Office of Research and Sponsored Programs
Overview of IRB Process

Contact Information:

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INTRODUCTION

Institutional Review Boards (IRBs) are committees charged by the federal government with protecting the rights and welfare of human subjects involved in research. Albany State University has an IRB Committee which is comprised of ASU faculty, staff, and community representatives. The IRB Committee reviews research conducted by ASU faculty, staff, and students.

If a project involves ASU personnel "engaged" in "research" involving "human subjects," an IRB submission and review is required. If there is uncertainty regarding a project meeting the basic criteria for review, use the attached form to determine ASU IRB Submission.

Once a determination has been made that an IRB submission is required it is important to understand (a) awareness of time, (b) submission requirements, (c) IRB review process, and (d) what to know once IRB approval has been granted.

TIMELINE

The time from IRB submission to approval varies depending upon the type of review conducted by the IRB. However, the Reviewers are asked to review submissions within 3 to 5 business days. Below is a description of the three review types, their process, and expected duration.

1. **Exempt**: Under federal regulations, certain types of research may be exempt from further IRB review if the study involves no more than "minimal risk" and falls into one or more of six exempt categories. For example: anonymous surveys; non-sensitive questionnaires or interviews; secondary data analysis on public data; and research on teaching or instruction. The determination of exemption may not be made by the investigator. Once submitted, allow approximately 3 business days for review. Either (a) determination of exemption, (b) request for revisions, or (c) notification that the project does not qualify for exemption, will be sent by e-mail. If the protocol does not qualify for exemption it will be processed for either expedited or full board review.

2. **Expedited**: The IRB may use an expedited review procedure when the research involves no more than "minimal risk" to the subjects and where the only involvement of human subjects will be in one or more of the expedited categories. For example: blood draws; non-invasive specimen samples; data collected from running on a treadmill; sensitive identified interviews;

and secondary data analysis from non-public sources. Once submitted, expect approximately 5 business days for initial review by a designated member of the IRB. Either (a) determination of expedited approval, (b) request for revisions, or (c) notification that the project does not qualify for expedited review, will be sent by e-mail. If the protocol does not qualify for expedited status it will be processed for either exempt or full board review.

3. **Full Board:** Submissions that involve more than "minimal risk," do not qualify for exempt or expedited review, or fail to receive exemption status or expedited approval, are sent to a convened IRB for review. For example: invasive clinical procedures; use of FDA regulated drugs or devices; maximal stress tests; and use of x-ray equipment.

SUBMISSION REQUIREMENTS

ASU requires that anyone engaging in human subjects activities (*e.g., recruiting, consenting, interacting, intervening, obtaining or accessing identifiable data must have appropriate training to assure that the rights, welfare, and safety of human participants involved are protected. ASU accepts proof of training from CITI (Collaborative Institutional Training Initiative*). For CITI training, please visit www.citiprogram.org.

Studies are submitted to the IRB for review via IRBNet. To submit a study, please visit www.irbnet.org. Training PowerPoint presentations are available.

According to the study, all IRB protocols must include the following items (these items must be uploaded in IRBNet as separate documents):

☐ Research Protocol Review/ Application Form (All sections completed)
☐ Consent Form or Informational letter and any Releases (audio, video, or photo) that the participant will sign
☐ Reference List
☐ Copy of Human Subjects Training Certification(s)
☐ If data is collected either from sites other than Albany State University or in cooperation with other academic institutions, hospitals or private research organizations, either a permission letter from the site(s)/ program director(s) or a letter of IRB approval from each entity is required prior to initiating the project.
☐ If e-mails, flyers, advertisements, generalized announcements or scripts, etc., are used to recruit participants.
☐ If data collection sheets, surveys, tests, other recording instruments, interview scripts, etc. will be used for data collection. Be sure to upload them in the order.
☐ If you will be using a debriefing form or include emergency plans/procedures and medical referral lists. (A referral list may be attached to the consent document).
☐ Written evidence of approval from either an academic chair/supervisor or IRB of the foreign institution if data is collected at or in collaboration with an institution outside the United States.

Be sure to do the following:
- ☐ Get all of the signatures for the paper application
- ☐ Share this package with all of the key personnel/Co-PIs
- ☐ All key personnel/Co-PIs signed-off on the package in the IRBNet system

IRB REVIEW PROCESS

Once submitted, IRB staff will review submission for completeness (e.g., consent forms, questionnaires, recruitment materials, data collection instruments) and appropriate review type (exempt, expedited, full board). Expedited studies are sent to three (3) available IRB members; when possible protocols are sent to the member whose expertise most closely matches the research topic. Exempt studies will be reviewed by one (1) IRB member. Full board studies are sent to all of the IRB committee members.

If a protocol is missing information or something is not correct, the IRB Administrator will issue a **Requested Modification letter** which explains what needs to be added or corrected to the protocol per the IRB Committee Reviewer(s) via the IRBNet.org system. An email notification will be sent to each person associated with the protocol. At that time, log into IRBNet.org and view the letter. Requested Modifications delay Approvals. As a result, be sure that you have completed all of the requirements when before you submit a protocol.

Packages are not unlocked for the modifications. They need to be uploaded in a new package. For information on how to upload new documents into a new package, go to **Form and Templates** and select *PowerPoint – How to Navigate IRBNet – Researcher Part 2*. Start with slide 7.

An IRB Approval letter will be issued when the Reviewer(s) notes that there are no modifications needed.

AFTER IRB APPROVAL

Once approval has been granted by the IRB, the following require future submissions to the IRB:

1. **Approved/Exempt for Continuation:** Federal regulations require expedited and full board studies be reviewed no less than once per year.
2. **Requested Modifications for Amendments:** Any modifications to the planned research must be reviewed and approved prior to implementation as they may affect the treatment of human subjects.

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