

**REGISTRATION FORM FOR AFFILIATE RESEARCH PROPOSALS**Affiliate: PPSDRC

Affiliate Contact Person(s): [REDACTED] (PPSDRC) [REDACTED] (UCSD)

Phone #: [REDACTED]

E-mail: [REDACTED]

Date of request: 02/13/12 Anticipated start date: 05/01/12 Estimated duration: 2 yearsTitle of Project: A multidimensional atlas of the human fetus: Comprehensive cellular and molecular characterization of fetal human tissues. – Amendment requestSponsor/Funding Source: NIH K AwardPrincipal Investigator(s): [REDACTED]  
[REDACTED]Is this a multi-center project involving other PPFA affiliates? NoPrimary Objective(s) of the study: To create a bank of high-quality fetal tissue samples and cell cultures, which we will be profiled using state-of-the art molecular characterization methods, as well as storing samples and cell cultures for future studies which can be used as new techniques become available; to obtain samples from normal as well as abnormal gestations.Summary of Protocol (attach separate sheet, if needed): Please See Research Plan

Are there any expected or possible side effects or risks for research subjects?

Yes \_\_\_\_\_ No X If yes, describe: \_\_\_\_\_

Will this study enroll minors (&lt; age 18 years) (See Section I-E-1 for specifics)?

Yes \_\_\_\_\_ No XHas there been **IRB review** of the project?Yes X (attach copy of IRB approval) IRB approval is pending \_\_\_\_\_

The IRB has determined that this research is exempt \_\_\_\_\_ (attach letter from IRB stating exemption, see Section I-E-1)

Is there an **Informed Consent Document** for this project?

**Registration Form**

I-E-2a

Revised June 2007

Yes   X   (attach copy of IRB approved consent) Pending        No        (if no, provide documentation that either research is exempt or the IRB has waived the consent requirement)

**Do contracts for the study exist with research partners?**

Yes        No   X   Enclosed        Pending         
 If yes, does the contract(s) include **indemnification** language (sponsor indemnifies the affiliate)? Yes        No        Enclosed        Pending         
 Indemnification not available for this study       

**CHECK ALL THAT APPLY:** *(Review all the options before choosing)*

		√
<b>TYPE OF RESEARCH</b>	Corporate-sponsored: new drug, device or test	
	Corporate-sponsored: currently approved drug, device, or test	
	Medical evaluation/diagnosis/testing	
	Medical management/treatment	
	Behavioral/educational observation	
	Behavioral/educational intervention	
	Administrative procedures/processes	
	Provider training/competence	
	Other (specify) Studies on gene activity in tissues and culturing of placental cells.	√
<b>METHODS</b>	Chart review	
	Written survey/questionnaire	
	Face- to -face spoken survey/questionnaire	
	Telephone survey/questionnaire	
	Group sessions/discussions	
	Collection of specimens for patient management	
	Collection of specimens for statistical or surveillance purposes only	
	Medical interventions	
	Behavioral /educational interventions	
	Other (specify) Studies on gene activity in tissues and culturing of fetal and placental cells.	√
<b>LOCATION(S)</b>	Within affiliate facilities	√
	Within non-affiliate facilities	
	In clients/subjects homes	
	In other community settings	
<b>PERSONNEL INVOLVED</b>	Affiliate medical /clinical staff	√
	Affiliate non-clinical staff	√
	Non-affiliate medical/clinical staff	
	Non-affiliate non-clinical staff	√

<b>CLIENTS/SUBJECTS</b>	PPFA clients	√
	Non-PPFA clients	
<b>STANDARDS/ PROTOCOLS</b>	There will be no departure from PPFA or affiliate written standards and protocols	√
	There will be some departure from PPFA or affiliate written standards and protocols Note: a list of departures or deviations from the standards or protocols <b>must</b> be submitted with the registration documentation	

**Required Signatures:**

Executive Director \_\_\_\_\_

Date \_\_\_\_\_

Medical Director \_\_\_\_\_

Date \_\_\_\_\_

Thank you. Please send this form to:

PPFA - Research Department  
 434 West 33<sup>rd</sup> Street  
 New York, NY 10001