



ARGOSY UNIVERSITY.

Institutional Review Board  
(IRB)



# When Do I Need to Submit the IRB Application?

- **BEFORE YOU BEGIN ANY DATA COLLECTION!**
  - Usually during Block II
    - development of formal proposal, orally defending the proposal, and submitting the application to the IRB.
  - Failure to follow this guidance is a violation of federal law and Argosy University policy.
  - It may result in the investigator's research being disqualified, and it may result in other disciplinary consequences, up to and including dismissal from the university.



# What is the IRB?

- What is the IRB?
- A committee made up faculty members who oversee the ethical conduct of research at Argosy University
  - Applies to all research studies or pilot studies conducted by or on faculty, staff, students, or employees of Argosy University, or by or on Argosy University as an institution
  - The Board DOES NOT approve the study!
    - Does consider design and data gathering procedures
    - Board may reject an application if the design is sufficiently flawed.



1. Student (principal investigator) and dissertation chair must have completed CITI Training Collaborative Institutional Training Initiative (CITI)
  - All applicants for IRB certification must submit a copy of their CITI certification with any new application for IRB certification
  - Modules to be completed
    - Background, Assessing Risk, and Consent Process



2. Student with support of their faculty research advisor determines the level of risk to participants in the study.
  - Complete the appropriate [IRB form](#)
3. Student submits application to faculty advisor for approval and forwarding to IRB.
  - The advisor should review the file to ensure that it is complete and all questions are answered fully
    - Review the [consent form](#) documents.
    - Be sure the voluntary participation statement follows the model



4. Both Faculty Advisor and student review the checklist to be sure that all necessary forms are attached.
  - Initial that application is complete
5. Faculty advisor and student sign the application
  - Original signatures are required!
  - Faculty advisor signature indicates approval that the study has academic merit and meets the requirements for IRB certification



6. Application is forwarded to IRB committee by faculty advisor
  - One hard copy with signatures submitted to IRB chair
  - One electronic copy sent to [\\_ausfirb@argosy.edu](mailto:_ausfirb@argosy.edu)
7. Reviewed to determine if correct level of application



8. The IRB makes every attempt to complete the process in the shortest time possible. However...

- IRB generally has up to 30 days for Exempt and Expedited applications
- Sixty days for a Full IRB Review



## 9. When a decision is made...

- A copy of the cover of the application with signatures is returned to the principal investigator,
- a copy is sent to the faculty research supervisor, and
- the original application with the original attachments (with original signatures) and original IRB signatures is placed in an appropriate secure file in campus administrative offices.



- Certification is for one year.
  - Must apply for extension if goes beyond that.
- Upon completion of the study, the principal investigator completes a project completion report form for filing with the principal investigator's original application for certification.



# Possible Outcomes

- “Certified” – Certified as written with no conditions (signed cover);
- “Contingently Certified”
  - The research application or the procedures for the protection of the research participants described in the application are deficient in one or more minor areas.
  - For these deficiencies, the IRB Chair or designated reviewer can, upon reviewing the Principal Investigator’s response(s) to the required changes, certify the research proposal on behalf of the IRB.



- “Not Certified”
  - The research application or the procedures for the protection of the research participants described in the application are significantly deficient in one or more areas (unsigned).
  - For these deficiencies, the IRB Chair or designated reviewer can, upon reviewing the Principal Investigator’s response(s) to the required changes, certify the research proposal on behalf of the IRB.



# Reasons for Disapproval

- Incomplete Application
  - Form not completed
  - Missing procedures on form
  - Consent form missing
  - Instruments missing
  - Letter from institution missing
  - No chairperson signature on application
  - No CITI training in evidence for student



- **Procedural Errors**

- Informed consent process inadequate for situation
- No screening process described
- Language problems with sample population
- Problems with confidentiality procedures
- No crisis plan for unexpected events (procedure may provoke strong reactions in subjects)
- Inadequate sensitivity to loss of confidentiality due to legal process (subpoena)



# Questions?