



IRB, IDEATE, AND HSR %

February, 2018
Manuel Gonzalez

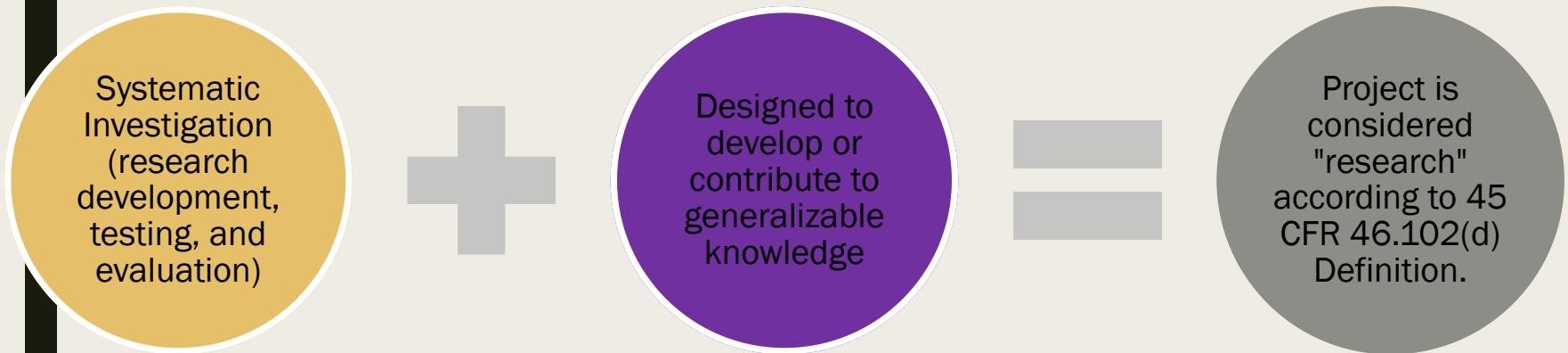
Outline

- What is the IRB?
- Human Subjects Research and Researcher Responsibilities
 - Citi Certification
 - Ethical Principles
 - Revisions etc.
- Submitting Studies to IRB and the Review Process
- Tips and Training Videos

CUNY University Integrated Institutional Review Board

- The CUNY UI IRB is charged with **protecting** the rights and welfare of **human research participants**.
- The IRB ensures that proposed research follows federal guidelines and accepted ethical principles.

Human Subject Research Definitions



*Both must be applicable to a particular research study in order for a project to be determined "research".

- **Human subject** – A living individual about whom an investigator conducting research obtains (1) data through **intervention or interaction** with the individual, or (2) **identifiable private information**.
- **If you are uncertain if your activities constitute human subject research, submit a Human Subject Research Determination form**
 - The HRPP Coordinator will issue a determination of whether the proposed activities constitute human subject research.

Researcher Responsibilities

■ Education

- Researchers are responsible for completing training on the conduct of human subjects research prior to engaging in research activities
- Taking the **Collaborative Institutional Training Initiative (CITI)** human subjects training is required for **all PI's and Key Personnel**
 - Make sure to complete the **Human Subjects Research** modules for **Social & Behavioral Faculty, Graduate Students & Postdoctoral Scholars**
 - www.citiprogram.org

Researcher Responsibilities

Ethical Principles

- Researchers are responsible for conducting research in accordance with the ethical principles outlined in the Belmont Report:
 - **Respect for Persons**
 - The **autonomy** of individuals to make an **informed choice** about participation in research; providing **suitable protection** for vulnerable subjects
 - **Beneficence**
 - Research that has a scientific or scholarly value in which the potential **benefits outweigh the risks**, which are justified and minimized
 - **Justice**
 - Ethical research is designed and conducted so that the **burdens and benefits are fairly distributed** regardless of age, race, gender, ethnicity, etc.

Researcher Responsibilities

■ Conduct of Research

- Researchers are responsible for the protection of human subjects throughout the research process:
 - Develop research studies using **sound research designs** which **minimize risks** to subjects and does not unnecessarily expose subjects to research-related risks.
 - **Maximize benefits** to subjects (see [Beneficence Principle](#) in Belmont Report for details).
 - Plan and implement **fair and equitable recruitment practices**, which **avoid** the potential for **coercion** and **undue influence**.

Researcher Responsibilities

■ Voluntary Participation

- Researchers must ensure that participation is **voluntary** by providing **sufficient information** to consent.

■ Informed Consent/Assent

- Researchers are responsible for **obtaining and documenting informed consent** with the consent/assent forms(s) approved by the IRB unless waived by the IRB for the specific project.

Researcher Responsibilities

■ Subject Enrollment

- Researchers may not initiate recruitment activities, including screening, or enroll subjects prior to the date of **IRB approval** or after the **expiration date** of IRB approval
- Researchers are responsible for enrolling only the **number of subjects** that was **indicated and approved** in application

Researcher Responsibilities

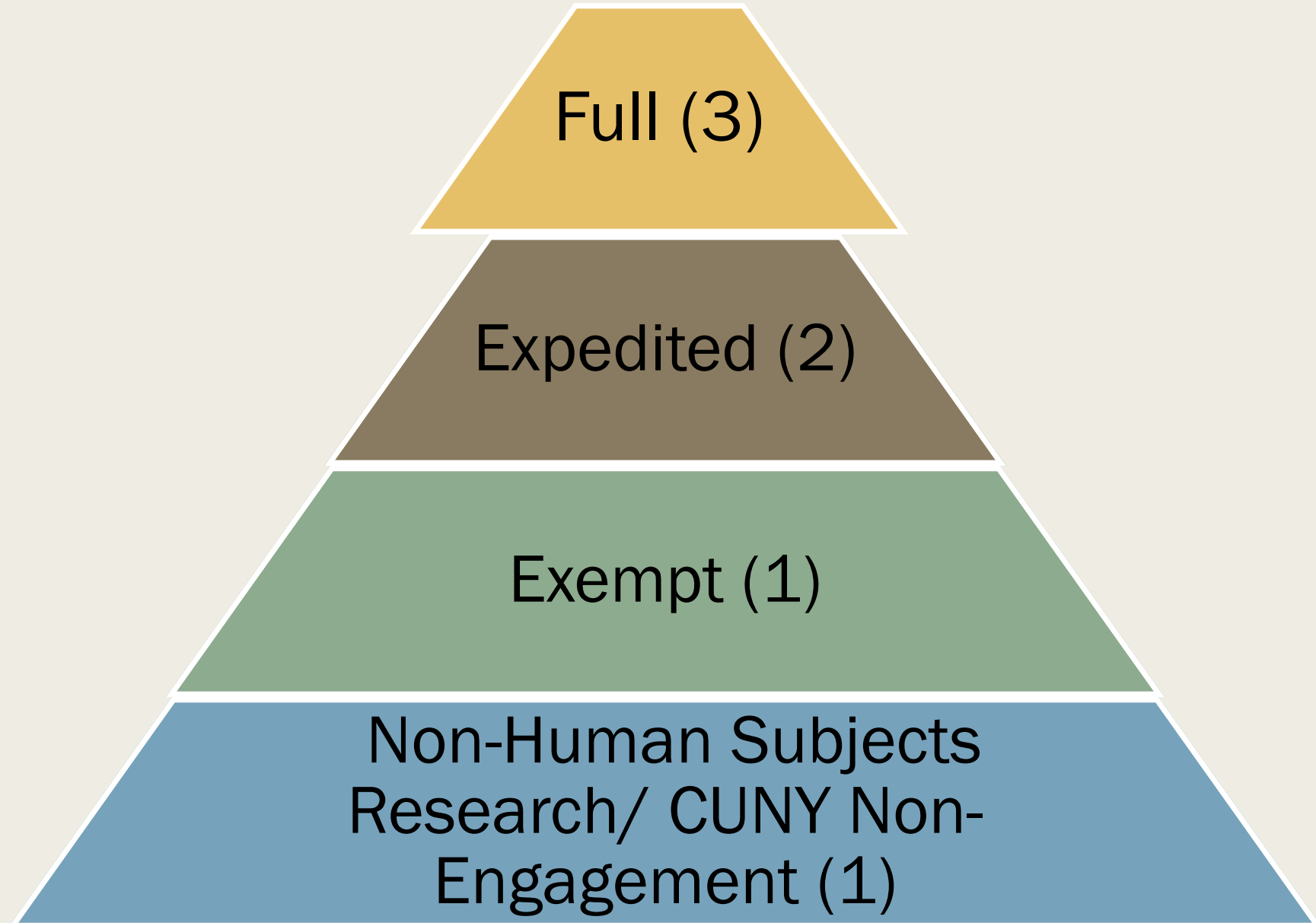
- **Revisions, Amendments, and Changes to Approved Protocol**
 - **Changes** to research design, procedures, number of subjects, etc. must be **submitted to and approved by the IRB prior to the implementation** unless the change is to remove an immediate hazard to subjects
 - If an **adverse event/unanticipated problem** occurs the HRPP Office must be immediately informed and a **report submitted**.

IRB Review Process & Tips

Activities that don't require HRPP/IRB Review

- **Classroom Activities** – Activities that are designed for educational purposes to teach research methods or demonstrate course concepts that are not intended to create new (generalizable) knowledge do not require IRB review.
- **Student Internships and Research Practica** – Activities associated with internships or practica may or may not require IRB oversight depending on the design of the activity.
- **Journalism, Oral History, Biographical Interviews, etc.** - interviews used to provide quotes or illustrative statements.
- **Program Evaluation** - survey procedures, interview procedures, or observations of public behavior that are conducted for Baruch internal purposes (program evaluation) only.

Levels of Review



Logging into IDEATE

- For NEW IDEATE USERS, email ideate@cuny.edu after completing the CITI HSR certification to request an IDEATE account
- Provide:
 - First and last name
 - CUNY Affiliation
 - CUNY Portal username
 - CUNY email address
- Request an account early

Online Application

- Go to IDEATE website and login
 - <http://ideate.cuny.edu>
- Create a new IRB Application
 - Add the relevant personnel to your project
 - Make sure your personnel have IDEATE accounts and have completed their CITI training
 - Complete the application
- Make sure that you have uploaded **all relevant documents**
 - Includes consent forms, recruitment statements, research materials, and CITI HSR certificates
- Communicate with your faculty advisor throughout this process

Tips for Major IDEATE Sections

Research Purpose & Hypotheses

- Describe the purpose of your research
 - What are you examining and why are you examining it?
 - What are your hypotheses?
 - Short, clear, and simple
 - Do not paste the intro of your thesis

Research Design & Methodology

- Describe design and procedures in detail
- Reviewer should be able to understand how your study proceeds from start to finish
- Attach measures and materials in a separate document

Procedures & Risks

- **Risk:** probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study
- There is **never** “no risk” (at least “minimal risk”)
- Explain how you mitigate **each risk** that you list
- Make sure stated risks are **consistent** across your application and your consent forms

Common Risks to Consider

- Breach of confidentiality
- Sensitive questions
- Deception (omission, commission)
 - Debrief

Benefits

- Direct benefits
 - Typically, no direct benefit
 - Compensation (class credit, money) doesn't count
- Societal benefits
 - Risk/benefit ratio
 - Can also include benefits to research or theory, and practical benefits

Recruitment

- How many people are you recruiting? How are you recruiting them?
 - Have consistent numbers throughout your application!
- If recruiting from only one demographic group (e.g., men, Latinos), need justification for why that group
- Attach recruitment materials (scripts, flyers, social media text, etc.)

Eligibility Criteria

- Who does (and does not) qualify to participate?

- Some example criteria
 - Must be 18 years of age or older
 - If recruiting minors, also need parental consent
 - Must be currently employed or employed for X months
 - Must work in X type of industry

Consent

- Make sure the consent form is consistent with your application!
- Several necessary aspects of consent
 - Sample consent forms on the Baruch HRPP website
- Use appropriate (understandable) language
- Can request a waiver of documented consent (or some aspects of it) in some cases, but some other form of consent is typically used
- If using audio/videotaping
 - Need to separately request consent for that data within your consent form

Privacy & Confidentiality

- **Privacy:** extent to which participation in a study is known to others
- Anonymous vs. confidential
 - **Anonymous:** data collected in a way that doesn't identify the source of the data (rare)
 - **Confidential:** participant data could be linked back to participant, but you are taking measures to prevent those links from being made (more common)
 - **NOTE: Qualtrics and MTurk data are not anonymous**
- How will data be coded?
- Where will consent forms and data be stored?
- Who can access the data?

Additional Tips

- Develop the study and materials first, then complete the IDEATE application
- Be consistent and specific
- Do not copy/paste from your proposal
- Have your advisor review the application
- Attach the CITI HSR (not RCR) certificates for every member of the research team, **including your advisor**
- If you need guidance, HRPP coordinators hold office hours

What the Review Process Looks Like



Develop the study, fill
out and submit
IDEATE application



Pre-review from HRPP
coordinator

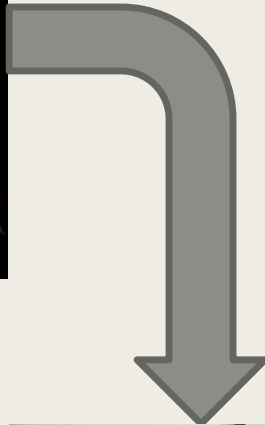
What the Review Process Looks Like



If revisions needed, HRPP coordinator sends feedback and adds comments throughout application



What the Review Process Looks Like

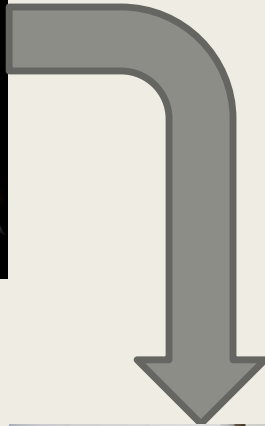


If satisfactory and
determined as
exempt...

Done!



What the Review Process Looks Like



If satisfactory and
determined as
expedited...

Sent to expedited
reviewer

Upcoming Common Rule Changes

- Human subjects research abides by the federal Common Rule
- Expected to change in July
- IDEATE may also undergo maintenance at that time to accommodate new regulations
- Informational videos for new regulations will be released at that point

Useful Links

- **Baruch HRPP Website**

- <http://www.baruch.cuny.edu/hrpp/>

- **Researcher Guide**

- <http://www.baruch.cuny.edu/hrpp/researchersguide.html>

- **HRPP Templates and Forms**

- <http://www.baruch.cuny.edu/hrpp/forms.htm>

- **IDEATE**

- <http://ideate.cuny.edu>

- **IDEATE Help Documents**

- Log-in to IDEATE and click Help in the navigation bar at the top of the page

HRPP Training Videos

- If you need assistance with IDEATE or Creating/Developing your IRB Application please go to the HRPP Website and view our instructional videos.

<http://www.baruch.cuny.edu/hrpp/trainingvideos.htm>

- Requires username/password if accessing outside of Baruch

HRPP Office Staff

- Keisha Peterson, **HRPP Coordinator**
 - Email: Keisha.Peterson@baruch.cuny.edu
 - Telephone: 646-312-2217

- Manuel Gonzalez, **HRPP Liaison**
 - Email: Manuel.Gonzalez@baruch.cuny.edu
 - Office Hours: Wednesdays 3:45-5:45 PM and by appointment
 - Office Location: VC 8-270, Cubicle B

Questions?

