

IRB Determinations

Brownbag Session April 2026

OBGYN Research

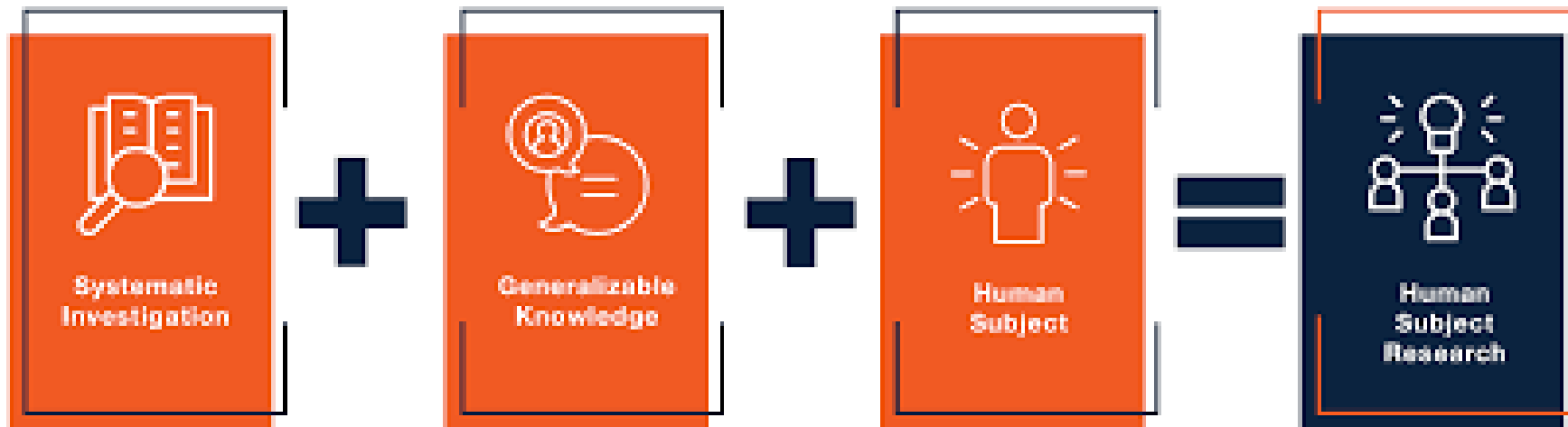
Agenda

- **IRB Determination Overview**
 - Categories of research
- **Determination of Human Research Form**
- **Human Subjects Research**
 - FHR
 - PARTO
- **Clinical Trial Research**
 - VEDA
- **Practice Cases & Poll Questions**
- **Next Steps: IRB Submission**

IRB Determination Code of Federal Regulations



- [45 CFR 46.102\(l\)](#) **Research:** *means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities.*



45 CFR 46.102(l) Research...For purposes of this part the following activities are **deemed not to be research**:

- 45 CFR 46.102(l)(1) **Scholarly and journalistic activities**
- 45 CFR 46.102(l)(2) **Public health surveillance activities**
- 45 CFR 46.102(l)(3) **Collection and analysis of information, biospecimens or records by/for criminal justice agency**
- 45 CFR 46.102(l)(4) **Authorized operational activities**

- [45 CFR 46.102\(b\)](#) **Clinical Trial:** Means a research study in which **one or more human subjects are prospectively assigned to one or more interventions** (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.
- [45 CFR 46.102\(e\)\(1\)](#) **Human Subjects:** means a living individual about whom an investigator (whether professional or student) conducting research:
 - [45 CFR 46.102\(e\)\(1\)\(i\)](#) **Obtains information or biospecimens through intervention or interaction**
 - [45 CFR 46.102\(e\)\(1\)\(ii\)](#) **Obtains, uses, studies, analyzes, or generate identifiable private information or identifiable biospecimens.**

- [45 CFR 46.102\(e\)\(2\)](#) **Intervention**: includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.
- [45 CFR 46.102\(e\)\(3\)](#) **Interaction**: includes communication or interpersonal contact between investigator and subject
- [45 CFR 46.102\(e\)\(4\)](#) **Private Information**: includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record)
- [45 CFR 46.102\(e\)\(5\)](#) **Identifiable private information** is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.
- [45 CFR 46.102\(e\)\(6\)](#) **Identifiable biospecimen**: is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

Determination of Human Research Form

Determination of Human Research

From the HSPP website...

- IRB Protocol for Determination of Human Research v2025-09
 - Use this form when it's unclear if the proposed activities require IRB review. This form is required if the project involves any of the following, and it is unclear whether the project requires IRB approval:
 - Access to an electronic medical record
 - Use or disclosure of Protected Health Information (PHI)
 - Requests for data or specimens from the Banner Clinical Research Data Warehouse (CRDW)
 - Projects supported by federal funds involving people
 - Projects involving the use of a test article in a human or generating data intended to support an application to the FDA
 - IRB certification for access to materials from dbGaP
 - Projects involving Native American/Alaskan Native or international Indigenous populations

Let's look at the Determination of Human Research Form!

Section 2 on the DHR form

1. Does the proposed activity involve a **systematic** approach?

☐ Yes

☐ No

----- 2. Is the intent of the proposed activity to **develop or contribute to generalizable**
knowledge?

☐ Yes

☐ No

If Yes to BOTH questions the study is Research. Proceed to Section 3.0: *Determination of "Human Subject"*.

If the answers to one or both questions are NO, skip Section 3.0 and proceed to Section 4.0: *Determination of "Human Subjects" per FDA Regulations*.

Let's look at the Determination of Human Research Form!

Section 2 on the DHR form

1. Does the study

☐ Yes

2. Is the study

known

☐ Yes

If Yes to

"Human

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45 CFR 46.102(l): Research - a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

A **systematic** approach involves a predetermined system, method, or a plan for studying a specific topic, answering a specific question, testing a specific hypothesis, or developing theory. A systematic approach includes the collection of information and/or biospecimens and analysis either quantitative or qualitative.

Activities **designed to develop or contribute to generalizable knowledge** are those activities designed to draw general conclusions, inform policy, or generalize outcomes beyond the specific group, entity, or institution (i.e., to elaborate, to be an important factor in identifying or expanding truths, facts, information that are universally applicable).

Let's look at the Determination of Human Research Form!

Section 3 of DHR Form

1. Does the activity involve obtaining information about living individuals through **intervention** or **interaction** with the individuals?
☐ Yes ☐ No
2. Does the activity involve obtaining **identifiable** and **private information** about living individuals?
☐ Yes ☐ No

If YES to either question, the research activity is research that involves human subjects. STOP and submit the [IRB Protocol for Human Subjects Research](#).

If the answers to both questions are NO, proceed to Section 4.0: *Determination of "Human Subjects" per FDA Regulations*.

Let's look at the Determination of Human Research Form!

Section 3 of DHR Form

1. Does the research involve **intervention**?

☐ Yes

2. Does the research involve **interaction** with the individual?

☐ Yes

If YES to either question, you must complete the form and submit to the IRB.

If the answer to both questions is "No," you do not need to complete the form.

45 CFR 46.102(e): Human subject - a living individual about whom an investigator (whether faculty, student, or staff) conducting research: (1) obtains information or biospecimens through **intervention** or **interaction** with the individual; and uses, studies, or analyzes the information or biospecimens; or (2) Obtains, uses, studies, analyzes, or generates **identifiable** private information or identifiable biospecimens.

Intervention includes both physical procedures by which information is gathered and manipulations of the subject or the subject's environment that are performed for research purposes.

Interaction includes communication or interpersonal contact between investigator and subject.

Identifiable is where the identity of the subject is or may be ascertained by the researcher or will be associated with the information. The research could involve the use of coded data/specimens.

Private Information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record).

Examples of Human Research

Let's look at a few study examples from our team!

Human Subjects: Fetal Heart Rate (FHR) Study

Information/Biospecimens Obtained:

- **Patient demographics**
- NST routine recording
- Acoustic fiber recording

NST recording would be matched up to the **interventional** acoustic fiber recording to test its accuracy in detecting fetal heart rate.

- Study in collaboration with MIT Department of Material Science and Engineering to test novel acoustic fibers developed to **detect fetal heart rate non-invasively** during a women's pregnancy
- Goal of this study is to **increase fetal monitoring from outside of hospital or clinic setting for high-risk pregnancies**
 - Decreasing fetal distress incidence and fetal mortality in utero
 - Increasing medical accessibility for patient populations with limited resources or opportunity to present for routine check ups

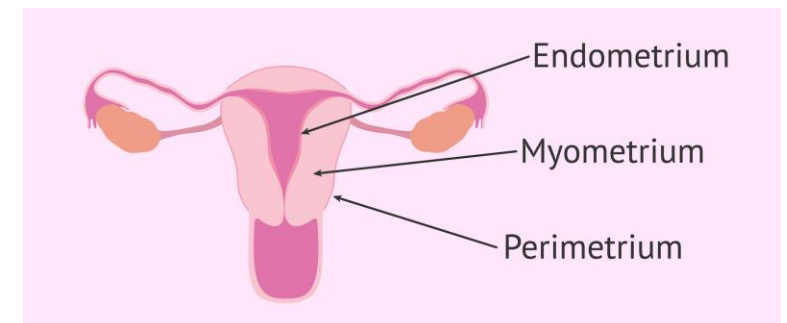


Human Subjects Research: Predicting Adequate Response To Oxytocin (PARTO) Study

Information/Biospecimens Obtained:

- **patient's medical, surgical, social history**
- **demographics**
- Pregnancy complications and medications
- Saliva and buccal swabs in Obstetric Triage
- Myometrium sample during Cesarean Section delivery

- NIH funded study studying genetic and epigenetic factors of **postpartum hemorrhage (PPH)** in response to antepartum Oxytocin medications
- **PPH** is defined as blood loss with hypovolemia or accumulation of >1000 mL blood loss within 24 hours after birth
 - Accounts for 25-60% of maternal deaths worldwide.



Examples of Clinical Trials

Clinical Trial: Vaginal Estrogen vs DHEA (VEDA) Study

Information/Biospecimens Obtained:

- **Patient demographics**
- Vaginal pH
- Vaginal swab
- Urine self-collection
- FSFI survey (sexual function)

- Randomized control trial where patients are randomized to receive Vaginal Estrogen cream or DHEA
- Unique notes about clinical trials:
 - Registered separately by clinicaltrials.gov
 - Usually require a lot more appendices for submission
 - Adverse events documentation require much more consideration

Let's Practice!

POLL QUESTIONS!

Let's Practice!

ACEs & Endo Study

- A fellow has proposed a project to you involving gathering data on patients undergoing surgery for endometriosis removal regarding their Adverse Childhood Experiences scores.
 - Her proposal includes surveys given to patients in pre-op to collect ACE scores as well as 2 pain perception surveys.
 - Additionally, she would like to pull data from a patient's chart to gather data on demographics, surgery history, medical history, social support, pregnancy history, and other relevant factors
 - Her goal is to determine if there is a link between Adverse Childhood Experiences and surgery outcomes/perception of pain in patients with endometriosis.
 - Her surveys are free to distribute as they are already developed and utilized by Banner. The coordinators she is recruiting to help her are paid by the department, not specific to this study.

POLL QUESTIONS!

Let's Practice!

IVF Success Study

- A resident has proposed a project to you involving gathering data on IVF success rates between two different procedure types at our clinic.
 - Her proposal includes a data pull from the clinic database on IVF procedure and birth outcome.
 - For this primary project she does not need any demographic data or past surgical history but may need it for a future project dependent on demographic.
 - Her goal is to determine if we can recommend a practice change at our clinic based on the success rates we've seen from our providers.
 - Her data pull request is going through Banner servers. The coordinators she is recruiting to help her are paid by the department, not specific to this study.

POLL QUESTIONS!

Next steps for DHR Form

Next steps on the DHR form

- There are several parts of the form to fill out if any answers are no to Question 2
 - Section 4.0 Determination of "Human Subject" per FDA Regulations
 - Section 5.0 Coded private information and/or human biological specimens per OHRP
 - Section 6.0 Other Activities
 - Select which type of study this is: Case Reports, Quality Improvement Project, Public Use Datasets, Preparatory to Research, etc.
 - Section 7.0 Summary of Activities
 - Section 8.0 Privacy and Confidentiality of Data
 - Specifically for Banner

Next steps for IRB Submission

What's next for IRB submission

- Gather your documents!
 - Preparation for your submission should include:
 - DHR Form
 - Protocol
 - ICF/Recruitment materials
 - Data Collection Tools: surveys, etc.
 - Waivers (If applicable)
 - Funding Support documents (If applicable)
 - Additional Appendices (If applicable)



What's next for IRB submission

- Often forgotten docs
 - Ancillary approvals
 - Pharmacy
 - Nursing
 - Pregnant/fetus waivers/assents
 - Language certificates of translation
 - Feasibility documents

