Data and/or Specimen Analysis ONLY Protocol Template – Placenta Immune

1. **PROTOCOL TITLE:** Determinants of immune response in the placenta

2. **VERSION DATE:** March 20, 2023
3. **Northwestern University or affiliate RESEARCH TEAM**

PRINCIPAL INVESTIGATOR:
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4. FEDERAL FUNDING:

(Complete the following matrix if this study will be supported by federal funds. Add additional matrices for each unique funding source. Remove this section if the study will not be supported by federal funds. Reminder: This information must match the information you provide on the funding page of the eIRB+ application.)

Funding Agency:	None	
Sponsored Research ID#:		
Does the grant indicate that covered activities will include Human Research? (Yes / No / Unknown)		
	Institution Name:	Human Research Assessment *** (e.g., Non-Exempt Human Research, Exempt Human Research, Not Human Research, etc.)
Prime Award Recipient*		
Sub-Award Recipients**		

* The prime award recipient is always engaged in Human Research and must have IRB oversight when one or more sub-award recipients conduct non-exempt Human Research. *Many federal agencies require that when more than one domestic site engages in non-exempt Human Research, all sites must rely on the review of one "Single IRB." If this applies to your study, you must obtain a Single IRB Letter of Support and IRB Fee Quote from the Northwestern University IRB Office before the Northwestern University IRB will review your study. Submit a Single IRB Consultation Request to initiate this process.*

***Include the activities of all non-Northwestern affiliated sites in the multi-site/collaborative research section of the protocol below.*

****The federal funding application should include plans for whether award recipients will engage in Human Research. Based on the funding application, provide an assessment of the activities at each site and update the table if the planned activities change or if another IRB reviews the activities and makes a different determination.*

5. STUDY PURPOSE:

The placenta is the first organ to form during human development and takes on roles of oxygen and nutrient uptake, protection from the elements, endocrine, and immune tolerance while the fetal organs are forming. Inflammation of the placenta, either acute or chronic, are associated with adverse pregnancy outcomes including preterm birth, chorioamnionitis, neonatal sepsis, growth restriction, and intrauterine fetal demise.

This study will use archived placental specimens existing within the department of pathology to characterize the immune cells and mediators present in the placenta in health and disease. The intended audience are placenta researchers, though insights could be useful to obstetricians and neonatologists.

6. INCLUSION/EXCLUSION CRITERIA

Inclusion criteria:

- Placenta examined at northwestern memorial hospital 1/1/2011-12/31/2022
- Delivery at or after 24.0 week viability threshold
- Archived tissue blocks available
- Patients may identify as men or women
- Age 18+

Exclusion criteria:

- Prisoners
- Children
- Non-viable pregnancies / neonates

7. PROCEDURES INVOLVED

Study type: Indicate if this study is 1) retrospective; 2) prospective; or 3) BOTH retrospective and prospective.

NOTE: if you plan to collect biospecimens prospectively solely for research purposes as part of this study (e.g., through biopsies), then you cannot use this template.

☒ **Retrospective Review** (the data and/or specimens already exist at the time this study is submitted for initial IRB review)

Date Range of data/specimens to be reviewed: 1/1/2011-12/31/2022

☐ **Prospective Review** (the data and/or specimens do not exist when this study is submitted to the IRB for initial review – for specimens, you can use this template only if the specimens are being collected for non-research purposes such as medical treatment/diagnosis)

☐ **BOTH Retrospective and Prospective Review**
Date Range of data/specimens to be reviewed:

8. **CHARACTERISTICS OF DATA/SPECIMENS TO BE ANALYZED**

Specimens were originally collected by the department of pathology at Northwestern. We will be analyzing archived slides and tissue blocks approximately 1000 pathology specimens obtained during the course of routine clinical practice within the pathology department. Slides will be linked to diagnoses and a combination of demographic information including age, gender, ethnicity, and race, treatment information, and clinical outcomes including:

1. Patient demographics (age, gender, ethnicity, race)
2. Co-morbidities, medical & surgical history, social and family history
3. General quality of health assessment and histories
4. Results of physical exams or other standard medical procedures
5. Procedure notes, operation notes, history & physical and delivery notes
6. Medical imaging/radiographic reports (radiographs, fluoroscopic exams, MRI/PET/CT scan results)
7. Lab test results

These specimens have been collected as part of standard clinical operations at Northwestern.

Dr. Goldstein works with pathology specimens in the course of carrying out his clinical work responsibilities as a pathologist. The following identifiers will be used in linking data prior to deidentification and *removed* in the data that will be analyzed.

PHI ELEMENTS:

8. Medical record numbers
18. Any other unique identifying number, characteristic, or code. Specifically: pathology accession numbers

Deidentification will be performed by Dr. Goldstein.

A key linking coded identifiers (ACC, MRN) to research identifiers will be stored in a REDCap database managed by the Feinberg School of Medicine. Coded identifier lists will be deleted 10 years after their most recent update. Deletions will be performed using REDCap's Deleting Individual Forms for Records function.

Fully de-identified clinical data and slides will be shared with external collaborators under a Data Use Agreement and Material Transfer Agreement as appropriate. Genetic testing will not be performed. This will be included as a condition for material transfer.

9. ACCESS, SECURITY, AND MANAGEMENT

- Patient data will be stored on a REDCap database managed by the Feinberg School of Medicine.
- Physical specimens will be stored in the PI's locked, access controlled office or lab.
- De-identified data will be retained by Study ID# to satisfy study reproducibility requirements (PHI will be separately maintained on the Coded Identifier List). Retained data will also be stored on FSMRESFILES.
- Data will be retained for 10 years after the closure of the study on FSMRESFILES. This data will be retained to ensure reproducibility of studies, and to evaluate future developments.

10. POTENTIAL RISKS

The risk in this study is disclosure of placental diagnoses. The probability of this risk is minimal since only coded identifiers are stored, the data to be analyzed will be stored in a deidentified format, and the key contains only a coded identifier and will only be accessible to the study PIs.

11. POTENTIAL BENEFITS OF THIS PROJECT

This project has the potential to inform the mechanism of many of the most common and severe adverse pregnancy outcomes. That information could be used in future studies to develop diagnostic tools or treatments to predict, prevent, or counter the problesm.

12. INFORMED CONSENT AND WAIVER OF CONSENT

We request a waiver of informed consent for this research with the following reasons:

-Minimal risk to subjects – the primary risk in this study is a breach of PHI resulting in disclosure of placental diagnoses. This risk is minimal since only coded identifiers (MRN, ACC) will be stored in a protected database managed by Feinberg School of Medicine. This study will also not impact the process of sample collection, including whether or

not a specimen is acquired, the amount of tissue or sample acquired, or the procedures used to acquire these tissues.

-A waiver will not adversely affect the rights and welfare of individuals we are studying – this analysis is being performed on specimens that are collected through standard clinical operations.

- This research cannot practicably be carried out without a waiver of consent due to the challenges of recontacting patients

-This research involves secondary analysis of specimens collected through normal clinical operations and not solely for research purposes

13. HIPAA AUTHORIZATION AND WAIVER OF AUTHORIZATION

We request a HIPAA authorization waiver for the following reasons:

-The risk to privacy is minimal. Coded identifiers will be stored in a secure REDCap database managed by Feinberg with access limited to authorized study staff. Coded identifiers will be retained but are required to avoid duplication of research identifiers for multiple specimens from a single individual. These identifiers will only be used for correct assignment of research identifiers.

-The research cannot be conducted without this waiver, or without access to these identifiers, as we would not be able to identify the specimens or to correctly assign research identifiers.

The protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information for which an authorization or opportunity to agree or object is not required by 45 CFR 164.512.