Ethical and Legal Obligations in Human Subjects Research

UNDERSTANDING THE INSTITUTIONAL REVIEW BOARD (IRB)

AMBER DEES, IRB COORDINATOR

What is the IRB?

The purpose of the IRB is to ensure that the rights and welfare of all human subjects are protected.

Basic tenets of human research are **voluntary participation** and the **ethical treatment** of the subjects in the research process.

- Belmont Report – defines basic ethical principles
- Code of Federal Regulations (45 CFR 46) - defines the basic rules

Why Do We Have the IRB?

To protect research subjects, particularly the most vulnerable populations who have historically lacked adequate protections: low income, minorities, children, mentally disabled, prisoners

- Tuskegee Experiments
- Thalidomide drug tests

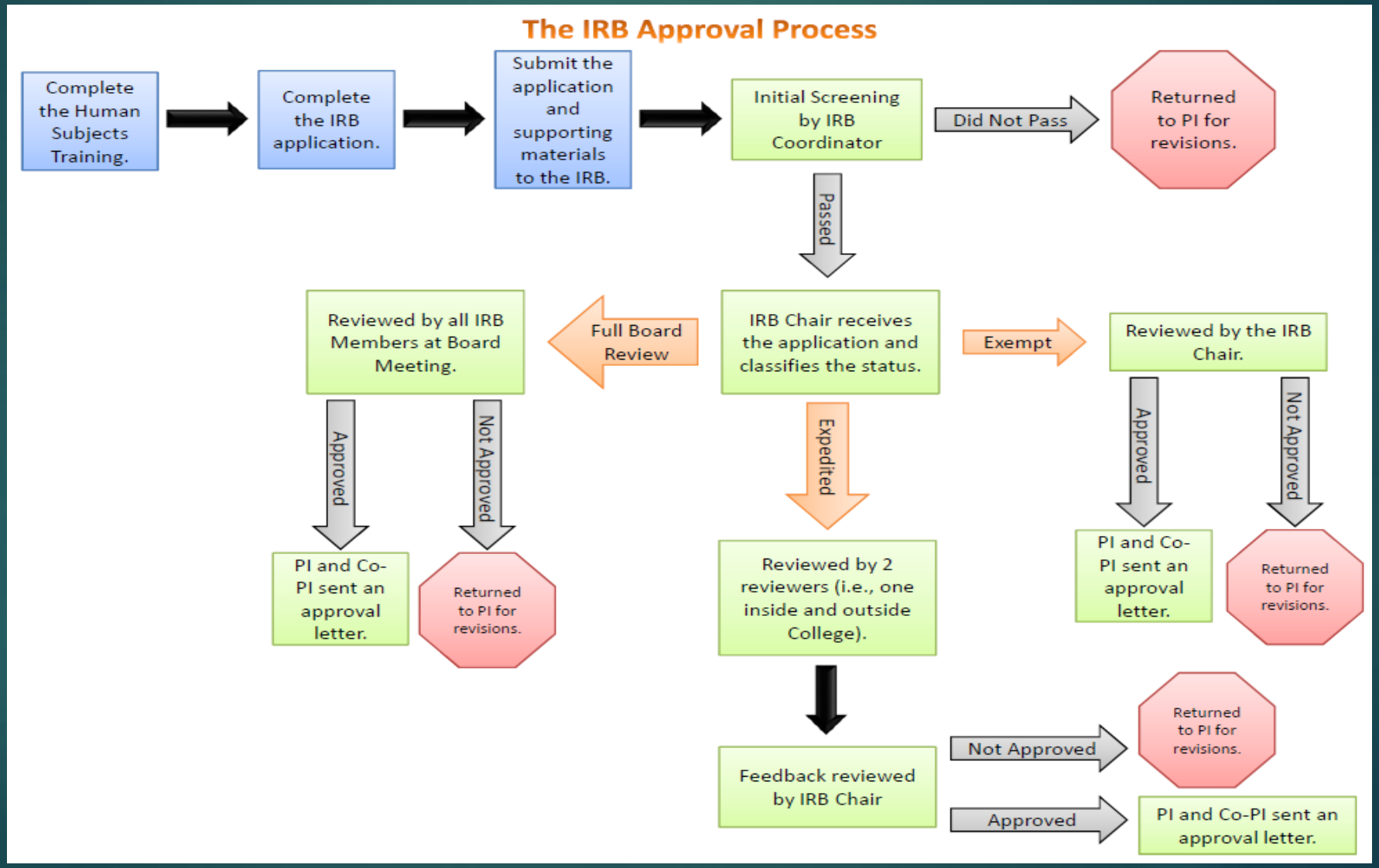
Congressional action in the 1970s led to the Belmont report, which outlined three key principles governing human subjects research

- **Respect for persons** – informed consent, free from coercion
- **Beneficence** – balancing risks and benefits, avoiding harm, is it necessary
- **Justice** – who receives benefits and burdens, and equality of burden

Understanding the IRB Process

1. Carefully ***read all*** IRB policies and procedures before starting the application
2. Complete the application
3. Create the merged addendum
4. Complete the application checklist
5. Submit the application packet
6. Respond to Revision requests
7. Receive approval

Understanding the IRB Process



Researcher Pitfalls that Delay Approval

- Do not follow submission guidelines
- Do not provide all required information in the application or addendum
- Do not respond in a timely manner to feedback
- Do not make all required corrections
- Include sections from academic writings – thesis, dissertation, research papers
  - Long and verbose
  - References or citations
  - Statistical tests
  - Theoretical justifications of research design
- Duplicate the same sections of text through out the application
- Conflicting information

Example Application Responses

Information Requested in IRB Application:

1. **How will the participants be recruited?** (Check all that apply.)

☐ In person	☐ Printed Materials	☐ Television/Radio
☐ Phone call	☐ Letters	☐ Listserv/Email
☐ Social Media/Web-based	☐ SONA	☐ Other (Specify:_____)

2. **Describe when, where, and how participants will be initially contacted for each method selected in #1 above.** (Attach a copy of any printed and/or electronic materials that will be used for recruiting in the addendum.)

First Response from Research Team – Does not provide requested information

1. In Person, Email, and Printed Materials
2. We will ask students if they want to take the survey. If they say yes we will give them the informed consent form and they will take the survey. Then we will run statistical tests to find out if there is a correlation between the variables.

Second Response – Provides requested information

1. In Person, Email, and Printed Materials
2. At the beginning of the Spring 2020 semester we will contact faculty teaching ENGL 1101 and request permission to recruit students during a face to face class the 3rd or 4th week of the semester. The members of the research team will visit approved classes and read the recruitment script (addendum #1). We also will pass out the study flier (addendum #2) and direct any students interested in taking the survey to put their name and email address on the sign up sheet we will pass around. After class we will email students the introduction email with the link to the survey (addendum #3).

Example Informed Consent Responses

Informed Consent Template Prompt:

VI. Confidentiality:
[In lay terminology, describe how the data will be de-identified, stored, and/or destroyed, who will access the data, and how it will be protected from unauthorized access.]

First Response from Research Team – Does not provide requested information
VI. Confidentiality
We will tell the participants that they don't have to participate and that their responses will be anonymous. Once we have collected the data we will de-identify it and keep it secure before destroying it.

Second Response – Provides requested information
VI. Confidentiality
The survey data we collect from you will be anonymous. It will be stored in a cloud site in a password protected account, and accessed by password protected computers. Only members of the research team will have access to the data, which will be kept for two years and then permanently deleted.

Common Questions

- **Do you have examples of applications that I can review?** – Yes, see our FAQ page for sample applications. Please note that you should provide answers to each section based on your actual project. Do not just copy what is in the examples or you will likely not pass screening. These are not 'perfect' applications, but examples of strong applications.
- **Can you review my application before I submit it?** – No, but we are happy to answer any questions that you may have about specific elements of the application or submission requirements. Email us at irb@columbusstate.edu
- **When do I need to submit my application so that is reviewed at the next IRB meeting?** – You don not need to wait for a scheduled meeting. We handle submissions electronically as they come in, unless your protocol requires full board review (unusual). Please keep the IRB Closure dates in mind when submitting. Dates can be found on our IRB Scheduled Meetings page.

Common Questions

- **How long does it take to get approved by the IRB?** – That largely depends on the completeness of the application materials, and the responsiveness of the research team to requests for revisions. You can see the average IRB processing times on our website, but that only includes the time we are processing on our end, not time we are waiting for responses from the research team. We generally advise submitting your application no later than one month before you need to start recruiting and data collection.

- What do I do if I don't understand the feedback I got from the IRB? Ask us, we are happy to clarify any feedback that you don't understand. Please do not re-submit your proposal without correcting the identified issue(s). You can email the irb@columbusstate.edu. Please make sure to identify the specific question/concern you have. The IRB will not tell you what answer to put(ex. 10 mins), that will vary based on your study, but we can tell you what information is missing (ex. how long it will take for the participant to complete the measure).

More Information

IRB Website

https://aa.columbusstate.edu/research/irb/

- Instructions
- Forms
- FAQ
- IRB Closure dates

Contact: irb@columbusstate.edu