

NAVIGATING IRB REVIEW FOR YOUR FINAL PROJECT

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AGENDA: Do you need IRB review, and if so what's it look like?

1. **Qualifying for IRB Review:** discuss **whether you need IRB review at all** based on whether you meet or fall outside the definition of “human subjects research”
2. **Level of Review You'll Receive:** discuss the two **likely types of determinations** the IRB will make on the capstone (either “exempt” from review or “expedited” review), and **what each means** for you
3. **If You're Working with Another University:** review what types of research **may need an agreement** with another institution, and how to obtain one

**PART I: DOES MY PROJECT EVEN
QUALIFY FOR IRB REVIEW?**

QUALIFYING FOR REVIEW: The **IRB** reviews human subjects research, but *only* **human subjects research**.

Must meet **both** of the following criteria to require IRB review:

“Human”

*A living individual about whom the investigator obtains data through intervention, **interaction**, or **identifiable** private information*



“Research”

*Systematic **investigation** of materials & sources to establish facts/**reach new conclusions** to contribute to **generalizable knowledge***

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Consider **whether your research meets the definition**, but also recognize that there are **gray areas for both**:



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working with de-identified or publicly available dataset

Human Subjects:

contacting subjects for surveys or interviews



Certain Social Media Uses: online ethnography of an isolated but searchable group on Facebook

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If you fall into this gray area:

- Complete the **Human Subjects Research Determination Form** at <https://irb.upenn.edu/initial>
- Send it to the **analyst team** in our directory and they will help you

QUALIFYING FOR REVIEW:

If you do need IRB review, apply via the **HS-ERA portal**.

- Log on to the portal via the IRB homepage: www.irb.upenn.edu
- **HS-ERA: Penn-specific platform that links researchers to all the committees on campus that might need to approve their study**
- **BONUS TIP:** click the “How to Submit” tab for **step-by-step instructions** on how to complete each type of application

Click Here to Access HSERA

UNIVERSITY of PENNSYLVANIA
HS-ERA
Human Subjects Electronic Research Application

Welcome to the IRB Homepage. Please note that the news bulletin posted here is always the most recent, but there are more news items on the **News page that may be important to you.**

Feb. 6, 2018 - Updated Letter Templates

In alignment with last year's release of the Reliance Agreement letter template with no IRB administrator signature, the IRB has new letter templates for the following determinations:

- Initial Exempt Approval
- Initial Expedited Approval
- Expedited Continuing Review
- Expedited Modification Approval
- Modification Acknowledgement

The new templates are being rolled out this week and will not require an IRB administrator signature.

The IRB SOP section GA 107 describes the written communications which will still require IRB Director, Chair or Executive chair signature. Those situations that require signature are unrelated to routine determination letters which have historically required Administrator level signature.

FOR IRB REVIEW: Welcome to the homepage! Click “Create” to begin.



The screenshot shows the HSERA (Human Subjects Electronic Research Application) homepage for the University of Pennsylvania. The page features a dark blue sidebar on the left with the Penn logo and the text "IRB Submission". The main content area is white and includes a header with "Help" and "Log out" links, the HSERA logo, and a main heading "My IRB Submissions and CTRC Request Home Page". Below this, there are sections for "My Submissions", "My Requests", "My Work In Progress", and "HSERA News". A callout box with a yellow border and arrow points to the "Create" link in the "My submissions" menu.

Help Log out

 Penn
UNIVERSITY of PENNSYLVANIA

IRB Submission

Welcome
BOGIA, MEGAN L

▼ My submissions
• Create
• Manage drafts
• Items to be resubmitted

▼ Submissions history
• Recent
• All

▼ My submission approvals
• View pending
• View history
• View assigned

▼ My CTRC requests
• Create
• Manage drafts

▼ Request history
• Recent
• All

▼ My CTRC approvals
• View pending
• View history

UNIVERSITY of PENNSYLVANIA
HSERA
Human Subjects Electronic Research Application

My IRB Submissions and CTRC Request Home Page

My Submissions
1 Recent Submission(s) (0 Under Dept. Review, 1 Under ORA Review)

My Requests
No requests within the last 90 days.

My Work In Progress
1 Submissions to be completed (0 Modification, 0 Continuing Review, 1 Initial Review, 0 Reportable Event)
✔ No draft CTRC requests at this time.

HSERA News
August 11, 2017
The IRB office is moving to a new location on August 11, 2017.
The new address will be near the Penn Vet School at:

**PART II: SO I NEED IRB REVIEW...
WHAT DO I NEED TO DO NEXT?**

TYPES OF REVIEW: First, submit your initial application, & the IRB will **likely** make **one of two determinations:**

After Your First Application, the IRB will Determine your Study to be...

Exempt from Further Review:

No further submissions to the IRB are required

Require Expedited Review

Submissions to the IRB to change the study, plus annual review, are needed

TYPES OF REVIEW: The IRB makes this determination by level of risk & by categories outlined in current legislation:

Example Traits of Exempt Studies

- Collecting non-sensitive information that can't be traced back to subjects
- Use of a limited dataset (de-identified with indirect identifiers, like dates or zip codes)
- Surveying or interviewing people on public behavior without identifiers or use of them to search data

Example Traits of Expedited Studies

- Collecting sensitive information or information that can be traced to subjects
- Use of an identifiable dataset that links subjects with other direct identifiers
- Surveying or interviewing on either sensitive behaviors or maintaining their identifiers

TYPES OF REVIEW: Even if you do need to submit though, it's a **straightforward** process!

Protocol Submission Type - Choose

Activities that Do Not Meet the Regulatory Definition of Human Research
The first question one should consider when assessing the requirement for IRB review is whether the activity meets the regulatory definition of human research. Anyone unsure about IRB review requirements and whether their proposed activity constitutes "human research" requiring IRB review should contact the Office of Regulatory Affairs. The IRB staff will determine if the activity is human research. If an activity does not meet the regulatory definition of human research, the IRB will, upon request, issue a letter stating that the project does not require IRB review or approval. Refer to the IRB Guidance: Is IRB Review Required?

Initial Review
Research must be reviewed by a convened meeting of the IRB unless the research is [exempt or is eligible for expedited review](#). Final review category and submission requirements will be determined by the IRB.

Continuing Review
Continuing Review for convened board or expedited review
The IRB Application for Continuing Review must be submitted no later than six weeks prior to the expiration date for full board review and no later than two weeks for expedited review.

Modification
Modification of approved or existing protocol
Changes in approved research, during the period for which approval has already been given, may not be initiated without prior IRB review (or expedited review, where appropriate) and approval except where necessary to eliminate apparent immediate hazards to human subjects.

Deviation
Deviations from the approved or existing protocol
An unintentional action or process that departs from the IRB approved study protocol and identified retrospectively, after the event occurred. If the impact on the protocol disrupts the study design or compromises the safety and welfare of the subjects, the deviation must be reported to the IRB within 10 business days.

Exception
Exception Requests from the approved or existing protocol
A one time, intentional action or process that departs from the IRB approved study protocol, intended for one occurrence. If the action disrupts the study progress, such that the study design and results would be compromised, and the action compromises the safety and welfare of study subjects, prior documented IRB approval is required.

Reportable Event
Reportable Event posing risks to subjects or others including adverse events
The IRB requires reporting of events that are: (1) unforeseen and (2) indicate that participants or others are at increased risk of harm. If yes to both, the problem is considered a Reportable Event involving risks to participants or others.

Click either “Continuing Review” or “Modification” to submit in HS-ERA

Remember: Be sure to check that “How to Submit” tab for the associated application form & tips on how to compose an application

TYPES OF REVIEW: Overall, the **key** is to remember **these three** important **takeaways**:

Consider exactly what you need to conduct your capstone
(e.g. storage of identifiers, etc.)

Only the IRB has to make the determination for level of review

Don't compromise the research you want to do just for the review level

PART III:
I'M WORKING WITH ANOTHER UNIVERSITY.
DO I NEED TO DO ANYTHING ELSE?

WORKING ELSEWHERE: Determining whether you need a reliance agreement first depending on your review level:

If Your Study is **Exempt:**
You're almost set.

You will need confirmation from the other university's IRB that they agree it's exempt.

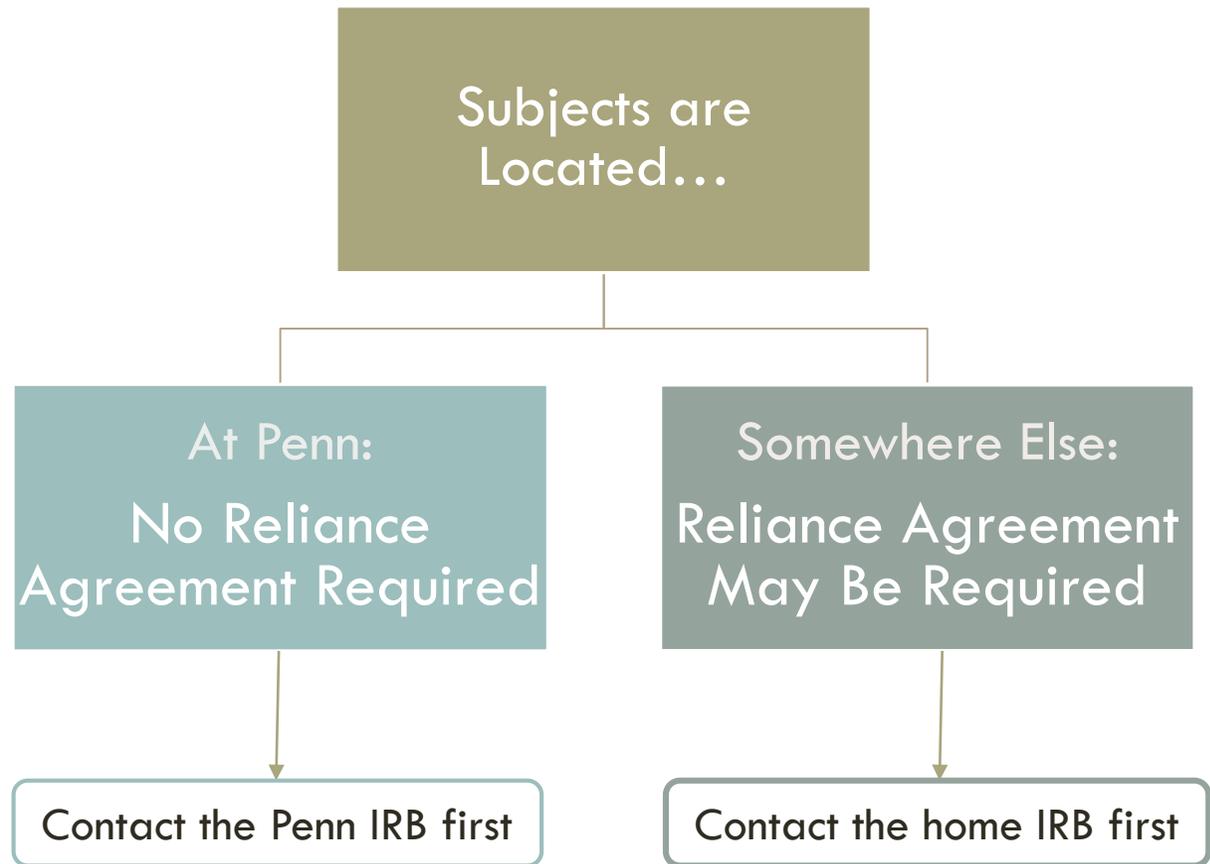


If Your Study is **Expedited:**
You need a couple more questions...

Since further review is needed, you will need to confirm if you need a reliance agreement.



WORKING ELSEWHERE: From there, it depends largely on where the subjects involved in research are located:



REVIEW: Do you need IRB review, and if so what's it look like?

1. **Qualifying for IRB Review:** determination of **whether you need IRB review at all** based on whether you meet or fall outside the definition of “human subjects research”
2. **Level of Review You'll Receive:** there exist the two **likely types of determinations** the IRB will make on the capstone (either “exempt” from review or “expedited” review), and **the subsequent requirements vary** based on this decision
3. **If You're Working with Another University:** expedited research **may need an agreement** with another institution if not working with Penn subjects