

Intro to Human Subjects Research

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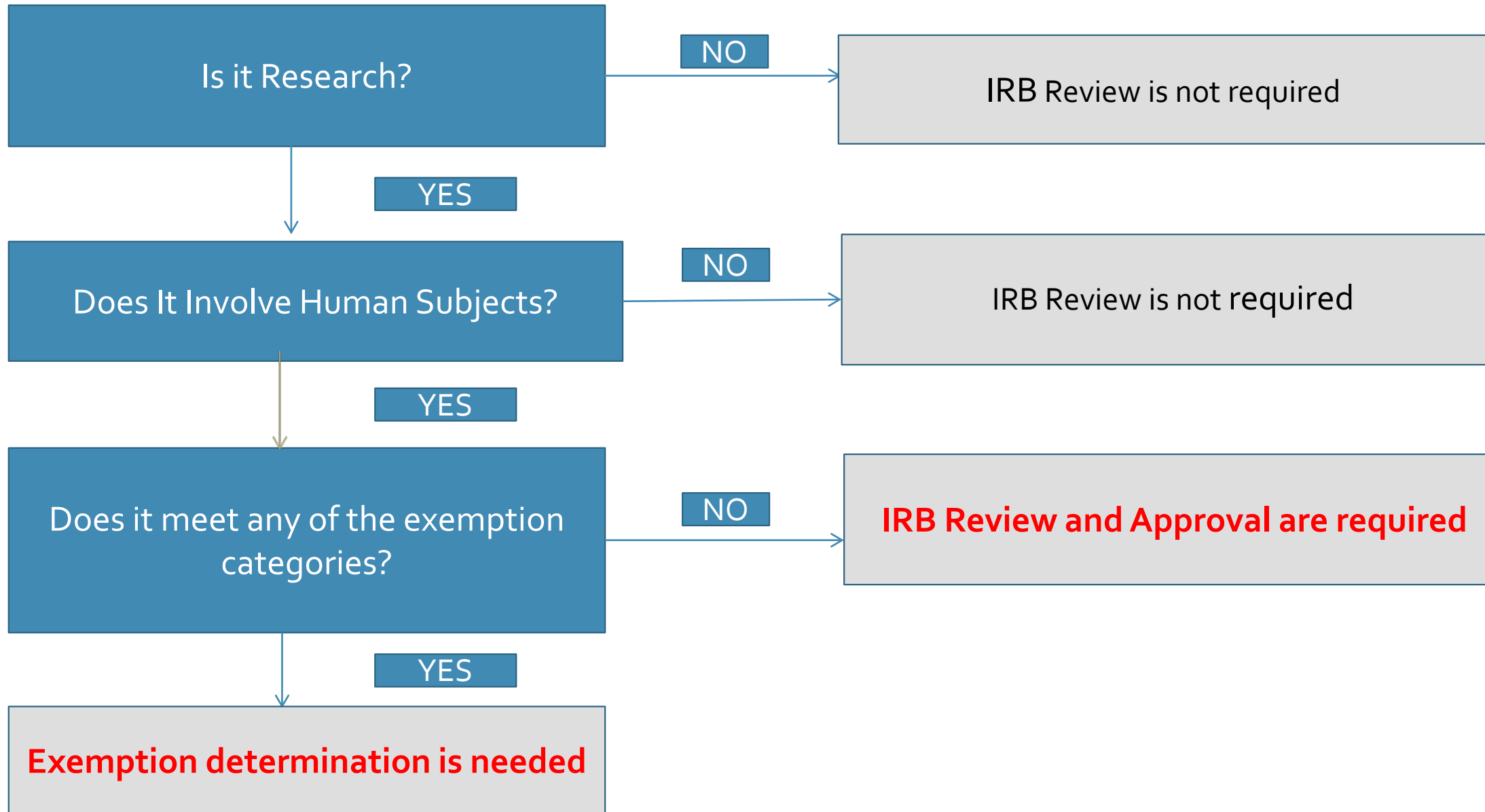
Human Subjects Committee (HSC)/Human Investigation Committee (HIC) III

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Learning Objectives

- **WHEN** do I need to submit my project for IRB review?
- **WHAT** documents will be required?
- **WHERE** do I submit the documents?
- **HOW** do I make changes to an approved study?
- What if something goes wrong once I start the study?
- What should I do when I am done with the study?
- Where do I get help?

IRB Decision Tree



Research

45CFR46.102(d)

Is My Project/Study “Research”?

- *Research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.



Examples Of Projects/Studies Not Considered “Research”

Quality Improvement (QI) and Quality Assurance (QA) projects are designed to improve clinical care, patient safety, health care operations, services and programs or for developing new programs or services (e.g. teaching evaluations, patient/employee service surveys).

- QI/QA is generally NOT generalizable, and is meant to be applicable to a particular setting.
- Ex: Patient satisfaction surveys to improve a specific clinic’s efficiency
- Yale University IRB Policy 100. GD.5 Quality Improvement and Quality Assurance Projects and IRB Review
- **Oral History** → “method of gathering and preserving historical information through recorded interviews with participants in past events and ways of life.” *Oral History Association (OHA)*
 - *IRB review not required: Collection of labor/birth stories to create an archive on women’s birth experiences worldwide*
 - *IRB review required: Interviews with new mothers comparing cultural norms around labor pain management*
 - Yale University IRB Policy 100. GD.1 Humanities Projects and IRB Review



Do I submit a proposal to the IRB if I have an internship?

If you are working with an institution/organization where the procedures/research would be carried out regardless of your involvement i.e. you are not carrying out independent research AND you are not using the data collected for publication, senior thesis etc, then you do not need to submit to the IRB.

Does My Project/Study Include Human Subjects?

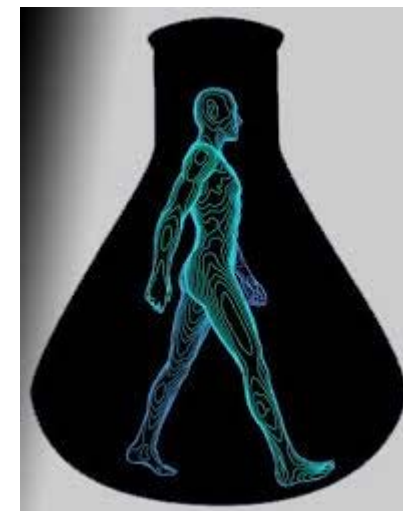
What is a
Human
Subject?

45CFR46.102(f)

- ***Human subject*** means a living individual about whom an investigator (whether professional or student) conducting research obtains

(1) Data through intervention or interaction with the individual, or

(2) Identifiable private information.



What Kind of Data Would NOT Be Considered Human Subjects?

- Data about health facilities, businesses or organizations that are not individuals. This data can either be obtained by interview OR as a secondary data analysis.
- Data on deceased persons
- De-identified human data or specimens

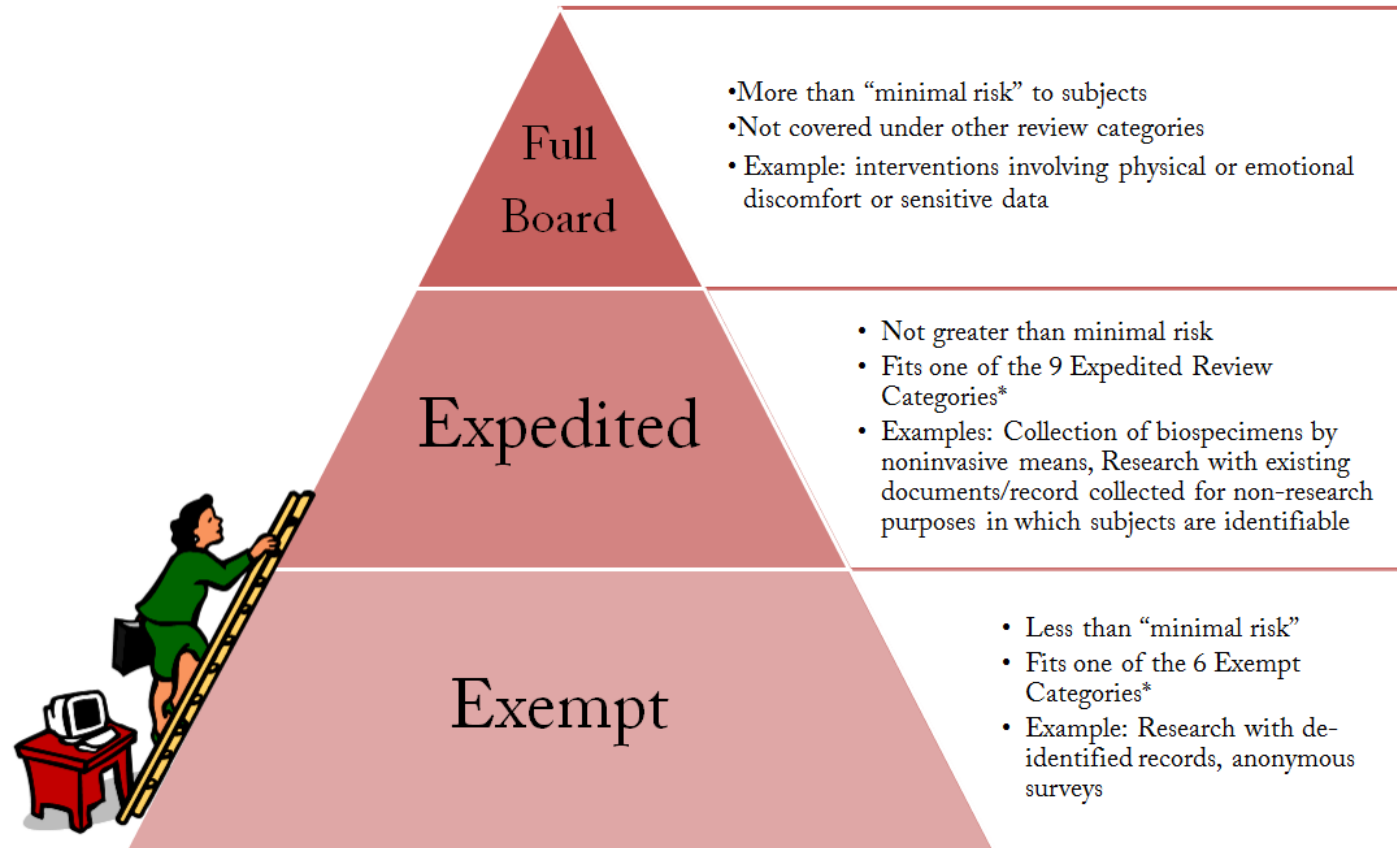


You have determined that your Project/Study requires IRB review, what are your next steps and what documents are required?

Step 1: What level of review is required?

Levels of IRB Review

Levels of IRB Review



*Defined by federal regulation (45 CFR 46)

What is an Exemption?

- A federally designated category
- Describes certain kinds of minimal risk research
- Means that the research is determined to be exempt from continuing IRB review



Exemption Categories 45CFR 46.101(b) 1-6

- **Category 1**-Educational Practices
- **Category 2** Educational Tests, Interviews, Surveys or Observation of Public Behavior
- **Category 3** Elected Officials (Educational Tests, Interviews, Surveys or Observation of Public Behavior)
- **Category 4**-Collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens
- **Category 5**-Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine methods and procedures of public benefit or service programs.
- **Category 6**-Taste and food quality evaluation and consumer acceptance studies
- **Category 7**- Research involving interviews, surveys, educational test or observation of public behavior in which participant interaction includes providing a response to a non- physically invasive stimulus or behavioral activities commonly performed outside the research context. *Created by Yale University*

What is expedited?

9 research categories:

Most common:

- 5). Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. [45 CFR 46.101\(b\)\(4\)](#). This listing refers only to research that is not exempt.)
- 7). Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

Step 2: Determine Appropriate Documents For Submission

- Log in to IRES-IRB submission system <http://ires-irb.yale.edu>
- Click on “Library” to access all IRB documents
- Exemption Request or full Protocol Application (*used for expedited and full committee protocols*)
- Faculty Advisor Attestation Form
- Informed Consent Form OR consent script (for verbal consent)
- Surveys, interview questions, standardized measures, etc.
- Recruitment materials
- Letters of Support-if you are working with an organization such as an NGO or clinic
- Local IRB Review-for International Research
<https://your.yale.edu/policies-procedures/forms/450-ch-1-international-research-checklist>
 - 450 GD.1 International Research: Required Documents and Additional Considerations <https://your.yale.edu/policies-procedures/guides/450-gd-1-international-research-required-documents-and-additional>



Points to remember when developing a research protocol/consent documents

- Describe in detail what it is that you are doing and why
- Describe your study participants and how you are recruiting them
- Include the description of consenting process
- Describe risks and benefits of the study
- Answer all the questions in the forms
- Include all survey questions or possible topics of discussion, when needed
- Include all required consent elements – use the template
- Make sure you and your faculty advisor have completed human subject protection training, HIPAA (if applicable) and conflict of interest disclosure (*for graduate students*). *Human Subjects Protection Training can be accessed at yale.edu/training*

Data Security

Procedure 400 PR.1 Protecting Participants' Research Data

<https://your.yale.edu/policies-procedures/procedures/400-pr-1-protecting-participants-research-data>

- Password protection
- Storage on Yale secure server or cloud
- Identifying information

Step 3: Submit all documents in IRES IRB

- All IRB submissions for HSC and HIC are required to be submitted through the IRES IRB online submission system: <http://ires-irb.yale.edu>
- When you log into the system, click on “Help”, which will bring you to a series of quick guides that gives you step by step instructions on how to create a new study.
- Make sure to add your Faculty Advisor as a “PI Proxy” in the system
- Email the Fellowship Email, if you have any questions:
Fellowships.HSC@yale.edu

Review Process

- Within 3 to 4 weeks, a regulatory analyst may contact you with questions
- If you have to revise your documents – use track changes!
- If the study requires full board review (e.g. it poses greater than minimal risk to participants), it will be scheduled to the next available IRB meeting
- Once approved, you will receive a determination/approval letter via email
- **DO NOT START RESEARCH WITHOUT THE IRB LETTER**

Retrospective Review

**There is no mechanism for
retrospective review of research
that was completed without IRB
approval.**

When things go wrong

- Contact your IRB Regulatory Analyst ASAP
- Certain unanticipated problems have to be reported right away (e.g. stolen computer with sensitive data)
- Minor deviations may wait till annual review (e.g. a participant missed an appointment and did two interviews on the same day even though the protocol includes 2 days of testing)

Research Integrity

- Guide to Undergraduate Research (WebGURU)

<http://www.webguru.neu.edu/index.php>

US Dept. of Health & Human Services: The Office of Research Integrity: General Resources

<https://ori.hhs.gov/general-resources-o>

When the study is done

- When you have completed analysis on identifiable data and the study has an expiration date, you can close it by submitting a Request to Close
- IRB does not need to be notified about closures of exempt studies
- Do not allow a study to lapse! If you need to continue your research or analysis on identifiable data, then submit a Request to Renew

Collaboration with other researchers

Only people affiliated with Yale and listed on the approved protocol can be engaged in the conduct of Yale study UNLESS they get approval from their IRB or we sign appropriate agreements (e.g. unaffiliated investigator agreement). Contact your regulatory analyst for help.

Where to get help

- Contact the HSC office by emailing human.subjects@yale.edu to set up an appointment

- Call the HRPP Office - (203) 785-4688

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