Perinatal Research Consortium (PRC)
Application for Participation

Date completed: ___/____/____

Name of Institution:

_____

Principal Investigators (2):

_____

Instructions: Please complete every section. Use additional pages if necessary.

1. General information:

- Provide a description of the department. Please include:
  - Clinical services offered OB/GYN, MFM etc., teaching/academic institution, number of physicians, perinatal electronic data systems.

Add pages if necessary.

- Delivery Statistics Including:

Payor Mix	Percentage
Government Assisted/Medicaid	
Private Insurance	
None / self- pay	
Unknown	
Total Annual Births	
2020	
2021	
2022	

General Information	Percentage
High Risk Pregnancies	
Preterm Birth Rate	
Primary C-section Rate (Primary: low risk, vertex, term)	
Total C-Section Rate	
Patients Receiving Prenatal Care First Trimester	
Clinic Deliveries	
Private Physician Deliveries	
Patients Available for Research	

Racial Categories	Not Hispanic or Latino
American Indian/Alaska Native	
Asian	
Native Hawaiian or other Pacific Islander	
Black or African American	
White	
More than One Race	
Unknown or not reported	
Total	

Ethnicity	Percent
Hispanic/Latino	
Non-Hispanic/Latino	

2. Research Experience:

- A description of the experience of previous and ongoing research at the site should be provided. Please include:
    - The Sponsor, PI, and a summary of performance including productivity and measures of quality.
    - Information regarding publications from faculty over last 5 years.

Add pages if necessary.

3. Infrastructure:

- A description of the research infrastructure at your institution, including:
    - Please include the CV of the 2 Primary Investigators, potential co-investigators if applicable and a designated study coordinator.
    - Describe your current dedicated research staffing (i.e., study nurses, research assistants, follow-up personnel, research pharmacist, ultrasonographer, etc.)
    - Describe in detail if an institutional Clinical Research Center (CRC) is utilized for research.
    - Description of how you will identify potential study participants. Please include:
        - If you have electronic access to EMR's or if you plan to identify patients by physician office referral only or you plan to use both mechanisms.
        - The type of clinical setting screening for patients will take place (i.e., clinic and/or private OBGYN offices, MFM offices, etc).

Add pages if necessary.

- Equipment – must have (or have access to) the equipment necessary to conduct research protocols.
    - Please complete the table below.
    - Please list other resources available if applicable.

Equipment Available for Research	**Check if Available for Use for Research**
20º freezer	
-80º freezer	
Refrigerated Centrifuge	
Centrifuge	
Dry Ice	
Scale	
BP device	
Exam Table	
IATA Training/Certification	

Other resources:

- Description of pharmacy services available for research.
    - Include if your site has access to a Research Pharmacy/Pharmacist.

Add pages if necessary.

- Description of Available Space.
    - Please include if your site has space for research staff including supplies/research charts and dedicated space to see research patients for study visits.

Add pages if necessary.

4. Data Management:

- Plans for data handling (collection, data entry, storage). Please include:
  - Your experience with collecting data and source documents, case report form (CRF) completion following Good Clinical Practice (GCP), experience with electronic data capture and storing/organization of study charts.

Add pages if necessary.

- Plans for quality assurance. Please include:
  - Internal quality assurance measures for following the study protocol including but not limited to; bio specimen collection/processing/shipping, study visit completion, chart abstraction and data entry.

Add pages if necessary.

5. Other Administrative Items:

- Name/contact information of IRB used by your facility:

  _____

  _____

- Does your IRB allow the use of a centralized IRB? Yes

  _____

- Does your institution have a Federal Wide Assurance for the Protection of Human Subjects (FWA)? If so, please provide number

  _____

- Please provide description of administrative infrastructure available to support research (at a department and institutional level)

Add pages if necessary.

- Is there a negotiated indirect cost rate with the federal government? Yes
  If so, please provide a copy of the current agreement
- Please provide the indirect cost rate used for industry sponsored studies _____and any administrative start-up charges. _____
- Please include a letter of support from Institutional Leadership/Chair of the Department including confirmation that the institution is committed to paying the current annual participation fee of $23,300.

Checklist for Response to Questions:

☐ CV's for both PI's (2)

☐ CV for Study Coordinator

☐ Federal Indirect Cost Rate Agreement (if applicable; if this is not applicable, please state this in your application

☐ Letter of Support from Department Chair

Questions:
Contact Stephanie Emmi RN, BSN, CCRC
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