



Institutional Review Board
For Human Participant Research
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Institutional Review Board Policy, Requirements, and Principal Investigator Instructions

IRB Purpose

The Federal Government requires all studies involving humans to undergo review by an Institutional Review Board (IRB) before it can be funded or carried out. The main goal of an IRB is to protect the rights and welfare of the participants in any research project. The laws and rules governing an IRB are described in CFR 45 Public Welfare part 46 Protection of Human Subjects.

For more information on the laws follow the link below or refer to the document included with this packet. <https://www.hhs.gov/ohrp/sites/default/files/ohrp/humansubjects/regbook2013.pdf.pdf>

University of Charleston's policy requires review and approval of all activities which involve using human participants in research be reviewed by the UC-IRB, or in special cases, the Charleston Area Medical Center (CAMC) IRB (see Cooperating Institutions or Sites for more information). The IRB is responsible to the Provost. Approval of the IRB must be obtained prior to involvement of human participants. Failure to have human participants research reviewed by the IRB, including those protocols believed to be exempt, is a violation of University policy and will be reported to the Provost for disciplinary action.

Cooperating Institutions or Sites

Regardless of the site of the research, all research on human subjects conducted by University of Charleston researchers must be reviewed by the UC-IRB, with the exception of research approved by the IRB of CAMC. If the research approved by the CAMC-IRB, copies of all forms submitted to the CAMC-IRB must be copied to the UC-IRB for record keeping. These copies should be sent to the UC-IRB Chair, Rebecca Linger, UC-Charleston, Box 9. All institutions that participate in human subject research with University of Charleston researchers must have a Federal Wide Assurance (FWA).

Training

Online training for faculty, students and research collaborators engaging in Human Subject Research at the University of Charleston is provided through our subscription to the Collaborative Institutional Training Initiative (CITI) Program (<http://citiprogram.org>)

A copy of ALL investigators' training certificates must accompany each application. It is the Primary Investigator's responsibility to furnish a current certificate for each investigator with the application, as the IRB does not track or maintain records of investigator training separate from the application.

If you have not completed the training within the past three years, please follow the link provided to complete it before submitting your proposal.

Type of Review and Application

Depending on the risk involved to participants of your proposed study, your research proposal may qualify for one of three levels of review: Exempt, Expedited, or Full Review. The following steps are designed to assist you in choosing the level of review.

If your project meets all of the following criteria, you should select Exempt Review Requested.

- Research conducted in established or commonly accepted educational settings.
- Research involving the use of educational tests if participants cannot be identified.
- Research involving surveys, interviews, or observations of public behavior that does not deal with sensitive or critical responses. All research using survey or interview procedures is exempt when the respondents are elected, appointed public officials, or candidates for public office.
- The project will not involve participants in high risk groups (See Expedited Application, Item 10).
- Research involving the collection or study of existing data or specimens that are either publicly available, or not individually identifiable.

If your project meets any of the following criteria, you should select Expedited Review.

- Collection of hair, nail clippings, dental plaque and calculus or teeth in a non-disfiguring manner, or secretions.
- Recording of data from participants 18 years of age or older using noninvasive procedures routinely employed in clinical practice.
- Collection of small amounts of blood (550 mL or two samples per week) by venipuncture from healthy, non-pregnant participants, 18 years of age or older and weighing at least 110 pounds.
- Voice recordings made for research purposes such as investigations of speech defects.
- Moderate exercise by healthy volunteers.
- Study of existing data, documents, records, pathological specimens, or diagnostic specimens.
- Research on individual or group behavior where the investigator does not manipulate participants' behavior and the research will not involve stress to the participants.
- Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.

If your project does not meet the criteria above, you must select Full Review.

Required Documents

All documents should be submitted 1) Electronically or 2) signed hard or scanned copy.

Electronic Copies to: irb@ucwv.edu or Hard (paper) copies to: Institutional Review Board, UC-Charleston, Box 9.

If you selected Exempt Review Requested, you must submit the following items:

- Application for Exempt Review (Application and Consent Form)
- Explanation of study for participants (informed consent optional)
- Appendices [eg: surveys, questionnaires, or tests] (conditional)
- Consent for photographic or voice recording (conditional)
- Permission to conduct research at a Non-UC site (conditional)
- Proposal
- Sponsored Research Form (conditional)

Timeline

Assuming that the proposals are complete and that no major revisions are requested, the timeline for processing applications will be as follows:

- Exempt Review: Four weeks
- Expedited Review: Six weeks
- Full Review: Eight weeks

How to Submit Your Proposal

- 1) Begin Early to allow sufficient time for review to be completed before involving participants. Refer to timeline for standard time based on your application type.
- 2) Use current forms found on IRB webpage at: www.ucwv.edu/Academics/Research/Institutional-Review-Board/
- 3) Use all forms/items, as outlined under Required Documents
- 4) Complete all forms in their entirety.
- 5) Verify that you have fully described the method of confidential storage of data.
- 6) Compile your proposal with the appropriate forms and materials.
- 7) Submit an electronic copy of your proposal to the IRB via email to: irb@ucwv.edu
- 8) Print a hard (paper) copy of your application.
- 9) Obtain all required signatures on your hard (paper) copy or Adobe Digital Signature.
- 10) Submit your signed (paper) copy via interoffice mail to: Institutional Review Board, UC-Charleston, Box 9.
- 11) Be Patient. Keep in mind the timeline for your category, while your proposal is “Out for Review.”
- 12) IRB Response will be sent to you in the form of an email letter, stating that:
 - a) Your proposal has been approved; that you may proceed with your research, and listing your IRB number. You will not receive your IRB number prior to the issuance of this letter. (Do not begin any work until you receive this letter.) Or,
 - b) You will be asked to provide additional information, forms, or to alter your proposal in some way. (If you receive this request, it is important that you respond quickly, delays in responding will delay the approval process of your application. Failure to respond will result in your application not being approved.

Follow-up

All correspondence to the IRB about existing protocols must contain your protocol number.

Studies which have a greater than minimal risk to test subjects must be reviewed on an annual basis; unless they are officially closed via the submission of a Closure Report to the UC-IRB. All proposals and related signed consent forms must be placed in the IRB files, where they are housed for at least three years after the completion of your study. Therefore, it is your responsibility to follow-up to ensure that you properly close your file or request a renewal.

If your project extends beyond the anniversary of your approval, you must submit an Annual Renewal-Progress Report.

Once you have completed your study or decide to terminate it, you must file a Notice of Closure form to close out your file.

These forms can be found on the IRB website: <http://www.ucwv.edu/Academics/Research/Institutional-Review-Board/>

Questions or concerns, please contact Rebecca Linger, IRB Chair, x-4998 or irb@ucwv.edu