



IRB (Human Subjects) Review and Submission Process

Office of Research & Scholarship



THE UNIVERSITY OF ARIZONA
College of Nursing



Introduction

- Information will be presented regarding:
 - IRB Protocol forms
 - Process in the College of Nursing
 - Process at the University of Arizona IRB
 - Modifications
 - Project conclusion
 - Resources and where to find them



IRB Protocol Forms

- Complete appropriate form
 - IRB Protocol for Determination of Human Research
 - IRB Protocol Request for Exempt/Flexible Review
 - IRB Protocol for Human Subjects Research
 - IRB Protocol for Human Subjects Research - Retrospective Data Review
 - IRB Protocol for Projects Using External IRBs
- For students, all human subjects material must be reviewed and approved by their Chair before submitting to Office of Research & Scholarship for review
- IRB Protocol forms available at
- <https://research.arizona.edu/compliance/human-subjects-protection-program/HSPF-forms>



IRB Protocol for Determination of Human Research

- Complete this form if:
 - Project does not meet the definition of research or human research which is a systematic investigation designed to contribute to generalizable knowledge
 - Project involves quality improvement, quality assurance, program evaluation
 - Finding apply only to specific program or setting (i.e., clinic)
 - Project is a needs assessment
 - Project involves analysis of de-identified research data or publicly available data
 - Project is a case study (no more than 3 cases)



IRB Protocol Request for Exempt/Flexible Review

- Complete this form if:
 - Project meets the definition of research
 - Project is minimal risk research
- Specific criteria for using this form which are listed on the form



IRB Protocol for Human Subjects Research

- Complete this form if:
 - Project meets the definition of research
 - Project involves collection of information or biospecimens through interaction or intervention with living individual or their identifiable private information or biospecimens



IRB Protocol for Human Subjects Research – Retrospective Data Review

- Complete this form if:
 - Project involves review of identifiable data or specimens only



IRB Protocol for Projects Using External IRBs

- Complete this form if:
 - Utilizing an external IRB for review that is not the University of Arizona IRB
 - Approval from the external IRB is Expedited Status or Full committee approval
 - In this case, the external IRB will be the IRB of record
- If approval from the external IRB is Exempt or minimal risk status, complete the IRB Protocol for Human Subjects Research
 - In this case you will have approval at both institutions, the external site and the University of Arizona
- IRB approval must be obtained from the external IRB before submitting documents in eIRB



IRB Forms

- IRB Protocol forms available at <https://research.arizona.edu/compliance/human-subjects-protection-program/HSPP-forms>
- Always use the current version of the form



Other Documents

- Include with IRB Protocol form:
 - Recruitment material
 - Recruitment flyer, Recruitment email, Recruitment script, etc.
 - Consent document(s)
 - Disclosure form, Consent form, Assent form, Parental Permission form
 - Data collection tools
 - Site authorization, if applicable

Other Documents (cont.)

- Include with IRB Protocol form:
 - Appendices, as applicable
 - Appendix for Children/Wards
 - Appendix for Cognitively Impaired Individuals
 - Appendix for Native American and Indigenous Populations
 - Appendix for Prisoners
 - Appendix for Pregnant Women, Neonates and Fetuses
 - Appendix for Devices
 - Appendix for Drugs
 - Appendix for Waiver or Alteration of Consent or PHI
 - Appendix for Exceptions from Informed Consent (EFIC)
 - Appendix for Multi-Site Research
 - Appendix for Department of Defense (DoD) Research

Attestations

- Advisor Attestation (Students)
 - Attestation form available or an email is acceptable
 - Office of Research & Scholarship will ask Dissertation/DNP Project Chair for the Attestation and send the student a copy
- Attestation for Scientific/Scholarly Review and Department Review (research projects)
 - Attestation forms available or an email is acceptable
 - Will be provided by the Office of Research & Scholarship if needed
- In eIRB, upload Attestation(s) in Local Site Documents, Other attachments as Institutional approval



Submitting Documents

- Submit documents to the College of Nursing Office of Research & Scholarship (Alice Pasvogel apasv@arizona.edu) for review before submitting in eIRB
- Things to remember when submitting documents:
 - Microsoft Word documents are required for IRB Protocol form, recruitment material, consent documents



Steps in the Review and Submission Process

- Submit completed IRB Protocol form and supporting documents to the College of Nursing Office of Research & Scholarship (Alice Pasvogel apasv@arizona.edu)
 - Revisions requested if needed
- Complete the Smart Form in eIRB
 - Assign Alice Pasvogel as Primary Contact
 - Assign DNP Project/Dissertation Chair as PI Proxy (Students)
- Email Alice Pasvogel with study number (STUDY0009183)
 - Alice Pasvogel will review the form and notify you when it is ready to submit in eIRB



Steps in the Review and Submission Process (cont.)

- Reviewed by IRB
 - Clarification requested if needed
- Conflict of Interest Research Certification (research projects)
 - Required for PI and study team members listed in Smart Form
- Approval/Determination
 - Determination/Approval letter available in eIRB
 - Stamped consent documents available in eIRB (research projects)



Project Approval

- Projects approved with Exempt or minimal risk status generally have no expiration date
- Projects approved with Expedited status or full committee approval will have an expiration date, generally 1 year
- Continuing Review needed for projects with an expiration date
- Submit Continuing Review 30-45 days prior to the expiration date



Timeframe for Review and Approval

- College of Nursing review
 - 1 week
- University of Arizona IRB review
 - 4-6 weeks
- Total average time
 - 1-2 months



Modifications

- For research projects approved with Exempt or minimal risk status, review guidance on IRB website for Exempt and Minimal Risk Research <https://research.arizona.edu/compliance-public/human-subjects-protection-program/guidance-researchers>
- For research projects approved with Expedited status or full committee approval, IRB approval needed for all changes/modifications
- Submit Modification in eIRB



Project Conclusion

- All projects need to be concluded
- Submit Continuing Review in eIRB to conclude research projects
- Closures for deferred studies, those using an external IRB, should be submitted via the main study workspace Comment section in eIRB
 - Attach the Closure Notice from the external site to a Comment and select notify “IRB Coordinator” to ensure the submission is processed
 - Once processed, the study status will be updated with the change; you can log into the study workspace to view the study update
- For projects with a determination of ‘Not Human Research’, contact Alice Pasvogel (apasv@arizona.edu) for instructions.



IRB Website

- <https://research.arizona.edu/compliance/human-subjects-protection-program>
- IRB Protocol forms
- Appendices
- Consent templates
- Additional forms
- Guidance
- eIRB information



College of Nursing Website

- <https://www.nursing.arizona.edu/resources/research>
- IRB process
 - IRB Review and Submission Process (PowerPoint)
 - Human Subjects FAQs
 - Additional Information Quality Improvement Projects
 - Additional Information Research Projects
- Tips on completing IRB Protocol forms
- Templates
- Step by Step Processes for submitting in eIRB
- Links to required training
 - Human Subjects Training (CITI)
 - Conflict of Interest Training and Disclosure
 - Research Security Training
 - HIPAA Training
- Link to the Human Subjects Protection Program which is the University of Arizona IRB



Assistance Available

- DNP Project/Dissertation Chair (Students)
- College of Nursing website
 - <https://www.nursing.arizona.edu/resources/research>
- Alice Pasvogel
 - apasv@arizona.edu

Summary

- Presented information on:
 - IRB Protocol forms
 - Process in the College of Nursing
 - Process at the University of Arizona IRB
 - Modifications
 - Project conclusion
- Multi-step process
 - Review in College of Nursing before submission in eIRB
- Process takes time
 - 1-2 months



Questions?

- Contact Alice Pasvogel
 - apasv@arizona.edu
 - 520-626-6656