

Appendix E: Instructions for IRB Application for Doctoral Students

Effective or Revised Date: 12/01/20

The purpose of the Institutional Review Board (IRB) is to ensure ethical research practices among its students and faculty. Anyone affiliated with UAGC who is pursuing a research project, called a “Principal Investigator,” must submit an IRB Application package and receive full approval from the IRB before commencing the study, including, but not limited to, solicitation of any human participants or collection of any data, including pilot data. For dissertation and Applied Doctoral Project (ADP) students, IRB approval is necessary before the study can be conducted regardless of the research methodology.

The following are instructions to assist in the preparation of an Institutional Review Board application package. Please read through the instructions thoroughly with any questions being directed to IRB@uagc.edu. The IRB Handbook provides additional details and should be referenced as necessary.

Do not proceed with the research until written IRB approval has been received. Absolutely no solicitation of human participants or data collection is allowed prior to receipt of IRB approval, including pilot studies. If this has been found to occur any applications in process or approvals granted will be removed.

Submission Instructions

The submission instructions for an application may be different depending on whether the submission is the initial application or a required resubmission. The following outlines submission instructions and the required documents.

Required Documents for Initial Submissions

Investigators are encouraged to use the templates and other forms found [UAGC IRB homepage](#), to ensure the appropriate information is included in the IRB submission. Investigators must submit one copy of the following for all initial submissions to: IRB@uagc.edu:

1. A completed *Request for IRB Review for Doctoral Students* cover sheet including a narrative response to all open-ended questions on the form. The Chair and student should ensure which application status is appropriate to select based on a thorough review of the IRB Handbook and based on the specific study design and participants (exempt, expedited, or full). The dissertation/ADP Chair must sign the *Request for IRB Review for Doctoral Students* cover sheet approving that the entire initial application is complete prior to IRB submission;
2. A *Research Summary* (the dissertation/ADP proposal will NOT be accepted) following the format specified in the *Research Summary* document. Use the *Research Summary Exemplar* and *Research Summary Template* to help write the *Research Summary*);
3. Informed consent document(s), if applicable;
4. Copies of any survey or assessment instruments or interview/focus/group/observational protocols;
5. All other relevant materials: copies of any communications to be used to solicit participants; organizational permission form(s) to access participants, data, or use premises; permission to use or modify instrument form(s) for instruments not in the public domain; and non-disclosure agreements, if applicable. Note: Permission is not necessary to use without modification instruments that are available for purchase. The student should provide information documenting the availability of any instruments available for purchase, such as copies of a purchase estimate or receipt; and
6. Copy of the CITI Completion Report for the two required CITI certifications (Student [HSR SBE]; Student [IPS]), with:
 - a. Overall passing score of at least 90% for each required set of modules, and
 - b. The expiration date for each module does not expire prior to the end of the twelve-month IRB Approval phase.
7. If Full Review is expected, investigator should have all application materials sent to IRB@UAGC.edu by the 15th of the previous month. Please see Full Review Specifics section below for more specific information on Full Reviews.

Additional questions regarding CITI certification can be directed to IRB@uagc.edu.

Formatting Requirements for Files – Initial Submissions

Initial IRB applications have formatting requirements designed to ensure the integrity of the documents and to reduce the length of time it takes the IRB to conduct a review. Please see below for the formatting requirements of an initial submission to the IRB:

1. All files must be in PDF format. Word files can be easily “Saved As” a PDF file.
2. All files must be saved using the same format for each file (Last Name, First Name, Name of Document).
 - a. Smith John Research Summary
3. File names should not include any special characters (e.g. & #).

IRB Feedback Timeframe

Applications to the IRB are submitted to IRB@uagc.edu. Applications will be acknowledged by the IRB Secretary within 24-48 hours Monday - Friday. There is one form for submission to the IRB that covers all three categories of review. The IRB Committee Member assigned will evaluate the application alongside the IRB Chair to determine whether the project qualifies for the type of review that has been selected (exempt, expedited, or full). More information on all three review types can be found in the IRB Handbook.

The category of review will be communicated back to the applicant within 7 working days. Action on Exempt research is generally taken within 7 to 10 working days of receipt by the IRB Committee. An Expedited Review requires review by one or more members of the IRB and action generally takes 12 to 18 working days. Lastly, a Full Review requires a meeting of the IRB and generally takes 15 to 25 working days. For most efficient consideration of the request for Full Review, all forms and materials must be submitted by the 15th of the preceding month. Please see the Full Review Specifics section below for more specific information.

Working days are considered normal days of operation (Monday – Friday), excluding any observed holidays by the University of Arizona Global Campus. Feedback will be sent by the IRB Committee via email to the Principal Investigator and the student investigator’s Chair will be cc’d on the communication.

The IRB strives to review submissions within the prescribed timeframes, but on occasion may need additional time for review.

Full Review Specifics

Full Reviews are conducted for research that involves protected classes or for research whose risk may be more than the benefit derived from the results. In the interest of a successful dissertation or ADP, research involving protected classes should be avoided wherever possible. A Full Review requires a virtual meeting with the IRB. The IRB meets monthly on the second Tuesday of each month, so long as there is a full quorum. If the IRB Chair deems an application to be a Full Review, investigators must have all application materials into IRB@uagc.edu by the 15th of the previous month of the next meeting. The student investigator’s assigned IRB Committee Member will provide information on dates, time, and any expectations for the meeting. *Following a Full Board Review, the IRB will make one of the following decisions regarding the proposal: approved, approved with conditions, or disapproved, in which case suggestions for major revisions will be given to the investigator. If the request is approved with conditions, the investigator may not proceed with the research until documentation of the requested changes is reviewed and approved by the IRB. As stated above, no data collection, subject recruitment, or interactions with human participants can occur until an IRB Approval Letter has been received.*

IRB Types of Feedback

There are four types of feedback that the IRB will provide following review of an IRB application (approved, approved with conditions, deferred, or disapproved). See the IRB Handbook for more information about Actions by the IRB. Investigators are not allowed to start conducting research until an IRB Approval Letter is received.

Applications following a deferred or disapproved feedback letter will require investigators to resubmit everything for a new initial submission plus an *IRB Change Matrix* and *IRB Change Matrix Authorization Form* to the IRB for consideration. The latter forms help to demonstrate how your new research differs from the research that was previously disapproved.

If an investigator receives a conditional approval, the resubmission will be required to include only the materials that are requested by the IRB. The IRB Number must be included on all Informed Consent documents. Resubmissions after conditional approval will be reviewed within three working days per document (e.g. student submits two CITI certifications under a conditional approval, the timeframe for feedback/action would be six working days).

Formatting Requirements for Files –Resubmissions

- All files must be in PDF format. Word files can be easily “Saved As” a PDF file.
- All files must be saved using the same format for each file (IRB Number, Last Name, First Name, Name of Document).
- IRB 16-XXX-XX Smith John Research Summary
- File names should not include any special characters (e.g. & #)

Any resubmitted applications that are not completed will be halted and require an investigator to resubmit his or her application to the specifications set above.

Student investigators or Chairs with questions related to this material may contact the IRB Chair by emailing IRB@UAGC.edu.

IRB Application Checklists

Initial Application Checklist

- _____ *Request for IRB Review for Doctoral Students* cover sheet is filled out, signed, and included.
- _____ Type of review has been selected (exempt, expedited, or full).
- _____ If the Principal Investigator is a student, the Chair has also signed.
- _____ If Full Review, all application materials submitted to IRB@uagc.edu by the 15th of the previous month.
- _____ Research Summary is included (See *Research Summary*, *Research Summary Exemplar*, and *Research Summary Template* on the [UAGC IRB Forms](#) page).
- _____ CITI Completion Reports are included (Student [HSR SBE]; Student [IPS]).
- _____ All supporting documents are included.
- _____ All documents submitted are in PDF format.
- _____ All documents are named using correct format (Last Name, First Name, and Name of Document) (example: Smith John Research Summary).
- _____ File names do not include any special characters (e.g. & #).

Resubmission Application Checklist (after Approved with Conditions)

- _____ *IRB Change Matrix* is included in resubmission application process.
- _____ If the Principal Investigator is a student, *IRB Change Matrix Chair Authorization Form*, (signed by Chair) is included.
- _____ All documents requested by IRB for resubmission are included.
- _____ All documents submitted are in PDF format.
- _____ All documents are named using correct format for Resubmission Application (IRB Number, Last Name, First Name, and Name of Document) (example: IRB 16-XXX-XX Smith John Research Summary).
- _____ File names do not include any special characters (e.g. & #).

Resubmission Application Checklist (after Deferred or Disapproved)

- _____ *Request for IRB Review for Doctoral Students* cover sheet is filled out, signed, and included.
- _____ Type of review has been selected (exempt, expedited, or full).
- _____ If the Principal Investigator is a student, the Chair has also signed.
- _____ If Full Review, all application materials (re-)submitted to IRB@uagc.edu by the 15th of the previous month.
- _____ Research Summary is included (See *Research Summary*, *Research Summary Exemplar*, and *Research Summary Template* on the [UAGC IRB Forms](#) page).
- _____ CITI Completion Reports are included (Student [HSR SBE]; Student [IPS]).
- _____ All supporting documents are included.
- _____ *IRB Change Matrix* is included in resubmission application process.
- _____ If the Principal Investigator is a student, *IRB Change Matrix Chair Authorization Form*, (signed by Chair) is included.
- _____ All documents submitted are in PDF format.
- _____ All documents are named using correct format for Resubmission Application (IRB Number, Last Name, First Name, and Name of Document) (example: IRB 16-XXX-XX Smith John Research Summary).
- _____ File names do not include any special characters (e.g. & #).