudible) Then it'll make things a lot easier, six fish in a bucket. They'll be able to hit us all.

Buyer: Shooting fish in a barrel.

PP: It's jsut being ready for it, being proactive about it, having your nose clean at all times.

Buyer: Who helps you to be proactive? Who helps you know what's going on?

PP: You mean in terms of audits coming? Or?

Buyer: Anything.

PP: Internally, we have our own people (inaudible) As far as having a heads up on a audit, we don't get anything. Yea, I just heard about that last week, I wasn't even aware that we had auditors in the area. They just show up, but it's not like they look over the entire facility. Their there, if they go searching for services (inaudible) They could but they don't expand the scope of the audit to include it.

Buyer: Yea, I was talking about that with Deb Nucatola, it was at the conference we were both at and she says "oh yea, in my hotel room, I was on the phone with someone while the inspector was in the room with them." Talk about triage, not just from the-

PP: Nature of the beast. It's pretty sad that you work serving the community and are subjected to that.

Buyer: How long have you been with

PP: October of 2006, so this will be nine years.

Buyer: And you knew what you were going in to?

PP: uh huh.

Buyer: And it didn't deter you?

PP: (Inaudible)

Buyer: You've seen "After Tiller."

PP: Huh?

Buyer: You've seen the movie, "After Tiller"- probably.

PP: No, I haven't.

Buyer: You know, Susan Robinson- Dr. Susan Robinson, one of the physicians who worked with him in Kansas and is now working with Curtis Boyd out in Albuquerque and still does some contract services with Planned Parenthood in California. One of her little on camera interviews in the movie, she talks about how she doing abortion care until the Brookline shootings in Massachusetts and she says you can have two responses to a bully, you can cower and pull back and try to get away from the bully, or you can go "Oh yea?" and that was her reaction, oh yea?

PP: I have a little bit of a different- same general thought about it but a bit of a different approach. I kind of have a unique background, I worked in accounting for many years, my mom was an accounting clerk. She used to do people taxes during tax season for extra money. When I was assigned chores by my mom, it was a stack of checks and a checkbook, so I got a money budgeting awareness very young. (inaudible) Not that I'm saying that's a great model for a lot of things but, I got some exposure to financials, then went into nursing , then went into reproductive health care and stumbled into clinical research.

048500

PP: In terms of areas that I can contribute to the organization both locally and nationally is diversification of the revenue stream, so we can continue to do good work, because as you said we have tremendous opportunity there, and knowing that our operations make us unique, in terms of research, sample acquisition, specimen procurement, these other areas too, that you know, we just have to have people that walk into the door that have these diverse backgrounds and can

actually analyze what we do and say, we can do this, and think outside the box, I mean that's such a common terms, but I mean there's more to what you can provide in services instead of just Paps, just birth control, just STI. There's more within the scope of that so, you can be inside the box, outside the box. I think I want your fish, this filet is huge, it's like a steak-

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PP: I might not eat this piece, because I got three huge bones in it. I clean my own fish so I'm very perturbed when I find bones in it, because I work very hard to titillate them out before I cook them.

001200

Buyer: Your financial background, I think that's what- you can see the benefit of this financially.

PP: Mhm.

Buyer: Just having that background and seeing its gold out there.

PP: Yeah.

Buyer: And it can be so beneficial, glad that you have that background. So you can see the financial benefits-

PP: Yeah, Yeah.

Buyer: of getting the right specimens, getting it intact, and changing the procedure just a little bit.

PP: Yeah.

Buyer: The framework that we use it, and we're all talking about it in the same way and the right way.

PP: Yeah.

Buyer: But the financial gain, and to your staff, just knowing this is, this is--

002800

PP: I think everyone realizes especially because my department contributes so much to the bottom line of our organization, you know we're one of the largest affiliates in the country. Our research department is the largest in the Unites States, larger than any the other affiliates' combined.

Buyer: Wow.

PP: But it's not, part of it is infrastructure, we've got the building, we've got the lab. Part of is also the attitude I was telling you about, taking this project and how we're going to integrate it for the patients. (inaudible) working in efficiency, but hiring more, hiring more, isn't always efficient. More cooks in the kitchen doesn't make for a better meal sometimes.

Buyer: Sometimes it makes it worse.

PP: Chaos is created, people who don't understand, or people in the way, the way you were talking about. I feel like I want to eat more of that. It's delicious, but it's a lot. I didn't realize it was such a big plate. But yea, I think that model is what makes us unique. Sometimes it's hard to keep the focus there, in terms of management and we do this certain stuff we can integrate and how we do it-that's one of the reasons that we bake it into job descriptions you know, bonuses and everything. we've done it so much and or so many years, we want people to think this is routine We don't want them to see it as extra, or extra work, or feel oppressed by it, that kind of thing. So, it's been pretty successful, very successful. You want to keep going, new opportunity- checking the time, thanks for reminding me.

PP: Just a subtle reminder. (inaudible) I think that 's why we have a lot of conversations (inaudible) Everyone else has other commitments already and we don't.

008000

Buyer: (inaudible) There's a lot of commitments in California. It's because StemExpress has the North, Mar Monte and the new Norcal affiliates and Novogenix has Los Angeles, with Deb.

PP: I think there's so much research with stem cells out there , they go the low hanging fruit.

Buyer: Yea, and ABR- you much have heard of ABR before, Advanced Bioscience Resources with Linda Tracy and Perrin Larton. They've been doing it longer than anybody, like twenty-five years or something. They're kind of a creature of the 1980's though, they're still using faxes and everything, they don't even have a website. Granted, you want to be careful with what you put on your website, but you want to have a web-

PP: Presence

Buyer: Presence, yea. So they have San Diego and maybe some other places scattered around that clinic, but StemExpress split off from them, and Novogenix (inaudible) that presence and that market has kind of been around California for a long time so it is- it's kind of saturated at this point.

PP: Oh well, good for you then.

Buyer: And it's kind of a mystery throughout the country, who is doing what. Allegedly, CAPS doesn't have the information, and it's not something the affiliates advertise so, you know.

PP: If we can get in Tram's ear for just a few minutes. (inaudible) I just have a hard time believing that we submit all of our information and it doesn't go somewhere, there's not a repository somewhere. It's frustrating too, you spend all the time collecting information and no one does anything with it. That's frustrating.

Buyer: It's just busy work- all the time it's taken to collect that information-

PP: And it goes away, it just goes out into Neverneverland and no one's doing anything with it to further the organization for business opportunities. Even if we don't have it on the national level, it's still important here, with what we do.

Buyer: This was a good suggestion.

PP: I'm glad you liked it. I'm just going to warn you they're going to bring a big obnoxious dessert tray over here. They have very good desserts here, if you're a sweets person.

Buyer:I'm weird, I like salty and savory.

PP: I'm not prejudiced, I like all different types of food. I think my moods are sweets, during the winter time, when it's cooler it doesn't raise the temperature of my house too much. My daughter and I get a lot of baking. Love to bake. They used to have all types of fish in there now (inaudible) At one point they have a smaller tank, it was all salt water, beautiful salt water tank.

Buyer: So this is fresh water.

PP: Yea, its a fresh water. They have a kind of fish in there its called (inaudible) it's from Africa. They're pretty easy to maintain in tanks, saltwater tanks are pretty expensive. The fish are easy harder to maintain, the fish have to be at a certain temperature, the right salinity, the right lighting. I had a saltwater tank once, never again.

Buyer: Expensive fish.

PP: They're very expensive, yes.

Buyer: (inaudible)

PP: Yea, you have to do your research on the fish too. Because they're are some fish that get along with this group and not this group, and the environment, if you're going to have this kind lighting, these are the only fish that go together, and they may not even be fish you're interested in. It's a lot more challenging. It's my sister, she's trying to get a job at NASA and they're calling her references. She says: "what do you think?" I said, "duh" it's a good sign.

Buyer: So science kind of runs in the family huh?

PP: Oh no, very not scientific.

Buyer: What's she want to do at NASA?

PP: She's in administrative, computer support. Her husband works at NASA too but his thing is networking and wiring. He works for- I'm trying to remember the division he works for- with the International Space Station, he runs the communications part of that. My other sister is a teacher, this one, she doesn't like to be outside, anything to do with animals, ugh. She is not an outdoorsy person. Her husband fishes though, we go fishing together.But not to much science at all, I can lose her in a conversation, if I start talking too much medicine or science, whoop, there she goes.

Buyer: What about the teacher, what does she teach?

PP: She teaches high school, down in the NASA area.

Buyer: What subjects? All subjects?

PP: English, Literature. It's funny to me now, considering how she was when we were growing up. She didn't like to read a whole lot, she was into drama, never pegged her as a teacher. Never pegged her as working with high school student, it's one of those things where people evolve into an area where you're like this is totally different from what you were as a kid.

Buyer: Oh, it might be. I thought that might be the dessert plate but-

PP: I haven't heard back from Tram yet, I'm very sorry that I, just didn't click-

Buyer: No need to apologize.

PP: -to schedule time up there with her.

Buyer: I'm happy to hear, does it mean a busy day? High volume?

PP: I just need to get information for you guys, what numbers, days, feasibility, actual sample collection. Tram walks by my office every morning, and I've been known to physically, hey come here, I need to talk to you for a minute, hallway meetings work sometimes so.

023500

Buyer: I want to underscore it again, double back if you need to financially, I want it to be profitable for you.

PP: Oh sure, right.

Buyer: And get a sense of what you need. And you know how to plan it so it all works out.

PP: And let me know also if you need help contacting and working with other affiliates. If we get everything in place, we have forms, we have contracts. One of the things I do for research on the national level is share. So after I've done the work, I give it away. So you can take it and say this is what we developed with PPGC. So that should help.

Buyer: Yea, did I give you [Name]'s company card?

Waitress: I'm sorry, anyone want dessert or anything?

PP Farrell: I don't have room for dessert, thank you. I don't know about you guys.

Buyer: No that was perfect, perfect amount, wonderful. What you would you say are the five affiliates with biggest research departments?

026500

PP Farrell: Ours would be first. Planned Parenthood Southeastern Pennsylvania, Southern New England would be next, Rocky Mountains would be next. Yea, that's about it.

Buyer: That's about it.

PP Farrell: Everyone else is pretty small, I mean they're are a lot of affiliates who are engaged, but they're all pretty small.

Buyer: It sounds like otherwise it's an ad hoc for this particular study

PP Farrell: A medical director who is also faculty at a local university, which is typical and they do a lot of academic studies, so not as much research. So that's probably, I know there is another one in Florida but you know, the turnover rate in this industry- research industry you know the coordinator stay there for two years and then they're gone. I think they had a program for about two year and then that's it. The other Texas affiliates, the one in the Austin area, I know they've done some research but I don't know what else they've done - structure wise they're nothing like it.

Buyer: Yea. Greater Texas right? That's where Amna Dermish, she's a provider there. She and I got to know each other at a meeting back in Miami and we had a really good conversation about all these different things and she she wasn't aware that they were doing any tissue collection over there, thought it was fascinating and wanted to help, wa trained by Deborah Nucatola does the who convert to breech thing anyway because it's easier. It sounded great, although her CEO is terrified of the idea. That CEO and Amy Miller from the independent group of clinic, Whole Women's Health, apparently they're both under the impression that you can't do tissue collection at all. No, fetal stuff in Texas. I said wait a minute, I know for a fact that they're are many researchers with many with published researches in Texas. I don't know.

PP Farrell: Alright, you're going to send me back to regulations, fine. I have to check, make sure that nothing has happened with these recent changes, but-

Buyer: I asked them to tell me what it was, I had our attorney's look at it and we just found the standard anatomic gift, you know, language which is standard, which is everywhere.

PP Farrell: I'll get (inaudible) from counseling too, and see if anything has come up on her radar. She's involved with all the challenges and everything because you know, the news laws get challenged and they go back and forth, back and forth between Texas district courts and now the supreme court. So she's aware if there was any language in the new laws that affect what you guys are doing, I think we'd know about it, but I'll double check.

Buyer: Sometimes, I wonder if it's a personal decision, maybe they can but they just don't want to get involved. Maybe they can in the future.

PP Farrell: I think there is a lot of opposition-

Buyer: I think you have to sign for it.

PP Farrell: -opposition fatigue, you get tired of (inaudible) all the time and you don't want to take on anything else.

Buyer: Like, I'm just fine right now, leave me alone.

PP Farrell: Pretty much. I find that some of our leaders who are closer to retirement have more opposition fatigue.

Buyer: I'm sorry, who?

PP Farrell: Our leaders who are closer to retirement, have opposition fatigue. They've dealt with it for so long, and they don't want to have to deal with something new,or have to decide if this is the right thing to do. I read teh regulations when I first get here and we had that project and that was ongoing so, we've had projects, since then that make it through local academic IRB's and usually there is some component fo a lawyer on that IRB-

Buyer: Pretty sure the IRB's in Texas are-

PP Farrell: Pretty sure if there were laws, I would have heard about it from them. I think it's just a lack of understanding about it and if they don't have a strong research department and know how to do it under the scope of research, then they might not want to go about it. That's why I said I'm happy to get the contracts, the protocols, I will even send it to a central IRB so that if they want to go ahead and apply under that later, go ahead, make it easy for them. We can do everything to make it easy for the other Planned Parenthoods that want to use the contracts.

Buyer: Does PPGC have your own IRB?

PP Farrell: No.

Buyer: No. We use- pretty much, industry sponsors will say we're using so and so, if they ask me I always say- it's called a central IRB, it's an IRB that is a business as a company.

Buyer: Right, like CORUM or something like that.

PP Farrell: Yea. I use one called Just Me IRB, they're amazing. They get it. They get the the types of studies we do, in terms of additional samples, IV, drug studies is a completely different ball of wax, they go through it all the time. Just Me IRB is the best one for the types of studies that we do. They've got a real good customer service- they're completely electronic, they meet virtually in any office, it's so amazing. They have this great customer service and they don't even have this big central building, they work remotely, very twenty first century.

Buyer: That's good. That's good.

PP Farrell: Yea, I even have an IRB (inaudible)

Buyer: That's good, so should we head back and see if we can-

PP Farrell: Hopefully Tram will be free.

040000

Buyer: Go ahead, I'll follow you.

PP Farrell: Hopefully when we can get something up and running, operationally work it out where we get all of the bugs worked out in our facility, I can help you work it out with the other affiliates in Texas. It makes the most sense, when we have it worked out, we can use it as our template.

Buyer: I hate to say it but if it goes down to six or eight centers, it will be a hub for a lot of things.

PP Farrell: Yea, the new facility we're building in Louisiana, we have a clinic there already. Oh, it's terrible, it's old, old, old, and it's in an old shotgun style house-

Buyer: Oh dear.

PP Farrell: It is in terms of portraying a professional type of image, it is not.

Buyer: So the image is not there?

PP Farrell:Oh no, so we have had campaigns to raise funds, and there's tremendous local opposition. The catholic church is on the war path on making sure Planned Parenthood doesn't expand there. You know, I love our organization but sometimes it would be nice if we could do things in secret, behind three layers of fake corporate names, just roll it out without making a big thing about it.

Buyer: That wasn't done this time?

PP Farrell: No. There's a whole different-

Buyer: Who dropped the ball?

PP Farrell: That's our MO.

Buyer: Dropping balls, just not-

PP Farrell: Just being very public about it, instead of trying to be more discreet and more in your face, especially in the south. That's another topic. One of these days- you know, the president of PPFA is Cecile Richards and she's from Texas.

Her mother was our governor back in the '80s. Sometimes I just wish, just give me five minutes with her. Just five minutes. I just want to say one or two things.

Buyer: Is her mother still alive?

PP Farrell: No. She passed away right before I started here, about 2005. It's funny because Cecile is like 6'4", she's really, really tall -

Buyer: I met here at the national meeting, I just briefly at the CAPS reception

PP: And her mother--mhm. Her mother was about my heights, and about my build, and Cecile is very tall, and very lanky. She apparently takes after her father. Yeah Cecile's you know it's very strange to me that TX has gone so far to the right, because growing up we had Cecile, we had David White, we had another governor who was Democratic and I'm really, just amazing to me to me how the boomerang. I do think a lot of it is based on the religious predominance of the- religious dominance here in Texas. You know what's funny- because I grew up catholic and occasionally you hear, ok you can't say any swears and ok, you're not supposed to get divorced. It wasn't something you were hit over with, back then the message was love thy neighbor, do things to take care of people, help the poor, raise money for people who have less than you. It's not like that anymore, it's turned into you know, religious warfare, you know, we need to impose these things I think about you and what you need to do with your life, because I believe in god and I want you to do that. It's really weird for me hearing, you know seeing how religion has changed.

Buyer: It's become more tribal and primitive almost. I grew up catholic as well, but they say regular catholic is bad but lebanese catholic is a whole nother ball game. Sarkis is lebanese-

PP Farrell: I was going to ask, I thought it was greek.

Buyer: They are very- there is a lot of mixture right there in the Mediterranean. They are very primitive, very tribal, very like, medieval- what I think too though, what we all need to face, is that they've been around for two thousand years they're (inaudible) they're not going away. That's just- I think that's a fact, they are not going away, and we need to realize that.

PP Farrell: So, not this exit but the exit off (inaudible) Just stay in this lane.

000000

PP Farrell: I don't think is the option, I think, you know, where we were in the '70's and '80's, where we're looking to coexist and understand that you can have science and believe in a higher power, they can coexist in the same person, you know? It doesn't have to be one or the other.

Buyer: Mhm. Right. I remember this is where it got a little tricky. I'm going to want to be on the left side-

PP Farrell: Just stay on this lane. We're going to purposely get off at another exit. If we take the loop back around then we have to cross over the fast traffic again, so I'm going to send you a little bit easier way. You're going to go through this light.

Buyer: Ok. Once you know where you are, it's not at all like L.A., it's just a new car-

PP Farrell: You know where I hate driving? I refuse, is D.C. You ever had to drive in D.C?

Buyer: Never.

PP Farrell: I wish that you never do. I wouldn't wish that on my worst enemy. Dallas is pretty bad too. Ok, you're going to keep going straight. See this little red car? He's going a different route. He's going to have to jump across a bunch of traffic, I don't do want you in this little car to have to do that, because then we might have to go around a few times.

Buyer: Ok.

PP Farrell: I tell you, I have never been more excited to hear from Tram. I so want to just (inaudible) Tram, ok, I need to know this, this and this. Tram is like me she is very- you're going to want to do a U-turn- she's very high energy, very hyper was the term I was called as a child, back before ADD was the diagnosis. "She's a hyper child." U turn again, and then you're going to want to say in one of these two lanes.

Buyer: This one?

PP Farrell: This one, yes. This is where people see the Planned Parenthood building, the see that and go "that direction?" That takes them to the U of H campus, you're going to want to stay under forty. It look like a freeway, it's actually a service road, its forty mph and cops hang out right over this hill. I don't know if I discreetly in the form I sent you or not, ok you're going to want to get into the right lane, because you're going to be turning right. There must be a meeting in the building today, because there is a ton of cars here. Oh, I know what it is, nevermind. Do you ever a have a duh moment, where you ask yourself a question and you realize you knew the answer. So, when you go to other Planned Parenthoods, they have quite a bit of protestor presence?

Buyer: Uh, yea. Yesterday, what was it? The day before? That was a little gruesome- I think it has less to do with the numbers, and more to do with the individuals. How vocal or aggressive they are.

PP Farrell: Yea, definitely how aggressive they are. So what do you think of the bus?

007700

Buyer: I'm confused, what is the bus?

PP Farrell: The bus is an ultrasound bus, it give free ultrasounds to show you what your baby looks like and tell you a bunch of medically inaccurate information in an effort to convince you not to have an abortion. The sick and sad indigestion causing thing-

Buyer: Do people buy it?

PP Farrell: -is that is funded by tax dollars.

Buyer: Seriously? I- No.

PP Farrell: I kid you not. Funded by tax dollars, not entirely but-

Buyer: What a mad house.

PP Farrell: Right? What do they call a colony of centers? They pose as abortion centers, and the sole purpose is dissuading women from having abortions or getting birth control. There's a lot of them in Texas, they're funded by the state as well. If you look, some of them have personalized license plates that say choose life and when you go online to order license plates for your vehicle, but there's no license plates that are pro-choice. Those license plates, part of the funds go to pro-life organizations. That is done in Texas. Can you belive that?

011000

Buyer: Well, all the more incentive for me to fund you! How's that?

PP Farrell: Sounds great.

Buyer: It makes it- that you can have such a state of the art, high level-

PP Farrell: I say look at this, 80,000 square foot, state of the art medical facility. Do you want to come here to get care, or a beat up raggedy ass bus? Yes, it had a nice wrap on it, but really?

Buyer: Yet people are doing it?

PP Farrell: I don't know how much volume they get, I know some of my study subjects that come in to see us come and mess with the bus, like those commercials "messin with sasquatch. (inaudible)

Buyer: I have mine.

PP Farrell: (Inaudible) You're good. Just a reminder for when we see Tram, obviously this is [Name], pointing at your badge.

Buyer: I have to use the restroom.

PP Farrell: Go ahead.

Buyer: It's back around this was, isn't it?

PP Farrell: There's one right behind this wall, if you loop around. And there's one here and one here.

Buyer: Ok, I'll use this one.

019500

Buyer: (inaudible) in the car, that's ok. I think I've got (inaudible) Keep in mind the state (inaudible) we could go in and make financial incentive- I'd really like to put our money there- it's almost like vote with your feet and vote with your wallet.

021300

I was just telling [Name] that I'm glad to know about the state taxes gong for that bus out there, it gives me more incentive to make sure our financial dealing are profitable, I'm funding you. I know it's a funny way to say it but we're funding you.

PP Farrell: I like to point that out to our sponsors sometimes, that we have- that in addition to the political attacks, our state tax dollars go to fund the oppositions.

Buyer: Attacks.

PP Farrell: Right. It bows my mind, and when I tell my family and friends who come visit, your taxes pay for that "what!" It motivates them as voters. Your tax dollar are paying for that, they won't pay for you to get a pap, but they will pay for this.

Buyer: I can't vote, but I can vote financially for our arrangement- Until she buys her ranch in East Texas.

PP Farrell: Ranch.

Buyer: Or your boat, we gotta get you a fishing boat.

PP Farrell: I think I would like to have a boat, but again boat's are a lot of maintenance. My husband and I talked about it, and we can charter from time to time. Yes, it's expensive for the one time, but maintenance and registration and storage and of that we can avoid. It's kind of like having a saltwater tank, you have it once, and it's beautiful, it's a lot of work, you can go look at it in a aquarium. I still haven't heard from Tram, let me shoot her another email, let's see.

024000

PP Farrell: I did follow up, if you need the information, on fetal tissue shipping, it's shipped as category B, like I was telling you earlier the category for flammables. The shipping requirements are in a receptacle, cannot exceed one liter of fluid so if there's any fluid, um- did ya'll say frozen or it depends?

Buyer: The tissue sample itself, should not be frozen

PP Farrell: Ok.

Buyer: But it gets shipped on either wet or dry ice typically.

PP Farrell: Ok, so we'll need the spacer then, between the tissue and dry ice. So yea, we looked that up and that just help me to know about how many we can put in a box. Do you require the material be dropped down to a certain temperature first?

Buyer: That's all going to depend on the researcher and they're protocol. It's going to change from-

PP Farrell: Project to project. I'm just thinking about those two in particular, right off the bat because those sound like your ones that- the one for the one the liver and thymus, and the other one for sickle cell one, those sound like the ones you have the most immediate need for. The more I'm thinking about it is the general sample acquisition, where we have an overarching protocol for any type of tissue, gestational age tissue and then as we have need, you guys send me a work order- we have this with other types of tissue, so this isn't unusual. Send me a work order that says, "Missy, I need these many specimens, during this period of time, during this gestational age, these are the unique features about it that we need, intact specimen or what have you-

031000

Buyer: Did I understand you correctly, that you have changed how you define or calculate that gestational age, so what we consider sixteen might be really, you might call it fourteen.

PP Farrell: Yes, and Tram is going to have to explain that. When House BIII Two was first enacted certain parts were effective immediately, and we have started using it, thats one of them. Other parts of it are being challenged in court and they have a stay on it so we're not doing it immediately so like the ambulatory surgical center requirement throughout Texas a lot of organizations are throwing in the towel, we know the were not going to to be able to go anywhere with this, the supreme court is not going to rule in or favor. Others have said we're just going to keep doing business under old rules. How it's defined in terms of weeks from conception versus gestational age, I don't know the exact time difference, in my head I'm think it's two weeks, about two weeks from LMP to estimated date of conception, EDC. Which is what is referenced in all the legalees. I just need to get the-

Buyer: Right, what's the change? Two weeks. And then, is there room to, well, we didn't know to hold the correct information from the patient, so we could stretch it for about three weeks? Is there any wiggle room there?

PP Farrell: I think that- everything the gestational age, estimated date of conception, everything is done by ultrasound, so it's-

Buyer: Ok, so it's really how get to define, you get to create your definition of that date and then speak to it that way.

PP Farrell: It's still- what it did, basically what it ended up doing is knocking two weeks off, instead of it going to twenty two weeks, it goes to twenty weeks, because it impacts in that direction.

Buyer: For us that would mean, we could ask you for a twenty two, in your language aht would be a twenty.

PP Farrell: I think so.

Buyer: Ok.

PP Farrell: Yea, I'll have to get her to confirm that, it's based off the little bit of information that I got at our last meeting about a year and a half ago when all of this started coming down.

Buyer: And then, I'm going to assume, and again, I don't understand this but I'm going to assume that if I'm asking for a twenty two week, you're calling it twenty, my compensation, I will automatically know this is got to be higher rate.

PP Farrell: Mhm. And we'll work all that out-

Buyer: Details.

PP Farrell: That's the part were I want to sit down with Tram and go over what's involved in the second trimester AB's that makes them different, unique, more complex, asking about the breech.

035000

Buyer: Converting the fetus to a breech position beforehand.

PP Farrell: What does that end up doing functionally in terms of preserving the specimen?

Buyer: So what that means is if you can, under ultrasound guidance, convert to breech at the beginning of the procedure, there's dilation that happens as the case goes on, because you're bringing the lower extremities out first, and then the trunk, and then the calvarium at the last step, and it's a way of being a little more gradual about the way you're doing it, so you're more likely to have intact structures, rather than at the start trying to bring the whole trunk through, or the whole abdomen, or the whole cal, or something, it's more difficult.

PP Farrell: Mhm. Mhm. I guess because I come from a labor and delivery background, and the head comes out first, because functionally the body fits like that in the fetal position, more of a bullet shape, so as you're saying that I'm wondering, how in the world is that better?

Buyer: Yeah, it's because you have the amount of dilation from the cervical prep, and then instead of trying to fit the whole cal though there right at the start, you just do two lower extremities, and then the trunk, and it's a way, you keep it all in line, and Amna and I had a long discussion about this at the Family Planning Forum in October, she said that you can even, you grasp the spine is another helpful, and you kind of keep everything in line that way, and the whole thing comes out in one piece. And that way, when it's the tech's job to go and find everything, they need liver, and thymus, and pancreas, and cardiac, and all these different things, it's just one dissection, as opposed to going fishing for—

PP Farrell: So, is that something else, do you guys need us to actually dissect that out or do you want the entire specimen?

Buyer: It depends on what the researcher's asking for. If the researcher is just requesting a liver and thymus pair, then it's just dissecting out that pair of tissues. Some researchers might request to have a larger portion of specimen, and especially I think we'll probably see that with intact brain tissues, because the

brain is a pretty fragile organ, and so if you can ship it mostly or entirely or partially as a calvarium—

PP Farrell: Mhm.

Buyer: You've already got that protection built in for that tissue, and some researchers are happy to do their own extraction anyway, because they feel like it's a delicate enough thing that they know exactly what they want. **PP Farrell:** Right. Because I was thinking in terms of integrating the process into the facility, Shawnda's a nurse practitioner, I'm a registered nurse, in the event that we had to have someone else do this, we could be the ones that could do this, to alleviate that additional step for the health center upstairs. So.

Buyer: Oh, you mean doing the dissection.

PP Farrell: Yes, yes. And again, I need to talk to Tram and see, how many procedures are we talking about, what are the days, because again, 2nd trimester, that's gonna be done on specific days. Because then we can funnel resources to those specific days. And see if it's something that she would want her staff to do, because of their work flow, because they're already busy with a lot of, that's where having the Research Department with a lot of dedicated, trained, credentialed staff, we could step in and do that, so.

Buyer: Mhm, mhm.

PP Farrell: That would be awesome.

Buyer: Yeah, yeah. I wasn't clear when she and I spoke in DC, whether, because she told me oftentimes they're getting pretty intact specimens, the whole, a pretty intact fetal cadaver coming out.

PP Farrell: Mhm. Mhm.

Buyer: So I was of the impression that she was mostly dissecting things out, that it wasn't hunting around in the pie dish for everything.

PP Farrell: Yeah. If you need the dissection, we would obviously need instructions, visual, you know, a little video snippet on the DVD would be awesome. On how to do it, look for these landmarks, this is what it will look like in a gestation 14, 16, 18, because it's gonna change, so. And then we could totally do that part.

Buyer: Yeah, it's just so much easier if you just know anatomically you're looking here, here, or here, for whatever it is. Versus you've got everything floating around and you're having to search through it amongst all the other pieces, and

endometrial tissues, it's just a lot easier of you've already got, the "container" already there, so to speak.

PP Farrell: Yes. Speaking about it now, it sounds, I can see why you would want everything intact. You know, from the entire perspective.

Buyer: And also, again, for cell viability, the longer that you've got a certain amount of circulation in those pieces and everything, rather than it's just, it's all traumatized when it's coming out, half of the liver is missing, it's bleeding out, and it's just—

PP Farrell: Mhm. Yeah, yeah.

Buyer: It's, yeah. Freshness, intactness. And there's just a lot of scientific and just practical reasons.

045300

PP Farrell: So, just again thinking inside the box, outside the box, if you have a researcher who needs neural, and we need, have another researcher that needs liver-thymus, we could have one donated specimen providing both.

Buyer: Exactly. Exactly. That's the other thing. Yeah.

PP Farrell: Okay.

Buyer: And that even starts to maximize volume in a pretty effective way.

PP Farrell: Yeah, okay.

Buyer: And this is true. However, if that provider is needing to change the technique a little bit, and I know, I'm going against my side of this but, I'm okay with, no, I want you to be paid per specimen, rather than, oh here, just ship this off. No, this is what we're looking for, and if you can do that, and it's compensated to you, financially, that's helping you, to grow your clinic, I'm willing to do that.

PP Farrell: Mhm, mhm. Yeah. And so if we alter our process—

Buyer: Mhm.

PP Farrell: And we are able to obtain intact fetal cadavers, then we can make it part of the budget that any dissections are this, and splitting the specimens into different shipments is this, that's, it's all just a matter of line items.

Buyer: Mhm.

PP Farrell: Knowing that this is what we plan to do. I mean, it almost seems wasteful at that point that if we've gone through the work, and we've got a liver and thymus, and we've got other parts that can be utilized—

Buyer: Right, right. And that's the thing is because, that's where we're really start to get into this becomes much more scalable.

PP Farrell: Mhm.

Buyer: Because if you get to the point where you can rely on having each case is gonna supply multiple samples—

PP Farrell: Mhm. Multiple projects, yeah.

Buyer: Multiple projects, then the amount of researcher volume that we can all process together—

PP Farrell: It's smaller.

Buyer: Is much, much bigger. No, the number of research clients—

PP Farrell: Well the number of sites you would need would be smaller.

Buyer: And the number of clients that we can accept requests from—

PP Farrell: Yes, is more.

Buyer: starts to go up, by a lot. Have you considered, I don't know if you guys would, just a thought. I guess because everyone's turnaround is so short, we'd just have to see. Depending on the volume, and especially considering, if House Bill 2 goes through, our volume is gonna be-

Buyer: Astronomical.

PP Farrell: We got a glimpse of it, because it was a two week period of time before the district court of appeals- the law went into effect, and then the law got stayed. So there was a two week period of time it went into effect, you couldn't find a parking space outside, there was standing room only only out here in this lobby-

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PP Farrell: -what happened is that people who had procedure scheduled throughout Texas, suddenly they went to the clinic and the doors were closed. They were here midway through, they had already had ultrasounds, they had

already paid for their ultrasounds, they were expected to have a procedure and yea. The volume is going to be very high, but my point was that –

000750

PP Farrell: Under a sample acquisition protocol where everyone that's coming in gets approached, not just African-American or whatever, everyone gets approached about donating fetal tissue, maybe we can even think, and I recognize that a lot of this has to be fresh, but maybe even banking, a tissue banking part, that we have it built into the consent form-protocol- in the event that you don't have a use- first trimester, you don't have a use for it currently, you saw the refrigerator freezer space we have, we have plenty of space. We can store it, and then if you have a need, because some researchers start with frozen specimens or preserved specimens first, we could look at doing that as well.

Buyer: Right. Right. There are some things like engraftment, xenografts in mouse models, it's not good for them because you do lose a certain amount of viability if you freeze and thaw but there are some, more like private biotech companies that specialize in cell extraction of primary tissues, and they to varying degree have optimized their processes to yea, even if your typical academic lab can only get twenty five percent of the cells out, we can get fifty or seventy five. They're potentially willing to purchase as much, probably not for as high of price for not as fresh, but they're willing to take leftovers so to speak, if it's preserved to pull what they can out of it and it's worth it for them.

PP Farrell: Right.

Buyer: So, I think it's always worth it- would you be able to store it?

PP Farrell: Yea, because we have the capacity. Yea because any of my IUD studies, my in vitro diagnostics, we keep it- the most we keep it for is a week,maybe a month in some cases. The refrigerator/freezer space is to handle a lot of volume and then it goes away, so we can have ongoing storage as well. In the grand scheme of things refrigerators and freezers are cheap. They're all on emergency power, I didn't point that out, I didn't point out the generators back here either. Your specimen's will be secure, the whole building is on emergency power.

Buyer: Mhm.

PP Farrell: Yea, in terms of feasibility in terms of how earlier- integrated into the facility. If everyone is approached and everyone collects samples if the patient consents. It's easier if we have all of these to choose from.

Buyer: The natural flow, of your operation-

PP Farrell: It's everything, everyone, it's not just pick and choose and have to filer. That's a lot easier.

Buyer: And store for a while, if it's not used and then-

PP Farrell: And we can have that baked in too, if we collect it, store it, we communicate about the inventory, if there is a certain amount that we have after a certain time, then we follow our sites procedure and destroy it, because our sites procedure is to store it anyway. So freeze it and if we don't use it then we destroy it under the same process.

007000

Buyer: So then having that integrated into your system, your profits can be even greater because you're not wasting any funds, your cost is so low so you can show a profit.

PP Farrell: Mhm. Yeah.

Buyer: That's excellent.

PP Farrell: Yeah. We were designing this area and I wanted this whole back to be refrigerators and freezers and I insisted on being emergency power on the grid. They said "But why? You guys don't need this, you ship all your stuff" Banking, tissue banking is something that is going to hit us at some point. Some sort of tissue.

Buyer: And here it is.

PP Farrell: And that's a perfect use for it. We have that because we have spike in volume, unbelieveable we enroll five to eight hundred patients a month. We have at least two specimens from each patient and they have go in one of those refrigerators or freezers. So, when it's that busy we have to have the capacity or we can use the capacity for medium term storage. I can't even think about what that means in terms of storage, I'll leave that to ya'll. Let me shoot her an email real quick. I was starting to- sorry, I started talking again.

Buyer: That's ok.

PP Farrell: It's very exciting, it's one of those things that when we get together with staff upstairs, a lot of them on their way by: "do you have any projects, it seems like a waste to throw away this tissue." I know. Everyone asks about it.

Buyer: It's a natural fit right?

010800

PP Farrell: It would be exciting too if you needed it dissected, because LaShonda and I are the most Curious George of the group. I know it's sickening on some level, but it's fun.

Buyer: Now, let's think about it.

PP Farrell: No, it's just that those of us who are into medicine and nursing, things that other people find gross, we enjoy. Obviously.

Buyer: Uh-huh.

PP Farrell: Except for snot. That's my- I can't do it, I could never be a respiratory therapist, I could never, that's why I have one child. I can't do it, anything that comes out of the body from here down, I'm fine. i can hold the bucket if you're throwing up but please don't sneeze on me. Just what I'm saying everyones got their-

Buyer: Everyone's got their little something.

PP Farrell: But that would be something that would be great, we hae this tissue, we have these companies that need this and you know work it out. Oh yea, they would just flip if I asked them for that. That would be right up her alley. Supplies. We would have to bake that into the budget too, if we needed sterile supplies or procure- there's that word. Procure disposable, whatever instruments we need to be able to do that because even though if the procedure is not sterile, if we are doing a dissection and doing anything to the tissues we would want sterile equipment.

Buyer: Yea, unless someone is doing some DNA typing or a genome study, it's not as much of a concern so long as there's nothing on there that's going to kill the tissue or the cells before they engraft it or whatever. Even if you were doing a genome study if you can get a clean sample from the core of the tissue, contamination is on the outside, it's not going to be on the inside of the tissue first of all. Second of all, and even if you do take it from the outside a good forensic geneticist know that any PCR reaction, the copy number of the samples is going to overwhelm the contaminated numer, just by the ratio.

PP Farrell: Right.

Buyer: But that's the difference between the academic sciences and the applied sciences. Academics aren't so good at that they're a little behind, but the applied science know how to maximize what they can get out of just a little-

PP Farrell: Yea PCR, we do a lot of work with people working with PCR. It's finally there in terms of diagnostics going past DNA and RNA amplification, which is lots of room for contamination to PCR real time PCR so. Yes.

Buyer: You can get a whole genome for a thousand bucks now. A couple years ago, it was twenty thousand. Now you can get the whole thing for about a thousand with the next gen sequences. Unfortunately there aren't that many people who can process that volume of data and interpret it for you, that's where the cost comes in now is hiring a bioinformatician to actually analyze the data you just produced so cheap.

PP Farrell: It's amazing.

Buyer: It's incredible.

PP Farrell: Tram, reply, reply. I'm going to have to send ya'll to the conference room for your conference call.

Buyer: Is there a way that someone can go up and see what she's up to?

PP Farrell: I'm not sure.

Buyer: Not to be intrusive.

PP Farrell: I need to see if the best person will go up there for me. The best person for the job, I should say. Oh you're still here, I thought you would have had herpes today too. Oh are they both- I know Southwest is here, is Stafford here too. All the cars out in the parking lot, yea well, Maryland. All the cars in the parking lot, I'm assuming there's more than one, and the classes had more than thirty people. Hey do you want to do a little mission impossible work for me? Start playing the music in your head and pop over. Ok bye. She used to work up there, so it's different, when it's one of your own going to there it's different. Gotta be aware of those group and interpersonal dynamics.

Buyer: For a really large facility and office like this it actually is a thing because there's multiple teams and multiple levels.

PP Nurse: Hi.

PP Farrell: Hi. So, I sent Tram an email a while back and I dropped the ball because when our guests were coming to visit I didn't put it together that I need to probably schedule tour time upstairs. I emailed Tram a while back and they are having concurrent clinic today. They're having procedures and ultrasounds at the same time. I emailed her a while back and she said that we could go see the front, but they need to see the POC facility.

PP Nurse: Ok. POC facility.

020000

PP Farrell: You know where they handle the POC in the little room, dishes. I just want to get a sense of where they are. I wonder who's working up in the front, I wonder if Jesus is working. Maybe peek in and see how it's going, how's looking, is it slow now. I can't see their clinic.

PP Nurse: Yea, you wouldn't be able to see- I could go up there and see.

PP Farrell: Yea, just go and do a little recon and see. Big bright GC smile.

PP Nurse: Hello! Becasue they close, they finish kind of early?

PP Farrell: Yes. Tram said they're running late and worst case scenario, if they can't see that area, I was thinking maybe we could take some pictures. Not sure.

PP Nurse: oooh.

PP Farrell: I know. I'll ask Tram for that, I'm not going to ask you to take pictures. We have a policy about pictures in the building.

PP Nurse: Yea.

PP Farrell: Yea, do some recon and see what's going on, we're having a good time and can continue to visit, plus I did my IRB submissions this morning.

PP Nurse: Well let me go up there and check it out.

Buyer: So pretty strict policy of no photos?

PP Farrell: Yea, but I think- there's times when-

Buyer: Everybody takes a selfie, once in a while.

PP Farrell: It's funny that you mention that I have an intern that got fired on his first day for doing that.

Buyer: No really?

PP Farrell: I am so serious. Yea, it was not good. It was the context of the selfie, so-

Buyer: In the POC lab?

PP Farrell: No, it was in my lab, but it was not very good judgement. I did not go well, but for business purposes I have taken pictures of my lab because we have sponsors that send investigational instruments here, where we're going to be using the instruments and yea, giving me the measurement work but look, this is the space that's going to be used, this, this and this and so pictures is helpful.I think again, Tram is going to give it her little blessing and we can move along with it. Even If she'll let me do it after the fact, that might not be a bad thing.

Buyer: Now have you been to NAF ever before, do you go or?

026500

PP Farrell: Nope. Never been, never been invited. I've gone to other Planned Parenthood conferences and spoken about research, the research piece. I'm on a National Advisory Committee for the research piece but I've never been to NAF. It's kind of Tram and her boss and a few people in that group who get to go. I don't ever get to go- Dr. Fine, did you ever meet Dr. Fine?

Buyer: Yea, I met Dr. Fine, he's funny.

PP Farrell: He's a hoot. He stole me from Baylor. He is a professor over at Baylor, he's such a mess, he's great to work with but his filter needs some work.

Buyer: Ok, so I can tell this story, I can tell this story. This is our first impression, well not our first impression, but first impression of Dr. Fine was at the reception evening in Orlando and Deb Nucatola. Deb Nucatola was the emcee of the whole thing, she's standing up with microphone, a pretty short lady and she was giving some kind of congratulatory something to Paul Fine, who's standing next to her, he's all six four or something.

PP Farrell: He's really tall.

Buyer: Towering over her, Hawaiian shirt and this bright, sparkly, not shawl but scarf -

PP Farrell: Dr. Fine had a scarf on?

Buyer: He had scarf on, in Orlando of all places.

PP Farrell: Scarf must have been a reference. Hawaiian shirt is classic for Dr. Flne. He actually doesn't have one in that picture-

Buyer: And the next day we're in the exhibit hall, and we have our exhibit booth and next to us is- was, I'm blanking on her name, your friend from Florida-

PP Nurse: So the front has slowed down, but the back still has thirty four patients checked in.

PP Farrell: Holy cow. Ok.

PP Nurse: They have a few patients they're still working on. Tram walked in, when I was talking to the people in the front, but she said within an hour and a half-ish.

PP Farrell: Would that be ok?

Buyer: Where are we at right now? She said she'll be done in an hour and a half?

PP Nurse: She said hopefully.

PP Farrell: Did she communicate about the back, because we had an exchange about the back.

PP Nurse: Oh yea, we were talking about he back anyways. 'They want to see the back too" (inaudible)

PP Farrell: Ok, tha's good

Buyer: Yea, within an hour and a half, yea we cold do that call.

PP Farrell: What time's your flight out? Oh wait, you're going to be out here tomorrow.

Buyer: Yea, we're going to be here through- yea.

PP Farrell: Oh ok, yea. We have time.

Buyer: Yea, we could do that call from the conference call or from the car either way and then.

PP Farrell: And then if you need more privacy I can- there's a conference room on another floor. Thank you for the recon, I appreciate it. So you haven't gotten a call, you won't be getting a call Northwest. Hey what about Northwest?

PP Nurse: Yes?

PP Farrell: What about Northwest?

PP Nurse: No. (inaudible) but Brooke is there so there should be. I don't have to ship.

PP Farrell: Yay, you don't have to ship. No driving for you. Ok.

Buyer: So, from choice pursuits, Ruth Arrick, I don't know if you've ever met her she does consulting for providers down in Florida and they have a side business kind of like supplying- instrument procurement, all kind of general clinical supplies. They also sell like diaphragms and iPAS and stuff like that and her organization is next to ours and Dr. Fine walks through, and they know eachother, and she says "Do you need new diaphragm?" And he's looking at the stuff on the table and he says "Hell no, I'm 68 years old, I need a new penis."

PP Farrell: Yup. That's Dr. Fine. We had this project- we used to have this event, years ago, that they called staff day, and it is what it is. All the staff gets together, and with all the funding cuts, we no longer have staff day. the last staff day we had, everyone was seated everywhere and of course, I get stuck to the table with Dr. Fine. So everybody is doing these team building exercises and I get put at the table with him. He goes "What are the odds I get to sit at the table with my research staff?" Oh god. So we had these pipe cleaners again we had this team building, I can't even remember what we were doing. I just remember we had to design things out of these pipe builders and wear it on your head. You know those pipe cleaners- the wire things with all the fuzzy- so he makes this things and wraps it around his head. I'm like to me it looks like, you know when doctors used to have those old time reflectors? I said are you going retro? is that and old time reflector? He goes "No it's a uterus."

Buyer: Me and my tech the first night, at the receptions we turn and look at eachother and say you know? He's a free spirit. We really admire that.

PP Farrell: Oh yea. He is, I -Dr. Fine. He is a free spirit, and it is ok with him if I put him in check, because there are certain sponsors- human subject research there is an industry requirement that there is active auditing and monitoring where the sponsors, auditors, and monitors come in every four to six weeks during active enrollment, depends on how fast we're enrolling to look at or consent forms and make sure we're following protocol. So, he's got to meet with the monitors all teh time, and remember what I said about the filter. I tell him, no jokes Because he loves to tell jokes but none of them are appropriate for the workplace, none of them. No jokes Dr. Fine. "Ok" But he's great, he's the reason this research department is here. He is actually a uro- he's an OB GYN but he's a urogynecologist, he specializes in bladder, bowel, prolapse issues and back when he did surgeries he was an excellent, excellent surgeon for those issue. And back at Baylor he worked in the urogynecologist department, he started the first urogynecologist fellowship in the United States. He did a lot of incontinence drug studies, and whenever these companies Pfizer and all these other companies did business with him, they'd say "hey, we've got this contraceptive study." He's say "not my population here, let's see if we can get this over to

Planned Parenthood where I'm associate medical director." He basically had to research programs at the same time.

041000

PP Farrell: This one, for a multitude or reasons, this research department generates more revenue than the entire OB GYN, research program at Baylor Medicine. Yes, multiple, multiple times more revenue. But, it's academia, you know, they're not- research is one of the tens of things they have to do, they're not doing it based on efficiency, productivity, profitability, they're not looking at it like that. It's one of these thing we have to do, we do research because we have to, not because we want to. They have their own lab studies that they really want to do. Yea, but this one has taken off and we've been able to grow it to be the biggest one out of all the affiliates. Yea, he's a lot of fun to work with, I also like the model too, out here we've only got one or two doctors, physicians, staff and service PI. When I was at Baylor I had six doctors I had to work for, and everyone's "My protocols are the most important because I'm chair of the department. Mine are most important because they bring in the most money. Mine are more important because-" you know, tug of war, all the time. And there was just one of me. That's typical in academia though, you have or two research coordinators or support amongst multiple doctors for all of their research, that's why the turnover rate is so high.it's just way to much work for one or two people. He's um, has been very involved in research, research on the national level too.

043000

PP Farrell: Kinda like I have been on the advisory committee, he has been on the accreditation team. So as he goes to other Planned Parenthoods, it's like our own self audit, they go in and review the charts and review the documentation, and make sure all Planned Parenthood's are following the prescribed standards and guidelines, to receive accreditation for the next two to four year cycle. So, he's been part of that team as well. I have a hard time visualizing that but apparently he has been part of that team as well. Just his nature, I don't see him being real serious, but like a lot of doctors he gets a little cranky. You ever worked with cranky doctors? They're not fun. He gets cranky too upstairs especially, with that volume, there are thirty four people up there right now, this facility is huge, but that's a lot of people all on the floor at the same time. So, if it's the doctor doing the procedures and the staff are on him to keep moving, he gets cranky. That's the pressure you were asking about at lunch, why is everyone so stress and tight? Those of us that are still providing abortions, there is a lot of volume. When we built this building, we moved in in 2010. We bought the building, gutted it, took it down to girders and beams and what I got, and the other managers got was build out for ten years worth of growth. Try to see- who can see? Try to see ten years out into the future, that's why I said I want refrigeration space, I want this and this in my lab. I need these rooms that are flux rooms they can either be this or that- that room that all the boxes are in?

Buyer: Yea.

PP Farrell: That's actually an exam room. We thought we would need to exam rooms, little did I know the IVD world would need a storage room for all the shipping boxes because we ship everything day in, day out. There's no way they could have known that we'd be one of six or eight providers in the whole state and have that kind of problem baked in upstairs. So yea, it's interesting to see what they're going to be doing with that.

Buyer: And how many years are we into that now?

PP Farrell: Five.

Buyer: Five years into that ten year build out.

PP Farrell:They've left space, like some of the hallways like this, they left them double wide where they could go in and put cubicles or enclose it and make smaller offices or whatever. They've left some flex space like that through out the building. So there's room for growth but in terms of boom, all of the sudden you've doubled in volume no body prepares for that, you do it in incremental growth. There's no way you can prepare for research earthquake.

Buyer: The building can maybe handle it, but the personnel is a different issue.

PP Farrell: Yea, and that's the thing,even bringing in all the personnel, people need time to learn, and get into a routine. Even if you bring on double your staff and you can do that, you're still not going to function at full capacity yet. And you're expected to perform at full capacity so I think that's where a lot of the angst that you got from the conference comes from. Did you get to sit in on meeting, you know, provider meetings?

Buyer: It always depends on the conference, NAF is more open, the Family Planning Forum, the Society for Family Planning was pretty open, the Medical Directors Council-

PP Farrell: Did you get to meet Mitch Creinin?

Buyer: No, I think I've seen his name on a couple different things but-

PP Farrell: He's not with Planned Parenthood he actually is a medical

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PP Farrell: He is has been involved in the product and he's very involved in Society for Family Planning, he's like their guru, so. I was curious if you met him, talk about personalities.

Buyer: Really?

PP Farrell: Oh, my gosh, yes. I'll just, I'm going to leave that a surprise for you. Very interesting personality, it's interesting and yea, I've never been to Society for Family Planning, I was going to go to- there was a conference in August for Society for Family Planning in 2008, or September, the year that we got hit with hurricane Ike, here in Texas, it was that week, I actually had to cancel. There was no flights, I couldn't get out. I was right after we got hit the storm, we don't have earthquakes but we do have hurricanes. You see those coming and you can leave, approximately, so.

Buyer: No warning with the earthquakes though.

PP Farrell: It sounds like you've been through a scary one.

Buyer: 7 point-

PP Farrell: Were you there for the big one in '89?

Buyer: mhm.

PP Farrell: Oh wow.

Buyer: Just passing through Southern California, but passed through just to feel that.

PP Farrell: Can't have that. I love California, I love Florida, I guess because I grew up on coastal area, I like both. I couldn't hang with the earthquakes, I'd take one and I'd be back in Texas, that would be to much.

Buyer: I think just growing up with them- well sometimes, I just enjoy the power of, you know, where's that power come from, you know it's just outside of yourself. You really don't know what it's all about.

PP Farrell: It's fascinating, for a brief stint, I worked at Penzole, I worked in their geology department. At the same times i was taking geology classes at U of H and learned about the mechanisms behind what causes them, it's fascinating, that this much power, these things happen on the earth all the time and the structure of the earth changes, it's changed over the millions of years, because of the earthquake mechanisms, the plate tectonics.

Buyer: And with all that knowledge we still can't predict, that's what bothers me.

PP Farrell: Yea, same thing with the weather. We know so much about the weather, but we can't predict the weather.

Buyer: Yes, somethings will remain a mystery.

PP Farrell: Surprise. Yea, earthquake surprise is not much fun, but surprise it's raining today, and it's not supposed to be. Ya'll would appreciate that right now, is the drought as bad in your part of California?

Buyer: It's the worst in Southern California.

PP Farrell: We had 2010, 2011, 2012 we had a three year period of time there. 2011 was the worst, where we had a horrible drought here. I' trying to remember rainfall totals, we had fires, you probably saw it i the media, where the whole freakin state was on fire. Right before the elections, I know governor Perry was campaigning to be president, he's going to do that again by the way. He was talking about the state, because of the wildfires, because of the drought, it was horrendous. Absolutely horrendous, there's still-like even our property in East Texas, the area of East Texas is called Piney Woods there's lots of pines. It gets more rain fall out of any area in Texas, even here, the Gulf Coast. It was so bad there's area on my property where whole trees have died. So what we had to do when we bought the property is- there were dead trees everywhere, and they were so close to the house, we had to go take those trees down and it was all because of the drought. We still have- there's a park that's here in Houston it got shut down, there's a huge section of the park where the trees died, they're having to go in and cut them out because now it's a safety thing. They are beginning to fall in there areas where bikes and hikers are so they're closed so they can take down the dead trees and replant.

Buyer: What year did you get relief? Was it '12?

PP Farrell: We didn't get relief, until 2013 when we started to get close to normal values, but they're still saying we're in drought conditions. It's not anything like it used to be in terms of rainfall. It's weird, I grew up here we never had- ever since I was a child we never had a period of drought like this, but apparently it's something that happens cyclically everywhere, so.

Buyer: Oh, Hope you get through it.

010000

PP Farrell: You learn to pick out voices in the hall. Visitors, I can hear certain people walking up because I know their gaite. I hear their walk so often that I know their gaite. So, how many different sites do you need to visit while you're here besides us?

Buyer: we have several researcher meetings scheduled tomorrow-

PP Farrell: Researcher meetings.

Buyer: Yea, tomorrow actually we're supposed to head North to Dallas area, tomorrow afternoon. Might have to postpone that until saturday though. Am I forgetting something- the call. I'm not as confident as you are about it.

012400

PP Farrell: I am looking for, you asked me earlier for an academic study (inaudible) um, I for the life of me I have no idea. That's bad, (inaudible) I'm curious too now that you asked about it because it didn't even register.

Buyer: Is that the same form we saw earlier? It looked like a different title.

014000

PP Farrell: It was a newer one. I look for one thing, and I find something else.

Buyer: What year is that from?

PP Farrell: From 2011

Buyer: Oh. That's PPFA or Gulf Coast.

PP Farrell: Mhm. Programs for donation and or aborted pregnancy tissue. I guess they changed the title of it. It looks like it's not all that different at all. Just reading the-

Buyer: That would be very interesting to compare though, to see what they did change. Who is responsible for compiling those?

PP Farrell: My boss. My boss, she takes all the standards and guideline every year and goes about disseminating them to the various departments and review them against the prior ones, and of course the give us a form that says this has been changed this has been added. She reviews all of those.

Buyer: And she's at this site?

PP Farrell: Mhm.

Buyer: I guess what I meant was who writes them?

017300

PP Farrell: The people at PPFA? Let's see, where's the protocol? They're with the immunobiology group.Humanized mice.

Buyer: That's what they were going to do? But they never got back to you? Interesting. So what are they- are they requesting just liver or liver-thymus? Liver-thymus, Longbone?

PP Farrell: Everything, CNS, brain, liver, thymus, kidney, spleen, femur, bone marrow, hematopoietic stem cells form 14-22 weeks.

Buyer: They're going to engraft all of those or just hematopoietic?

PP Farrell: It doesn't say. 22 weeks.

Buyer: Including CNS, brain, wow they want everything. So that's the thing for a study like that if we could provide a whole cadaver and hey could-

PP Farrell: Take what they want.

Buyer: With the full quality and everything, that would be ideal for them.

PP Farrell: the purpose of this is to obtain cadaver, fetal tissue for humanized mouse model for study innate and adaptive response to viral cancer autoimmune disorders to facilitate treatment options for deadly human disorders.

Buyer: Sounds about right.

PP Farrell: Well, it would make me very happy for us to finish up what we need to do and then I can put you in contact with them.

Buyer: Are they- what kind of media are they requesting? Is it something specific?

PP Farrell: Not specific.

Buyer: No, and their range is 14-22 weeks is what they're saying?

021000

PP Farrell: Oh, and I was wrong, they wanted 120 samples.

Buyer: 120? This is huge.

PP Farrell: Uh-huh.

Buyer: This is the budget you said was insulting or they never got back to you about that?

PP Farrell: They never got back to me. It was not- I mean we never got to budget, I sent them a contact that had budget numbers in it, this is from a previous project, it will be similar. We need to negotiate it based on how you want us to collect-

Buyer: Yea.

PP Farrell: What days, media, how are we going to get it to you, you know, we need to work out those details. He did this before, he fell off the face of the earth after the initial contact. so again, my slightly derogatory comments about academia. i'm going to grab that off the printer real quick so we can look at it.

029000

PP Farrell: Be right back, interesting, I never read anything about humanized mice. these are curious because we had no contract with them they have no confidentiality about this. Not that I'm trying to be blatant but-

Buyer: Oh, this is the PPFA. The font is nicer, it's more recent.

PP Farrell: Mhm. So we know what we need to do about shipping, that's covered. We just need to think in terms of the sample itself.

Buyer: I'm sorry in terms of what?

PP Farrell: Specific in terms of the samples themselves, you need us to dissect them you need them whole.

Buyer: Right. Right. Right.

PP Farrell: I wonder- I'm just thinking out loud, I wonder if that was something he realized, because the last discussion we had where I reiterated that these are samples from abortions that are second trimester. they typically aren't intact-

Buyer: To the researcher?

PP Farrell: Yea, I wonder if he-

Buyer: Did he say intact specifically in that protocol or?

PP Farrell: He didn't. Again, a lot of times with academia or industry sponsors, they bake so much of their project based on assumption. They assume what a clinical practice or procedure is without- I have some sponsors that before they

even write the protocol, they'll call me up "Missy, how do you guys do this? How is this done? Do you know how the industry does it? Academia, how do they do it?' And, because we don't want to build this protocol based on these assumptions, when we're finding different people are saying it's different out there. When the standard of care procedure isn't done in a standardized manner. Which, that happens all the time, that makes sense to call and get information from boots on the ground, rather than I'm this doctor or this researcher and I think I know so I'm going to put it in here. Which I've experienced that a couple times. So have you seen anything that's materially different.

Buyer: It looks like a revised and slightly streamlined, updated form.

PP Farrell: Do you have that other form with you? I'm curious if this number stays the same, I can look up the number.

Buyer: I'd have to look in the care, I think I had it in there.

PP Farrell: I think it's the same number, will you humor me while I search a little bit?

Buyer: Mhm. And then we're going to be coming up on 3 o'clock here in here in just a little bit.

PP Farrell: I can show you how to use the phone ext door if you'd like. I'm probably going to take the opportunity to visit with my staff and see how- just get a pulse on everything.

Buyer: And then if we plan to check in with Tram about 3:30-3:45.

PP Farrell: Yea.

Buyer: If it seems like it may be substantially longer, we may have to save it for next time.

PP Farrell: Their clinic starts really early, they're here working by 7-7:30 generally unless there's a lot of unexpected events, everybody is out of here by 3-3:30. I mean physically gone, they're done, done. So, I think that time frame will probably work.

Buyer: Did you say you were printing out the other researchers protocol or, I forget.

PP Farrell: No, I was just going to print that one up but, once we get things moving along, I'd be happy to give them your name. Give you his name. What's that called again? Programs for Donation. Very frustrating. Used to be a table of contents where you could look up the name or that number. I don't see that

number I don't know where I can get that number. No, that' a completely different group. I found it, it says Fetal Tissue Donation, but when I try to open it, it says cannot open specified file.

Buyer: Maybe you can get the hyperlink for it separately?

PP Farrell: Under sections (inaudible)

012000

PP Farrell: Some of them, on the other side, there's Margaret Sanger, we attribute Margaret to being our founder at Planned Parenthood, some of trying to remember if it was actually somehow or another I was 11ata conference or something someone was reading letters from women who in that era were sending letter to her saying thankyou so much for what you are doing. It was from women who were able to get on some form of birth control. It was women who had four kids, grossly anemic, grossly malnourished and she was too because she'd had babies back to back to back. Her husband was a steelworker who was injured and was out of work. This is before unemployment and disability this is what these people had to face. Thank you for giving me this path, because I can see if I kept having babies, it would be the end of me.

Buyer: Yea.

PP Farrell: And you know it's so simple we take it for granted to the point where they're encroaching on our right to have it.

Buyer: Yea.

PP Farrell: And so- yes, yes. Now she's the one saying are you still coming up?

Buyer: Ask her to save the biggest specimen for us. Just kidding.

PP Farrell: (inaudible)Ok. Are you ready? (inaudible)

Buyer: How funny.

017000

Buyer: Is this where we need to get our scrubs?

PP Farrell: We'll see what she requires.

Buyer: No it worked out.

PP Farrell: Sorry, shouldn't be so open. I wonder if I can get her faster than they can.

Buyer: take a lot of my list.

PP Farrell: Sorry, in a good way- Hi how are you?

020500

PP Tram: Hi. Sorry about the time. Hi how are you?

Buyer: Hey. Good seeing you again. How are you?

PP Tram: Good seeing you again. How are you?

Buyer: Pretty good.

PP Farrell: This is [Name], [Name], Tram.

Buyer: We've met.

PP Tram: We just finished clinics. Sorry.

PP Farrell: Sorry, that is totally my a fault for not putting it together.

PP Tram: No it's ok, it all worked out. Come on back. This the lab, we're just one big square. this is where we do all of our preoperative ultrasounds here, all of our education offices, pharmacy. Like I said we're done for the day so.

Buyer: Excellent.

PP Tram: This is our preop exam area, where patients get ready, get premedicated.

Buyer: Good stuff.

PP Farrell: Are we gonna need to get scrubbed up?

PP Tram: We are done. We're done! Our procedure rooms pretty much mirror each other and then our O.R. there, all procedures over 16 weeks go there. We're done, we are done.

023000

PP Tram: All procedures over sixteen weeks have to be done in the O.R. So this is our tissue lab where we float everything-

Buyer: Is this the only tissue lab? Or are their others- this is what we're most interested in- can we step in?

PP Tram: Yea.

Buyer: Are their any fresh specimens from today that we can still look at?

PP Tram: We had a really long day and they're all mixed up together in a bag. If I would have known ten minutes ago, I would have saved something.

Buyer: Yea. Yea. It's not like we need something today, but if we could get a visual, is that possible?

PP Tram: Yea, let me see. I have one that's probably frozen.

025000

Buyer: We're looking for a visual baseline of intactness-just so that we know.

PP Tram: How intact they are. Right.

Buyer: Just on a typical day, kind of what that looks like.

PP Tram: It varies by gestation, sometimes they come out really intact. Do you want to do- You know, there's nothing intact today. When we collect the tissue, it all gets collected into one container.

Buyer: What is the latest case you did today?

PP Nurse: The latest case we did today was a five week and three days. Oh, it was twenty- I know what, you mean gestation. That was the very first one so, I'm assuming that one is frozen. This tissue we don't float it ok, it comes straight out of the O.R.

Buyer: Oh, because the second tri's you don't float.

PP: Everything is collected in the tray and once there's an questions or anything, then we'll separate it out-

Buyer: Because these are just D&E's so everything is just in the tray.

PP Nurse: So, this is what it's looking like at this point, that one is frozen, we collected this kind of early, yea.

PP Tram: And then, I'm gonna show you, let me see if I can get--

Buyer: That is so much easier than the first tri's though, because we're looking for specific organs and tissues. You can see lungs and liver and everything-

PP Nurse: Oh yea, you can definitely see organs and tissues in here.

Buyer: So it's not frozen yet" How long has it been-

PP Nurse: No, it's cold, it's starting to freeze. It's been in there since morning.

Buyer: Is that cal right there?

028300

PP Tram: Calvarium, yes. You can't see it on this one- you can see the top of the calvarium on this one-

Buyer: Oh, that's really frozen.

PP Tram: Yea.

Buyer: [Name], I think this is a better visual. As far as-

PP Tram: When you see like some of our-

Buyer: Seeing how it is without even trying to keep it intact-

PP Tram: Oh, Dr. Beasley, she is one of our two physicians that do our D&E's, so fetal collection-

Buyer: [Name], [Company], we do tissue collection for stem cell research.

PP Beasley: Ok.

PP Farrell: So, we're working with them and look at a contract for long term tissue collection and donation.

PP Beasley: Ok.

PP Farrell: --Anything more than collecting samples, anything we don't have immediate need for

{*Audio file:* **150409 001.MP3**

06:44:58

Tram: So it all depends, sometimes like I said, they come out really intact.

Dr. Beaseley: Yes.
Buyer: Mhm.
Tram: And sometimes—
Dr. Anitra Beasley: Yes, yes.
Tram: So that's what, they wanted the visual of what the fetus looks like after a D&E.
Dr. Anitra Beasley: Oh. Okay. We're the best to get it, we're good.
Tram: Yeah. Uhuh. Because I'm like, we can't really intend to bring it out intact.
Dr. Beasely: No Saturday? I was gonna-Tram: Oh no no no. No good deed goes unpunished. So no Saturday.}

PP Nurse: Want to see some more?

Buyer: That's gauze wrapped up?

PP Nurse: This is gauze-

Buyer: Oh, what organ is that, I don't think that's an organ.

PP Nurse: Let me move this and see what else we have- this is placenta.

Buyer: That's just placenta, yea. So, we're often times looking for liver and thymus. Two of the most in demand- Is that lung or liver, that's liver right?

PP Nurse: No these are the lungs.

Buyer: Those are the lungs?

PP Nurse: Kidneys.

Buyer: That is a kidney, I can tell, it came out intact so.

PP Tram: All of these come out well-

PP Farrell: And you've got your thumb on a- yea you had intestine and you had spine, and you had, that's part of the liver, I believe.

PP Tram: Liver, intestine get a lot of it.

Buyer: Liver and thymus are huge, that's one of the biggest things in humanized mouse models.

PP Tram: If you can get that- they, yea. Like Dr. Beasley said, we can never intend to complete the procedure intact- you can't intend to, but it happens.

Buyer: You have an intent statement, yea?

PP Tram: That's correct, there's an intent statement, which you have to document. Correct.

PP Nurse: You good with that? You want to see some more or? You want me to rinse it for you and put it in a tray.

Buyer: Do you mind? Do we have time?

PP Nurse: If you're ok with it. The reason we don't have, they just collected this morning so that's why we don't have more samples. Thank you-

Buyer: Well, anything from older- anything they collected this morning would be frozen right? This is fresh from today?

PP Tram: Uh-huh. From this morning.

Buyer: Is this the only second tri case from today.

PP Tram: Yea.

Buyer: Oh, got it.

PP Tram: Most of our cases are going to be tomorrow.

Buyer: Oh, ok.

PP Farrell: That was going to be a question. Originally I remember hearing about second tri's only occurring on certain days, now is it certain times a day, is it everyday?

PP Tram: It's everyday, with the exception when Dr. Bond is here, but all our other days, but our Thursday, this a rare Thursday but usually Thursdays and Friday are stacked with D&E's. There's some days when we do like eight, nine easy?

PP Farrell: Oh, yea.

PP Tram: Yea, Thursdays and Fridays are usually stacked.

PP Farrell: So when you're setting up the space, what is your flow? Because I see your little sign and everything so-

PP Tram: And everything in this room is technically dirty. It just flows from each room, there are the samples, they keep everything on that side. The little basin is or us to disinfect the collection bottles, they get soaked in bleach. Instruments

are on the left side, of the sink. Tissue is in the middle sink. She'll float everything on the tray, on the view box and the other instrument that we need to dry, we move them to the utility room for processing so.

PP Farrell: Bye Dr. B

PP Beasley: Ok, bye.

Buyer: I feel bad that everything was all clean already.

PP Farrell: It's ok, she'll give you the bottle of bleach.

PP Nurse: We'll give you an apron.

Buyer: Services in kind right?

PP Farrell: They're disposable, we'll get you one. I spoke with Lashanda on the back section, if ya'll need that, we're totally cool with doing that.

Buyer: Excellent.

PP Nurse: Alright, here we are.

Buyer: Am I going to get in trouble if I take a photo for baseline?

PP Farrell: Uh, probably you can't do it. Gonna have to use your memory. Sorry.

PP Nurse: You want tweezers or something?

Buyer: The great this is, this is big enough you don't need tweezers.

PP Nurse: Ok.

Buyer: See now, this- Tram can you help me out? I think this is lung right?

PP Tram: That's correct.

Buyer: Yea because this is trachea in the middle here, and liver. You see, liver and thymus are the other two things I'm looking for. That's is yea- orbits, really good orbits.

PP Tram: Yea. There's the-

Buyer: That's the cal-

PP Tram: That's the calvarium here.

Buyer: That's brain- is there neural stuff still in here?

PP Tram: Some.

Buyer: You met [Name] in DC right?

PP Tram: Yes.

Buyer: He should really be here because he's the tech and I'm- this is liver, is it not?

PP Tram: Yes.

Buyer: There you go. Piece of liver, is this spinal cord? White matter?

PP Tram: No, it depends on where it came from. It could be part of the umbilical. So, it's just a little bit different, but that's more umbilical. So the intestines are here, right here, see? Like I said, the organs come out really well, like you can see all the intestines.

Buyer: Right. This is a big placenta right here.

PP Tram : Yes.

Buyer: Do you ever see thymus?

PP Tram: It depends, whenever we do twenty, twenty-two weekers, we do. We get a lot better-

Buyer: But it's difficult to find thymus at this gestation?

PP Tram: Yea.

Buyer: What gestation is this?

PP Tram: This was an eighteen week- she was about eighteen weeks or so. She was also a minor.

Buyer: Oh, so this one wouldn't be for collection?

PP Tram: No. She was a minor.

PP Farrell: We're not going to go there. No. No.

Buyer: Yea, that's complicated.

PP Nurse: No minors, no incarcerated people.

Buyer: So, the thymus is shaped like two little flasks right? But you rarely see it a this gestation. Because requests are often times paired thymus and liver from the same door. That's used for the immunology studies in the humanized mouse models. Is this? This is limb and this scapula, got it.

PP Tram: So the reason she had to wait so long, is because she didn't have parental consent.

Buyer: Oh wow.

PP Tram: So she had to go through judicial process.

Buyer: Oh my gosh. So then her mom found out, and she came in a gave consent.

PP Tram: So that's the only reason that-

Buyer: Here we go, this is kidney right here. I don't know who told me that, that's with the renal.

PP Tram: Yea that's it.

Buyer: And this-

PP Tram: That's lung.

Buyer: This is the, other one. Wait is this thymus right here?

PP Tram: You have to kind of- it's easier when it's flat out-

Buyer: Yea, you can see those pieces better,? kind of. Do you think I'm right?

PP Tram: I don't know, it's hard to, it could be though. It could be-

Buyer: With a different technique it could be intact. So that's what I-

PP Tram: And you know the other thing that plays a major part in this all, is the dilation.The dilation you can obtain-

Byer: Exactly.

PP Tram: It depends on how cooperative with the procedure.

Buyer: Oh really? Are they under conscious sedation?

Pp Tram: Yea it is conscious sedation. There's also times where they're maxed out- there's tolerance so it's a little bit more difficult.

Buyer: Oh.

PP Tram: Sometime if they're completely relaxed, it's easier to not have to do so many passes with the forceps. So, it really varies and like I said, a lot of it depends on the dilation that was obtained. All of our procedures over twenty weeks go through a two stage dilation process (inaudible) for this procedure it's usually about three centimeters.

Buyer: LAMs and Miso or just Dilapan and Miso or?

PP Tram: We usually don't do combination of dilapan or laminaria. Any of our procedures that are twenty weeks, they'll come in they'll get dilapan for three to four hours and we take them out and we send them home with laminaria, and they come back the following morning. So it is a two day procedure-

PP Farrell: It's a two day.

PP Tram: Yea, it's not a three day (inaudible)

Buyer: Most places don't do it that anymore, yea.

PP Tram: The other providers in town all do-

Buyer: Oh, the independants.

PP Tram: It depends on preference, like there's a provider down the hill doing three days, if you're fifteen weeks and six days. So- that we usually find with the more experienced providers, who've been doing this for a long time.

Buyer: Yea, because this is a very- this an excellent cardiac specimen for example. But, overall this is still a very mangled case. We were talking about, for at least a procurement tech, it's a lot easier to say, if you have the body cavities in one piece so if you;re looking at liver or thymus or whatever, it's just matter of locating it anatomically, rather than if you have a whole thing like this and picking through.

PP Tram: There's actually a thing, when the patients that are further along, usually what you'll find is it's a lot less disarticulated. And the calvarium and a lot of times it come out in three to four. When they come out, you know, before we take them out for package or incineration, what we do in the office is lay them out

to kind of account for everything before it gets sealed up and packaged up, we actually do al lot of cases for sexual assault cases.

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PP Tram: It's different in placenta and long bone but it's still very, it's very cleaned up, so it's different than this as well.

Buyer: These orbits are good too, at this stage you start to get the retinal pigment epithelium in the back, which is- you've collected that before.

PP Tram: Orbits, yea- orbits are so easy, like ninety-five percent-

Buyer: They're easy to find too, even in their early gestations because you just look for the-

PP Tram: Yea, they come out firmer and very-

PP Farrell: This is where having a research department would come in handy because other-

Buyer: This is an orbit that was split open and you can really get retinal pigment.

PP Farrell: -if we need to step in certain places, like instead of the usual process going straight to- after it's checked, if we need to come in and start this process before it becomes frozen, we can step in and do that. Other facilities, this would be a whole other step added-

PP Tram: I actually did one study with the university and each time they had so send someone here they had to hang out, all day to collect what they needed. She didn't enjoy that too much but-

Buyer: She didn't enjoy that too much.

PP Farrell: If we have ongoing contracts and we have things that we need, we can build that into it.

PP Tram: As far as actual D&E cases, like I was telling you in D.C. it could easily, easily be like forty or sixty in a month.

Buyer: Forty to sixty in a month.

PP Tram: You know, there was one month where it was pretty high.

PP Farrell: In terms of second trimesters, how many are you doing per month, per week? If you are able to guess off the top of your head.

PP Tram: Probably about thirty in a week, as far as further alongs like over sixteen weeks, because I really don't count anything between fourteen and sixteen weeks since they are not really D&E's. That's when you get the forty a months so it whittles down some.

PP Farrell: Is that a viable number for you?

Buyer: How many per month? Or the gestational age? Fourteen to sixteen or? **PP Tram:** From sixteen to twenty two.

Buyer: Is how many?

PP Tram: Forty or fifty, easy.

Buyer: Per month?

PP Tram: Yea.

Buyer: Yea, and those are all being done on the same day per week, you diad? Or others?

PP Tram: Yea, typically Thursdays, Fridays, and Saturdays.

Buyer: Ok.

PP Tram: Those are the typical days where the volume is concentrated whereas on Tuesday, we'll probably be doing two to four second trimester cases, sometimes like eight. But, like I said they're heavily stacked on Thursdays because those are my two providers that go up to the state limit at twenty-two weeks, and they're also more- we do residency training with them and things like that.

Buyer: Are they experienced in that if they need- if they are looking for something for us they could adjust a little bit-

PP Farrell: Those two in particular, yes.

Buyer: They would be able-

PP Tram: Yes, one-

Buyer: And that's a Thursday, Friday, Saturday?

PP Tram: Yes.

PP Nurse: Hey Tram, sorry to interrupt, I'm going to let one of the girls finish up ok?

PP Tram: Yea. Thursday and Friday are the two who are-

Buyer: Experienced enough.

PP Tram: Yes, experienced enough, come from academic institutions, participated in research. One of them came from University of Columbia, an active researcher, and she's very well versed in what she needs to do.

Buyer: To just change it up just a little bit.

PP Tram: Oh yea.

Buyer: Ok.

PP Tram: It's the same thing, you know, we don't do evidence collection on second trimester as frequently as we do first trimester, so it's a little adjustment here and there. As far as- you know, it was a learning process for us as well, when we started going up to this gestation and needing assault cases, at first we were packing everything, and they were like: "We don't need all that." Ok, tell us what you do need. And then, you know, we sent placenta some time and the pathologist was like: "That wasn't enough." It's like what do you mean? It's a twenty-two week placenta. It's been a learning process for us as well, but we've got very, very good at it. So, that's what we do.

PP Farrell: Well, thank you so much, thank you for accommodating. Can we help clean up? I've got scrubs, I can put gloves on.

PP Tram: It's ok. We're going to take care of it.

Buyer: Ok.

PP Farrell: Ok. Very good. I'll probably have some other questions that came up today and I'll shoot those over to you.

PP Tram: Yea.

Buyer: I wish I could see thymus. The thymus is always the tricky one, that is really difficult to identify, it's just small and fragile. As far as hand washing sinks, where can I find-

PP Farrell: Hand washing sink, over here.

011000

PP Tram: Are you going to be at NAF?

Buyer: Oh yes. We'll be there and [Name] will be back there as well. Yea, NAFyou'll be there as well.

PP Tram: Yes.

Buyer: Are you presenting anything at all?

PP Tram: No.

PP Farrell: They've already talked with PPFA, Deb Nucatola and everybody up there. Because fetal tissue donation varies so much state by state, PPFA is moving away from a standardized policy.

PP Tram: Yes, I attended the patient service day and Kristen Flood did talk about fetal collection and stuff like that.

PP Farrell: Very interesting. Remember when I first got here and it was like you have to have this form and you have to do this?

PP Tram: You had to have this particular consent form, very specific. Yea, no that's what Kristen was saying.

012000

PP Tram: They [PPFA] are encouraging more participation [in fetal tissue procurement] but they don't want to get too into the mix of it.

PP Farrell: Interesting. Ok cool. Any idea why the other affiliates in Texas think it's illegal?

PP Tram: Really?

Buyer: Do you know Amna Dermish?

PP Tram: Who?

Buyer: Amna Dermish, she's a provider with greater Texas. I think she was a fellow a couple years ago in the family planning fellows program. She and I met back at the society for family planning meeting, back in October. We had a great discussion about all- her IUD studies, and her second tri cases. She was really interested in the idea of tissue procurement, but then she want to talk to her CEO at the same meeting, and he was like: "Oh no, it's not allowed in Texas." I know for a fact there are multiple published researchers that use fetal tissue.

PP Tram: We have.

Buyer: I think it came down to what you and I-

PP Farrell; You have to do it under research umbrella, and you really have to know your regulations and follow- keep up with them, I think if they don't have someone there who is able to do it they-

Buyer: No interest.

PP Farrell: No interest, yea.

PP Tram: You know, I'm puzzled by that.

PP Farrell: You know I'm puzzled by that too. I'm going to send Kimmy an email about that, did anything get worked into house bill two that has to do with research?

PP Tram: Nope. You know I tore that thing apart, up and down.

PP Farrell: I never trust it too, so I've read parts.

PP Tram: Because now they've introduced the Down Syndrome bill and all this other- no, there's nothing.

Buyer: You know, I was going to ask you because you guys said that you could go up to twenty-four weeks for certain indications, how broad is that allowance?

PP Tram: It's actually very narrow. So, in order to be considered a lethal anomaly, the wording in the law is very specific so we require documentation from a maternal-fetal medicine doctor or a geneticist. It has to specifically say on the notes or on the ultrasound, you know, lethal, will not survive-

Buyer: Incompatible with life.

PP Tram: -the chances of viability are like zero-five percent. that's when we do the cases over twenty-two weeks, so it's between twenty-two and twenty-three six is the max. Those are typically the cases where we see one of the more common ones that we see is an encephaly that we see, those are the more common ones that we see. So we get a variety.

Buyer: Those are for maternal indications?

PP Tram: We don't do any maternal indications, because even though it's not illegal, it's such a grey area that you have to be a little bit more conservative. So that' why we don't go there.

018000

Buyer: Best case scenario, would we it take to navigate that?

PP Tram: Maternal Indication? If there was any documentation in the hospital, where you're having multiple organ failures, even if you're in a hospital, in that case it requires two physicians, two different departments, that's the only case where-

PP Farrell: We have the opposite here in Texas, they won't even- pardon my bluntness- they won't even pull the plug if a woman is pregnant, because they want her to carry as long as possible. Even if she has DNR orders, it's still really hard to do. We're Texas! I told them about the bus.

Buyer: The welcoming committee.

PP Farrell: Our state funded bus.

PP Tram: Yea, state funded. (inaudible)

PP Farrell: And the license plates that say choose life. Tax dollars at work.

PP Tram: Tax dollars. It's a beautiful thing. I'm still stuck on Greater Texas and this whole illegal thing.

PP Farrell: We need to talk more anyway, so we need to figure that out.

020400

PP Tram: "We've also kind of always done other things that other people were just not necessarily comfortable with, just because it takes a little more work as well. And it is, there is a little more risk involved, obviously."

PP Farrell: Mhm.

PP Tram: But it's like, it's for a good cause. Why the hell not?

PP Farrell: Mhm.

PP Tram: It seems so simple to me.

Buyer: There's people who hate you for what you do anyway-

PP Tram: So, like whatever. It's all the same.

PP Farrell: Yea, were excited. Cool. Other affiliates in California, they've had this type of tissue procurement going for years. It's on going, we talked about this, this will be nice.

PP Tram: Because every since the UTMB, we'd be like Missy? Can we get anything? Anything?

PP Farrell: I told you they ask me. The patients ask, they ask if they can donate.

Buyer: Ever since, what did you- the acronym you refer-**PP Farrell:** UT study, the last academic study that we did where we donated. Where did Dr. Theiler go?

PP Tram: Now, she is at Dartmouth.

PP Farrell: Oh she's not at Planned Parenthood anymore?

PP Tram: Not at Northern New England anymore, now she's like chairmen or something like that.

PP Farrell: Oh. ok.

Buyer: So that was the placenta study you were telling us about. How long ago was that?

PP Farrell: 2000- it was right before she left, 2012?

Buyer: So you haven't done any fetal collection in three years?

PP Farrell: No.

Buyer: Wow.

PP Farrell: Why do you think I keep doing this? I keep going yay! I can't even contain myself, I'm so excited.

PP Tram: I'm always bugging her about it. This is good, the up side.

PP Farrell: And because of all this, the clinic flow and everything, the electronic medical record and stuff, our other studies are incompatible. So, they're left out of a lot of research studies so.

PP Tram: It's very exciting.

PP Farrell: Ok. Well, we're going to get out of your hair, but I will set something up where we can visit later. Talk some logistics and how to see this, and put some papers together. Thank you so much for hanging out.

Buyer: Good to see you again. See you at NAF.

PP Tram: See you at NAF.

PP Farrell: Ok thank you.

PP Tram: No problem.

PP Farrell: (inaudible)

Buyer: Huh? Oh. There is a big difference in trying to find any of those pieces in even twelve weeks-

PP Farrell: They don't spray anything they don't do anything they just-

Buyer: They just pick it up and yea.

PP Farrell: So, water is- Did ya'll just finish up?

PP Nurse: I was in cashiers training all day.

PP Farrell: So many training's going on today.

Buyer: So what are the other floors? Were we just on the second?

PP Farrell: Third. This is the third floor, there are six floors in this building.

Buyer: (inaudible) It's just different?

PP Farrel: There is one whole floor dedicated to meeting room and conference rooms, the other floor is admin. Another floor is HR and Fiscal- accounting. Accounting and HR are on the same floor. If you notice the building is shaped like a stair and the top flow is IT.

Buyer: So the only floor our patients are seeing is floor one and floor three.

PP Farrell: Mhm.

Buyer: Got it.

029000

PP Farrell: That was fun.

Buyer: That was wonderful, thank you so much for (inaudible) at the last minute.

PP Farrell: It was no problem, if you notice the staff that were coming in were very concerned. I was like it's ok, it's ok.

Buyer: Yea, like who are these people? It hasn't happen in three years I guess.

PP Farrell: Yea, and even then, either research would go collect it and it would be this big box full of containers, or Dr. Tyler would collect her own and take it home with her in a cooler. Yea, that's it.

Buyer: So, how do you think? Did you keep them at ease?

PP Farrell: I kept you from being jumped on, yes. Dr. Beasly the one who performed- who's on today was like it's ok, I got it. She notices me, and she's like "Oh." I told her and she's like "Ok.Ok."

030500

PP: The two doctors that Tram was referencing, that do the abortions at the later end of the 2nd trimester, Dr. Beasley and Dr. Schutt-Aine, we are grooming them to be the principal investigators on our studies, because Dr. Fine is nearing retirement, and my boss who is the P.I. on some of our other studies, is nearing retirement. So yes, and both of them have expressed an interest in doing more fetal tissue, more stem cell type stuff. So yes, if we make this a protocol, a research protocol where it is a sample acquisition protocol, I will insist on one of the two of them being the principal investigators.

Buyer: They're very skilled in their technique and are able to?

PP Farrell:: Mhm.

Buyer: Yes, skilled in their technique and are able to enough if they need to creatively tweak it, change it a little bit--

PP Farrell: Mhm, yeah.

Buyer: That it would ensure intact specimens, what we're looking, because they would know what we're looking for, that would be coordinated.

PP Farrell: Mhm. Mhm.

Buyer: The thymus is right up here. It's smaller, it's fragile and unless you've got integrity in here, it's hard.

032900

PP Farrell: She mentioned that when we do have the disarticulation, it's a limb and the head so usually we have the torso and it's really going to depend on the disarticulation if it does involve pulling.

Buyer: This one was very disarticulated, I don't know what happened, Maybe it was because the patient was a minor and so-

PP Farrell: The patient was a minor, and they've already done their- it's been handled, and smushed up and put in the thing.

Buyer: Oh. I find that the patient not being cooperative affects it a lot too. Women being cooperative with- women that I worked with the young women especially, if they know what- this end of it. That could, not persuade like you said- the decisions made but- I like knowing this. Yes, the decision is made but their cooperation is easier for us. If we can get them to cooperate- then the doctor, getting creative, we will be able to get what we want.

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PP Farrell: And some of it- and I didn't want to go into detail- I've administer conscious sedation before. If you have a patient with any kind of polysubstance abuse, they have a higher tolerance and the medication doesn't work as well and there are limits to how much you can give. The cooperation maybe something they don't even have control over because the medication is not going to work as well on them, unfortunately.

Buyer: Mhm.

PP Farrell: Where I've done conscious sedation before, we didn't have an upper limit, I just kept pushing as long as the doctor said keep pushing and had the narc hand right there, ready to go. I mean that's what we could do but in here they have limits so, we just- it's a little more restrictive so- and we don't know that. I don't know if that form listed any kind of substance abuse. Or even asked about it, and probably wouldn't. People would be resistant to answer that not knowing that it impact their-

Buyer: They're not going to tell the truth so what's the point of asking.

PP Farrell: And you know, from a medico-legal perspective we probably don't want to collect that information and document it anywhere. So yea, I'm very

excited to have that. (inaudible) I could do that, if ya'll needed specifics, I could do that.

Buyer: You could see the future, you can see financial benefit, the-

PP Farrell: I could personally be available to go up on those days, the biggest challenge would be Saturday's because we can't do next day delivery anywhere. So we're going to be limited to just Thursday's because if we ship Friday, do any of your labs have Saturday hours where they can even receive it on Saturday?

Buyer: Actually, a lot of researchers are requesting something very specific, and it's special to them, they will make themselves available at 10 o'clock at night, at 6 in the morning- yea.

PP Farrell: Yea so then we would just need to question the Saturday ones, because if we can make arrangement for Saturday, Saturday the only other time would be on Monday. You could have it sent out and delivered on Monday. It's on dry ice, it' still going to viable but-

Buyer: Some people will take that, but it's definitely not first tier.

PP Farrell: Oh yea, so they're looking at Thursday- Friday.

Buyer: And also, people within courier distance, on a Saturday. That's another logistical thing as well, if there are requests that are-

PP Farrell: You got someone local. Sometimes local, like you said send their residents and med students here to wait for the samples to be presented to them.

Buyer: So as far as action items for the near future, do we-

PP Farrell: I need to send you, I've got my list um I'm going to meet with Tram to talk about some of the logistics. Probably Tram and two doctors, I'm going to send you the protocol and consent form. She and I are going get with the doctor or someone to figure out what's up with the other affiliate. It could just be that-

Buyer: Set them straight

PP Farrell: No, I think really, its just making it easy for them. If we can put all of this part in place, I think that will be half the battle. If you don't have anyone that's experience in how to do this, you're not- it's going to be a bigger bite to take.

Buyer: Mhm. But, I know that their are motivated providers at that affiliate so.

PP Farrell: Yes, and we can look at that, I think we'll need to get a little further ahead here, and establish some guidelines on what we're doing and how we're going to do this that can be replicated elsewhere. That the other affiliates in Texas can use, so I have my questions for her. And several of them we asked let's say- because I'm conservative. That's of second trimesters.

Buyer: That's the late second tri right, that she was talking about?

PP Farrell: Yes, and that's a very good number.

Buyer: And that's with the two week wiggle room built in right? How you determine the actual date versus what the actual date is, so that makes it later stage.

PP Farrell: Mhm. So sending you that general protocol and we can just start working on a general contract, budget. I need to meet with Tram first though, to talk about what this is going to look like, in terms of where I see it going and-I mean do you guys have the volume, the capacity for everything?

Buyer: You're talking about all the client volumes? Immediately- it's something that's going to grow because it's very scalable. As soon as people find out that you have that kind of capacity, you have that product available. Because what will happen- let's say there's an academic research client-

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Buyer: For example, the researcher that sent you the request for 120 cadavers for SCID mice studies, they probably sent that same request to StemExpress and ABR and several other- and especially the larger, the private biotech companiesif they have a big, high-volume study like that they'll send the request out to multiple agencies and see either who can do it first or, it's a large number over a long period of time like 120. They'll be getting two or three a week from one company, two or three from another one. And once people start seeing you can deliver on your promises they will start to switch over. It's a very dynamic relationship.

PP Farrell: We can start off with, what I would like to do is have the protocol be general, for any and all gestational ages, within the state limits. Then start off with the most urgent ones that you need, and then as things start to bubble up, I really want to roll this out. In terms of have staff approach everyone, if we have specific needs we will sort those out, everything else gets banked. Then we can work on disseminating the bank specimens. We have to get to the point that you need first. You don't want to have to go through all that expense, if you don't have a need yet. That would be like the long term goal.

Buyer: Yea. Then, there's a tension there between us being able to promise it, and then do we disappoint our clients, then what do we-

PP Farrell: So yea, we can work on the immediate ones first, because those sound like, based on what you said most interest, immediately. The IRB that we work with, we have not done any fetal tissue projects with them so I can't tell you how they will be. Everything else we've done, they're very fast, very customer service oriented so if there are questions I get a phone call from my liaison and says "Missy, in the protocol, it says this, this and this, we have a question about this." If you've worked with IRB's before you know how challenging it is because it is not easy because they don't tell you what they need. "You haven't discussed how you're going to de-identify the specimens." And you're like what is it you want to hear? What do you want to know?

Buyer: Yea, we've all been there before.

PP Farrell: Yea so working with that particular IRB will be good. Especially if I use this, the specimen acquisition protocol that I have used before for IVE studies and I use the consent form, I know that the general language has already been approved. All I have to do is strip out the stuff about the other specimen type and replace it with fetal tissue. The general language is there, the consent process is there, everything else is already in it.

Buyer: It's already been approved by that IRB, twice. They just don't realize it. So I can send you that and then ya'll can look at it and see if you're cool with it. You don't have to reinvent the wheel, it already exists. As terms of the contracts, same thing. We've already got some contracts in place for this type of general specimen acquisition for other specimen types, we just have to make it specific to this type that's why I have to meet with Tram first to get the logistics. Say "Hey Missy-"

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PP Farrell: You've said work this in, how does this look and any more information you can provide in terms of timing the specimens, whether or not I need to freeze them immediately or if I can have them at room temperature for a while, while we're dissecting, any information you can provide that helps me work out logistics better with her, then I can plan and budget.

Buyer: So when you're working with her, if you can get an idea from her, just how difficult is this? Where do we want to set our minimum compensation, and let her know this is a minimum bar, we can go up, if we need to. We can go higher compensation but she is the one who to say oh yea it's pretty difficult because the doctor would need to be creative in that so let's ask a higher price

for that specimen. If you could give us kind of a baseline, knowing that that's not in concrete, that's-

PP Farrell: Yea, that's something to start with, yea. Again, when we had these types of protocols in the past, we've had these types of a la carte budgets. A la carte budgets, the specimens is relatively easy to obtain, you're in. You give them a cup and tell them what to do, either clean catch or first catch, very low price. Any endocervical samples where we have to put speculum and visualize the cervix and collect it a certain way, that's more. So you know, obviously we do that accordingly and there's flexible budgeting in terms of data. You haven't mentioned if your clients are requesting data. Anything besides gestational age, or sickle cell status.

Buyer: Disease screening, mainly STD, HIV, Hepatitis B um-

PP Farrell: They do- they don't do HIV and they don't do Hep B, gonorrhea and chlamydia-

Buyer: Just like standard right? You guys do have the capability to do HIV testing right?

PP Farrell: Mhm. Hep B, we can do it, we don't usually do it upstairs.

Buyer: It can be done in house?

PP Farrell: It is a send out but it can be done. **Buyer:** Oh, it is a send out. Ok.

PP Farrell: Yea, it can be done. That's something else that we can work into it, if disease status is required then we can put it in the consent form, specimen collection, blood, specimen, we put it all in the IRB submission as well.

Buyer: Yea. That's kind of an a la carte service that's been added to the tissue procurement service for a researcher so, not everybody will request it although, many people do depending on the study.

PP Farrell: We just need to bake it in, we just need to bake it in. It gets a little touchy when it comes to the patient though, because technically we can't reimburse the patient for donating the fetal tissue, but if we're collecting an additional specimen, like Hep B if it's something we need to know is Hep B and it's not something we do clinically. That does fall under my research part where we reimburse the patient. It's challenging because she's coming in for an AB but we're not paying her for that AB but we're paying her for this blood and yea.

Buyer: How do you fame that? Do you have to think about how to framing?

PP Farrell: You be like just look at the results of this test. It's a free test for you, it's covered under the protocol. Just not have any compensation for the-

Buyer: But we could absorb that? So that that's not on you.

PP Farrell: Mhm.

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PP Farrell: Because we have contracts with central labs for those tests anyway, just a matter of having a, we have a special legal fund code where it's not charged to the patient, it's not charged to her insurance, it comes to the research department's specifically, so when we do like a pap smear or whatever--

Buyer: Okay.

PP Farrell: Any of those logistics, we can work out. We've had variations on this theme before, so yeah I think that's it. I just need to get with Tram and sit down and put our heads together about what all is involved, and then probably tomorrow, or Monday, I can send you a protocol and a consent, just some general stuff in it. You know the tissue, obviously. Yes Ma'am? Oh, so I'm guessing you're not going to ship today. Yeah, I'm guessing if they haven't said yes, I wouldn't. Yeah I mean they're two hours behind us, they should have responded by now. Okay, thanks. Yeah, bye. Sorry. I knew what she was gonna ask. So, yeah, and I can get you that tomorrow or Monday. I'll have to go through and strip out all the other references to all the other specimen types and then we can put in there, whatever. Whatever, just you need to get real creative on things your clients could ask for in addition to the tissue in terms of data, other data, other types of specimens. I don't know what they would ask for, urine, the one Dr. Theiler did, she got a tube of blood while she was doing hers. I don't remember what it was for.

Buyer: Yeah, yeah it will probably happen that there will be requests for like blood samples, along with the tissue.

PP Farrell: Mhm. Yeah, we can make that work. Yep. They draw blood up there for other things, but again, if this is something that we're working into research, my staff are experienced, we all draw blood, we could work it out. Cool.

Buyer: Excellent. This has been very productive.

PP Farrell: I'm very happy to have spent the day with you. Yes, I'm very excited about this.

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Buyer: This will be mutually beneficial.

PP Farrell: Yeah!

Buyer: Financially beneficial for both of us.

PP Farrell: Did you see the fire in her face when we started talking about that bus being funded by tax dollars?

Buyer: You know what, I didn't know how she would take it if I said we're gonna be funding you. So, relax.

PP Farrell: [laughter] It's just one of those things. It just grates on you.

Buyer: It does. So tell her, they are going to be paying top dollar, we're gonna be funded so relax.

PP Farrell: Yes. And they bug me. They bug me at least weekly, do you have anything? Do you have anything? So, yes. And it's like, I can't make something appear, so. I think that's probably why I answered your e-mail faster than anyone else.

Buyer: Because you knew that they would be waiting for--

PP Farrell: Yes, if I don't answer that, and Tram CCed me on that, she's gonna be in my doorway. Saying why didn't you answer your email today Missy?

Buyer: Very good.

PP Farrell: Well great. I was happy to have met you guys. And thank you so much for lunch, it was awesome. Good way to spend an hour while we were in limbo here.

Buyer: Yes.

PP Farrell: And hopefully you won't need me, but you have my cell phone in the event that you have issues getting back.

Buyer: Yes, yes.

PP Farrell: You all take care, have a safe trip back, and we'll be back in touch with you tomorrow.