Chatham University IRB

IRB Proposal Submission: Student and Faculty Guide

Chatham's Institutional Review Board is registered with the National Institutes of Health Office of Human Research Protection. As such, Chatham's IRB committee is charged with the protection of human subjects' rights, welfare, and well-being. This checklist is designed to help student and faculty with research studies and evidence-based projects submitting proposals to the IRB avoid some common mistakes.

1. Proposal type (this is not an exhaustive list):
    - **Exempt**:
        - The population involves adults 18 years and older **(excludes** involvement of a vulnerable population as defined by NIH: children, pregnant women, fetuses, prisoners, impaired decision-making, impaired cognition, educational or economically disadvantaged, institutionalized individuals, seriously ill - medical or mental) **and**
        - Practices are established or commonly accepted
        - It is related to an educational activity in the classroom such as assessing or testing of the course content or methods **or**
        - The research is a single encounter using an anonymous or no risk survey, interview, or observation of public behavior and the behaviors cannot place the participants at risk for liability, be damaging for financial standing, employment, **or**
        - Research examining public benefit or service programs.

    - **Expedited**:
        - Has only minimal risk
        - Does not include intentional deception
        - Uses informed consent
        - Has multiple encounters with participants
        - Is noninvasive or minimally invasive
        - Adult population that does not include vulnerable populations

    - **Standard**:
        - Studying a vulnerable population
            - Children, pregnant women, fetuses, prisoners, impaired cognition, or impaired decision-making related to educational or economically disadvantaged, institutionalized individuals, seriously medically/mentally ill)
        - Proposal moderate to high risk (has greater than minimal risk)
        - The research uses intentional deception
        - The procedures are personally intrusive, stressful or potential traumatic

Note: If you have questions about the type of proposal to submit, please reach out to Melissa Bednark at MBednarek@Chatham.edu.

2. Completing the IRB Wizard questions:
    a. Remind students to verify the type of proposal determined by the wizard matches the type of proposal determined using the criteria listed above. Answering certain questions yes or no, will lead to the specific template: either exempt, expedited, or standard.

Proposal: Please include the following information in your IRB proposal:

Q1. **Purpose**:
- a. Research: include a clear statement of **purpose** and **specific objectives**
- b. Evidence-based practice projects: provide evidence (**minimum of 3 studies**) that support the *use of the intervention*, not the problem. Follow with a *brief* description of the project and the *expected outcomes*.

Q2. **Subject/population**
- Define population in detail, including limits on: age range, gender, ethnicity, characteristics that may impair decision making (if appropriate), status (inclusion criteria)
- Define exclusion criteria
- Include the estimated number of participants you are recruiting for.
- For research using vulnerable subject populations, indicate clearly why the use of such subjects are necessary.

Recruitment: please provide specific details on recruitment, including:
- How will individuals first learn of the project i.e., how will project be announced or shared? How will they be recruited?
- How you will minimize coercion?
- What method are you using for obtaining consent: informed or implied? Describe in detail including when, where and how the process will occur.
- How and when will you give interested individuals a chance to ask questions prior to signing consent?
- How will you inform interested individuals that they are eligible or ineligible for the study/project?
- Attach recruitment flyers/emails/scripts on how to contact the PI.

Q3. **Research procedures**
- Clearly outline the research/EBP steps in detail.
- Start with the consent form procedure.
- Clearly state the expectations of the participants.
- State the total amount of time they will be committing to.
- If coding is being used, are you stating that you are not collecting names or other personally identifiable information?
- If compensation is being offered, please provide a justification for the amount and type of compensation that does not increase the risk of coercion.

Q4. **List of permission letters from outside agencies**.

- These letters must be on the agency's letterhead.
- Signed by authorized person/ *person with the authority at the site to decide on the research*
  - Include their title.
- Letter should not include any reference to active recruitment.
- Letter should state that they are giving permission for the PI to conduct research or EBP at their site/organization with the following conditions:
  - Pending Chatham IRB approval
  - Participants and their data will be kept confidential
  - Participation in the research or project is voluntary

Q5. **List of materials that will be used.**

- List necessary materials or supplies related to the research/project

Q6. **Surveys to be used listed**.

- Include name of survey and if it is in the public realm.
- If it is not, include a letter of permission to use or a license agreement.
- If this is an IRB author/PI-created survey, please state this clearly.
- Upload a copy of the survey (check to make sure that the copy is readable and available for review)
- Do not include a link to the survey: attach the actual survey instrument(s).

Q7. **Research involving the collection of information from existing data**.

- Secondary analysis studies, if the data is it the PI's, there needs to be a letter of permission on the agency's letterhead with name and signature of authorized person in authority
- Clarify if it is de-identified data or not

Q8. **How will anonymity or confidentiality be maintained?**
Anonymity: participant is unseen and unknown to the researcher
Confidentiality: participant is seen in person or personally identifying information have been collected and steps are in place to maintain their confidentiality

- Describe your plan for protecting personal identifiers and confidentiality (or anonymity).
- Remember anonymity is only when you cannot see the individuals participating, such as an online survey through a listserv.
- Clarify how unique identifiers will be established and utilized for confidentiality.
- Acknowledge if you are collecting consent forms that they will be kept separate from survey data.

Q10. **Plans for securely storing data records during and after research.**

- During the intervention, where and how will you store paper and electronic data that will be safe and secure?
  - Include the length of time you are storing the data after research.
- Describe how will you destroy both paper and electronic data at the end of the time period.

Q11. **Who will be given access to the stored data?**

- For student PI, include faculty advisor upon request.

Q12. **List of all relevant correspondence and materials that will be submitted.**

- Letter of Permission
- Recruitment Documents/Flyers/Posters/email scripts/verbal scripts
- Cover Letter
- Consent forms (if accessing medical record, put in the consent that they are granting you permission to do so, then you do not need a HIPPA waiver)
- Surveys
- Data collection forms
- Powerpoint presentations (slides only)
- Handouts
- Video links
- HIPPA form if needed

Q13. **Does study potentially place participants at minimal levels of <u>inconvenience</u>?**

- Describe the minimal inconvenience
- Describe how you will minimize this

Q14. **Does study potentially place participants at minimal levels of <u>discomfort</u>?**

- Describe the minimal discomfort
- Describe how you will minimize this

Q15. **Does study potentially place participants at minimal levels of <u>risk</u>** (potential of something negative happening to the participant that was not intended?

- Describe the minimal risk
- Describe how you will minimize this

Q16. **Does the project offer a direct benefit to each type of subject needed for this study?**

- If so describe the benefit.
- If not, please describe why it is necessary to do this research without benefit?