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***

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

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

Not 'Research:'

only submitting it for class with no publication

Research:

submitting study for publication

QI Projects: research that seeks to improve internal department but also publish

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Not 'Human Subjects:'

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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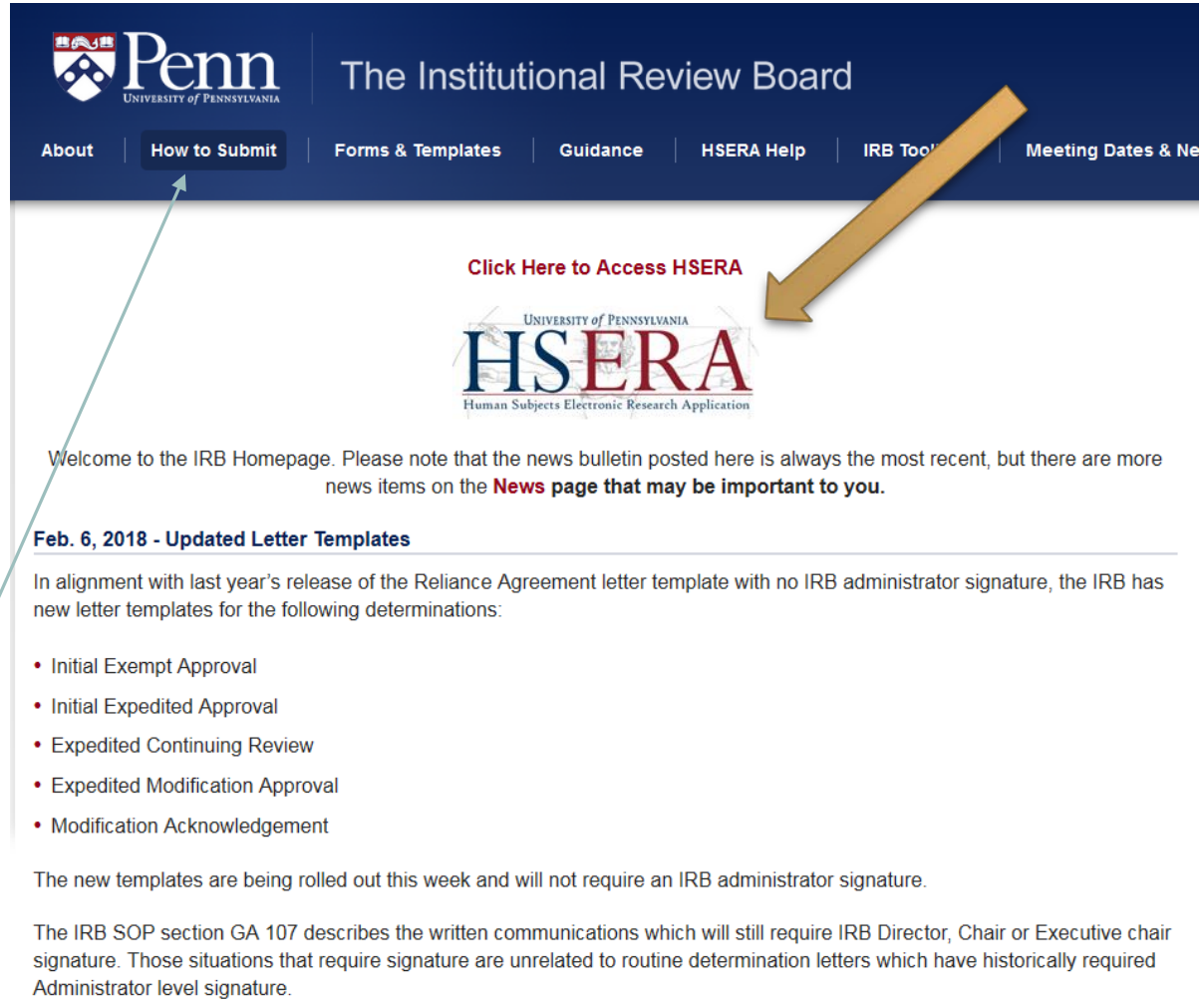
If you fall into this gray area:

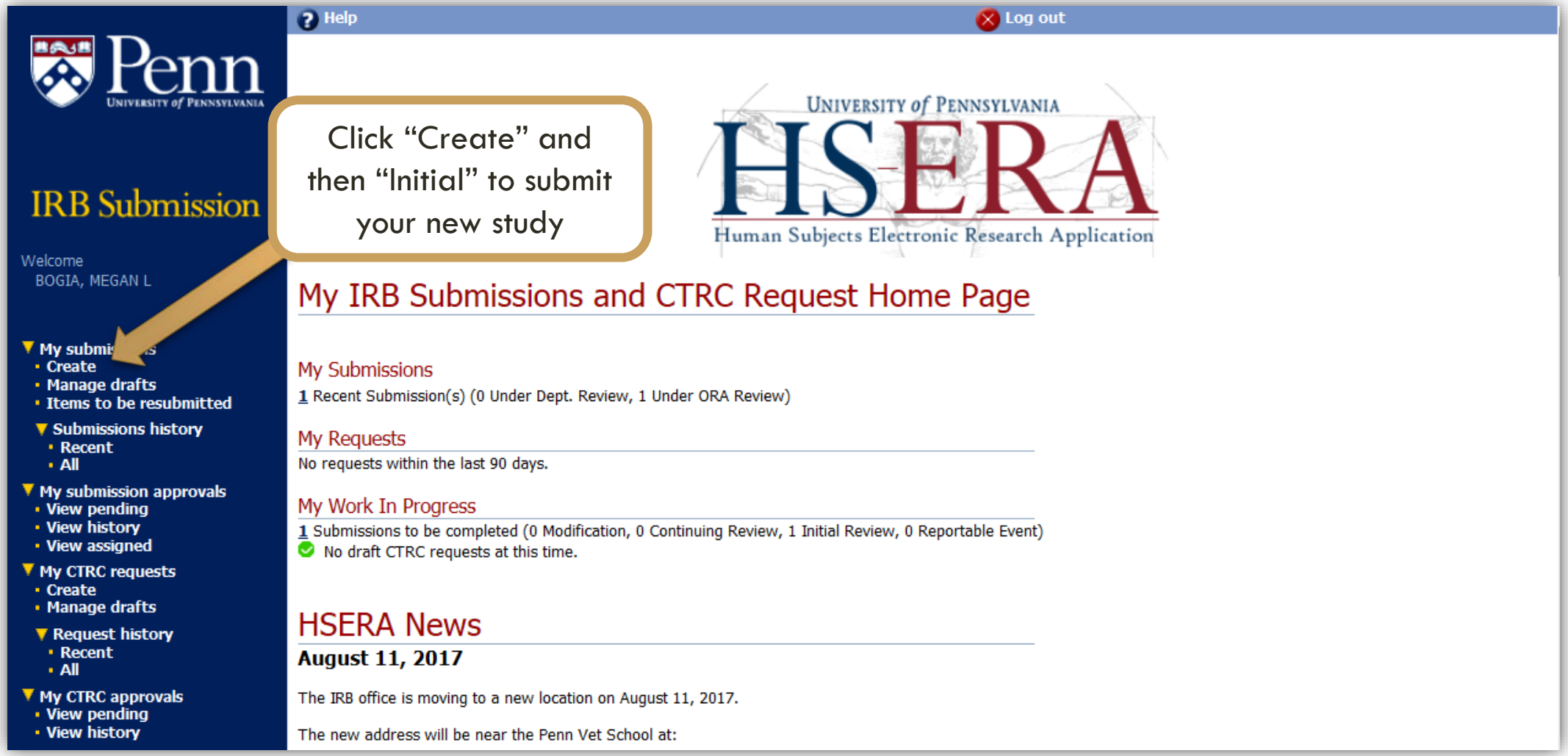
- Complete **the Human Subjects Research Determination Form** at https://irb.upenn.edu/initial
- Send it to the **analyst team** in our directory and they will help you

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



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



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:

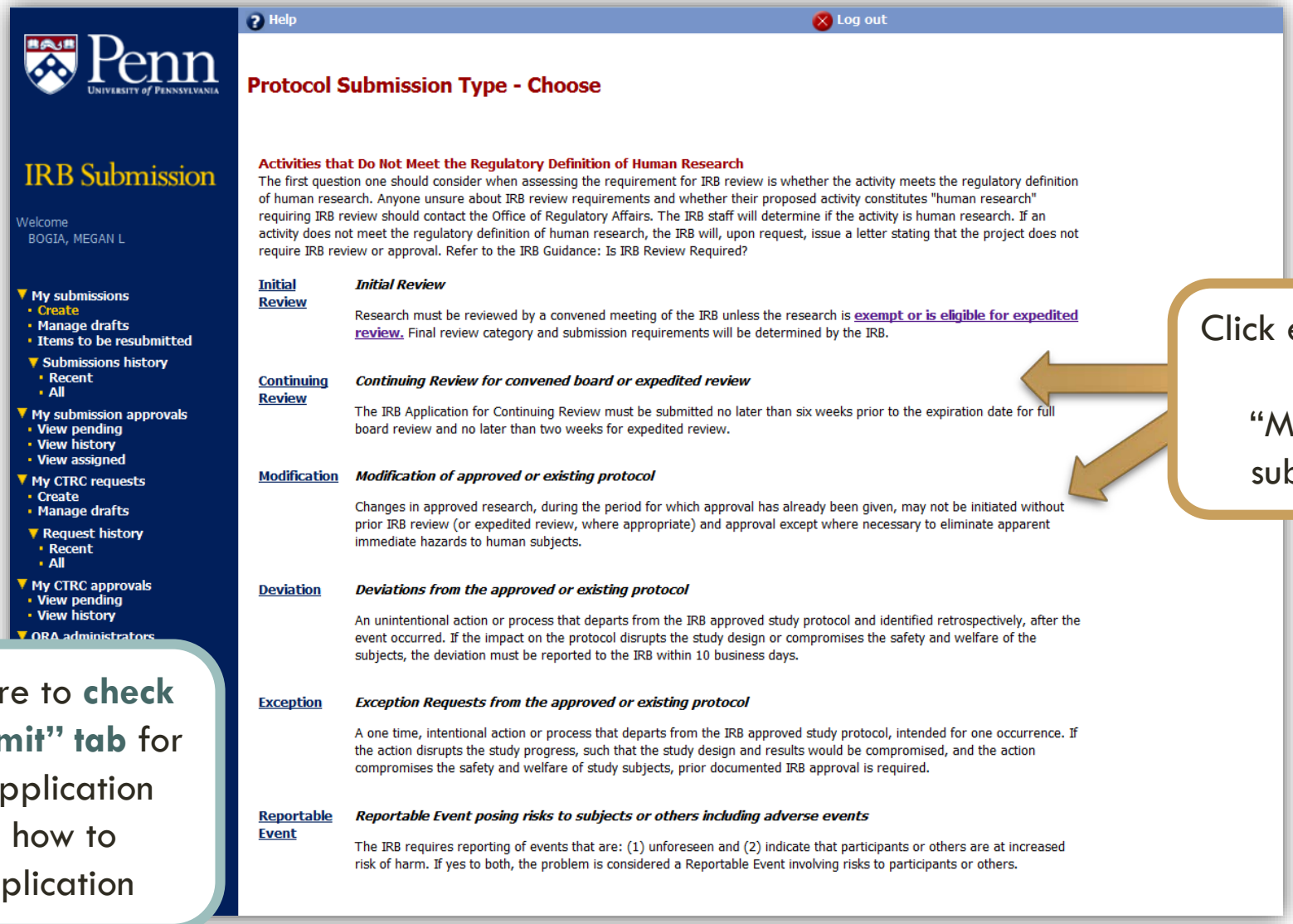
Example Traits of Exempt Studies

- 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!



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.

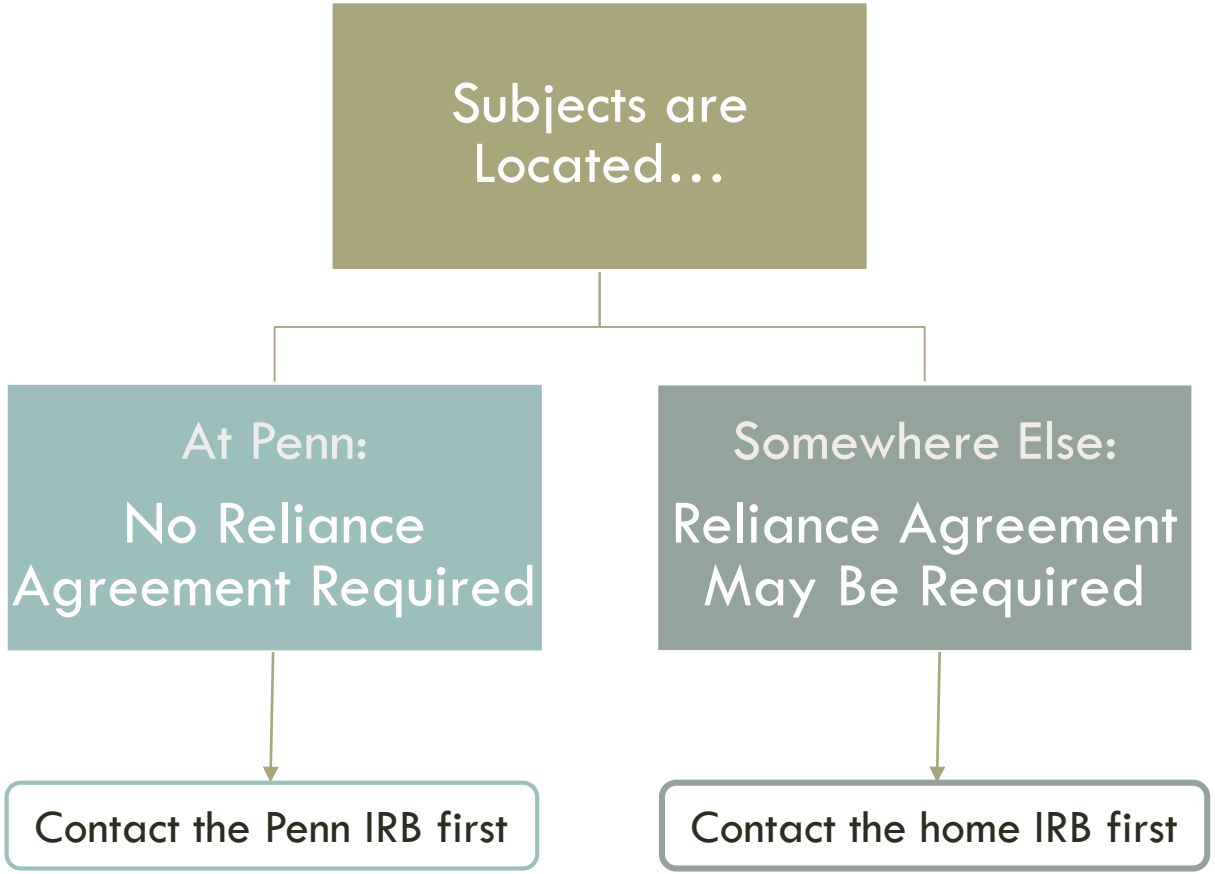
You will need confirmation from the other university's IRB that they agree it's exempt.

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