Preparing for the IRB

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Key Ethical Principles: The Belmont Report

- Principle of respect for persons
- Principle of beneficence
- Principle of justice

Respect for Persons/Autonomy

- Respect for the right of persons to make individual decisions for themselves as *autonomous agents*
- Rationale agents involved in making informed and voluntary decisions
- Being aware of coercion as takes away autonomy
- Protect individuals with diminished autonomy (e.g., children, prisoners)
- Basis for informed consent

Beneficence

- Duty to be of benefit
- ‘Are research subjects treated the way I would like to be treated’?
- Risks are justified based on potential benefits to the individual and/or society.
- Risks are minimized and benefits are maximized.

Justice

- Potential risks of research should be borne equally by society.
- Obligation to treat participants equally
- Need to be particularly cognizant of vulnerable populations

Conditions Evaluated for IRB Approval

- Voluntary consent to participate in research
- Informed consent to participate in research
- Selection Treatment of Subjects Equitable
- Risks are reasonable in relationship to benefits
- Privacy and confidentiality
- Right to withdraw without penalty

- **So when you submit an application you should be asking yourself if you are meeting all these standards.**

Role of the IRB and Membership

- The mission of the IRB is to protect the rights and welfare of research subjects.
- The focus is on issues that directly relate to protection of human subjects.
- NOT focused on critiquing methodology….UNLESS protection of human subjects is of concern
- NOT to be avoided or feared
- Approach with honesty and transparency

Types of Projects Requiring IRB Submission: Questions to Ask

- **Is this human subjects research?**
  - ***Human subjects****: a living individual about whom an investigator (whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.*
  - ***Research:*** *systematic investigation designed to develop or contribute to generalizable knowledge*
- **What does systematic mean?** is the opposite of a disorganized, random venture. In other words, researchers need to have constructed a research plan with ideas about what they want to learn and how best to do that. Both qualitative and quantitative researchers use systematic investigation
- **What is generalizable? to** derive general conclusions from particulars. Therefore, the essential consideration is whether it was the researcher's intent to contribute to a body of knowledge or whether the results were replicable
- If Research does not meet the definition of human subjects or research then it does not need to be reviewed by the IRB (exception at RIC is quality improvement projects)

IRB Review

- **Determinations:**
  - Not Human Subjects Research
  - Exempt
  - Expedited
  - Full

https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts-2018/index.html

Determining Level of Review: Exempt

- It is recommended that investigators not be given the authority to make an independent determination of their research as exempt and instead should rely on the IRB chair
- There are 8 categories of Exempt
  - **Research in Established or Commonly Accepted Educational Settings**
  - **Educational tests, surveys, interviews, or observations of public behavior (must meet 1 of 2 criteria)**
    - **Not identifiable**
    - OR **Disclosure outside of research would not put at harm**
    - Information can be identifiable but IRB has done a **limited IRB review** and determined that there are adequate provisions in place
  - **Benign behavioral interventions (NEW)**

Determining Level of Review: Exempt

- **Secondary Research** – covers use of identifiable private information or identifiable biospecimens. Does not require informed consent under 4 conditions
  - Publically available
  - Info recorded so not identifiable
  - Research use of identifiable health info when regulated by HIPPA
  - Analysis of data on behalf of federal agency
- **Research and Demonstration Projects**
- **Taste and Food Quality Evaluation**
- **Storage and Maintenance for Secondary use (Not implementing at RIC at this time)**
- **Secondary Research for which Broad Consent is required (Not implementing at RIC at this time)**

Determining Level of Review: Expedited

- Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more categories

- Categories are (https://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html)
  - Clinical studies of drugs and medical devices only when conditions are met
  - Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture
  - Prospective collection of biological specimens for research purposes by noninvasive means
  - Collection of data through noninvasive procedures routinely employed in clinical practice, excluding procedures involving x-rays or microwaves
  - Research involving materials (data, documents, records, or specimens) that have been collected
  - **Research on individual or group characteristics or behavior) or research employing survey, interview, focus group, program evaluation, human factors evaluation, or quality assurance methodologies**

Determining Level of Review: Full Board Review

- Proposed human subject research which does not fall into either the exempt or expedited review categories must be submitted for full committee review. These are studies that **involve more than minimal risk.**

Continuing Review

- Under the revised Common Rule, continuing review (meaning once a year) is not required for:
  - Research that is eligible for expedited review,
  - Exempt research conditioned on limited IRB review,
  - Research that has completed all interventions and now only includes analyzing data, even if the information or biospecimens are identifiable,
  - Research that has completed all interventions and now only includes accessing follow-up clinical data from clinical care procedures.
  - Importantly, the IRB can override this default and still choose to require continuing review, as long as the IRB documents the decision and the rationale for this decision.

Review Process

- **I review applications ALL the time that are exempt and expedited.**
  - For exempt/expedited: Expect no more than 2 weeks to get initial feedback. Might take 4 weeks total with changes.
  - At RIC history of all EXEMPT applications getting Limited IRB review (this also includes QI projects)
- **Applications that might need full board review (question of risk level) need to be in to me at latest by the beginning of the month.**
  - Typically, I will give you initial comments within a week
  - App will go to full board review
  - You will receive comments from full board within a few days
- **How quickly the review process goes for minimal risk studies is MOSTLY in your control**

Working with a Student on an IRB Submission

- Key: student and faculty active involvement from the beginning. Faculty role is to teach, guide and coach student NOT to just sign the submission.
- Ensure student completion of **CITI training** AND review understanding of the ethical implications of the project.
- Discuss the review process and what to expect including timeline.
- Jointly discuss and complete any requested revisions.
- Upon approval/exempt determination, review plan with student and emphasize the importance of adhering to the protocol EXACTLY.
- Meet with student and monitor progress and adherence to protocol.

Submitting Protocol in Topaz: Intro

- First need log in information – email irb@ric.edu
- When log in decide on which application to submit (Exempt of Expedited/Full)
- Follow the directions exactly. Include what is asked for and no more or less.
- Attach documents where they are requested.
- DO include CITI information for faculty PI(s) and student(s).
- Be sure that statements are consistent throughout!
- Do SAVE frequently

- **NOTE.** Topaz is sometimes finicky – I am not a technician and if you can't solve the problem using online resources on the IRB website I probably can't either.

Submitting in TOPAZ: Recruitment and Consent

- Sample size: better to over-estimate than under-estimate: can only recruit as many as are requested and no more.
- Recruitment: upload email script, recruitment flyers, letters etc.
- Use the RIC template for consent and assent.
- Clearly spell out procedures;
- Do not overstate benefits or understate risks;
- If identified risk, identify whom specifically to contact for support/ counselling

Consent

- Must be easily understandable and written at reading level of target audience
- Consent vs. assent
- Must obtain permission if minors under 18 involved
- Must use stamped copy and provide a copy to participant
- Special circumstances:
  - May request waiver of signature: i.e informational letter. Includes all of the elements of consent but does not require signature. Requires justification.
- Use of photos, videos or audio recording.

Conducting Research with RIC Students

- Research should not interfere with class and learning
- If will take class time then needs to be explicitly relevant for course
- Extra credit incentives for students
- In most cases it is not appropriate for professors to recruit or collect data directly from students in their classes. There are exceptions to this but need to maintain boundaries

Methods

- Location: support letter signed and on institutional letter head
- Approach: specify and clarify
- Spell out study procedures in detail, chronologically
- Write for someone who knows nothing about the study.
- Materials: Attach all measures (easiest if in one file); data collection tools
- Use of incentives (must be equivalent across multiple groups)

Privacy/Confidentiality

- Privacy: how will you ensure privacy while participants are providing data?
- On-line: email or IP addresses
- Data storage and confidentiality
  - Password protected drive; locked file; three years
- Anonymity vs. Confidentiality

Risks

- Identify type and level
- Describe the identified risk(s). How will risks to subjects be minimized?
- Dual roles/conflict: how will these be managed?

Non English materials

- Involves principal of justice
- New policy explicitly outlined in Manual
  - For more than minimal risk needs to be translated by certified translator or needs back translation

Funding/Approval from other Institutions

- If yes, upload other approval letters and documents
- Best to coordinate between institutions in advance

QUESTIONS?

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