INSTITUTIONAL REVIEW BOARD
STUDENT (OTHER INVESTIGATOR) INSTRUCTIONS & INFORMATION

Do NOT begin work until written IRB approval is issued!

Please read these in its entirety, before you begin. Note that only faculty members can serve as “Principal Investigators”, students are listed as “Other Investigator”. You should work with your faculty member in determining what forms you need.

**Type of Review and Application:**

You should meet with your Principal Investigator (Faculty Member) to determine the forms required for your project. 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 **Exemption Requested Review**.

- 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 do 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 (On 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 2 samples per week) by venipuncture from healthy, non-pregnant participants 18 years of age or older and weigh 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 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:**

Refer to the checklist on your application, to ensure you have attached all required documentation. Some of the documents may include, but are not limited to:

- Application,
- NIH Training Certificate (For Each Investigator),
- Informed Consent,
- Proposal or Informational Survey,
- Explanation of study for participants (informed consent-optional),
- Appendices (surveys, questionnaires, or tests) (conditional),
- Consent for photographic or voice recording (conditional),
- Permission to conduct research on non-UC Site, if applicable,
- Electrical equipment safety check memo (conditional),
- Sponsored Research Form (conditional)

**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: [http://www.ucwv.edu/IRB/](http://www.ucwv.edu/IRB/). Download forms no more than two weeks prior to submitting your application, to ensure you are using the most current version of the application.
3) **Use** all forms/items, as outlined under Required Documents and complete them in their entirety.
4) **Verify** that you have fully described the method of confidential storage of data and access to it.
5) **Print** a hard (paper) copy of your entire proposal and **obtain** all required signatures. (Adobe Digital Signatures are acceptable).
6) **Submit** your fully completed and signed application via one of the following methods:
   a. Electronically – Scan entire application packet into one PDF and email to [irb@ucwv.edu](mailto:irb@ucwv.edu)
   OR
   b. Interoffice Mail To - Institutional Review Board, UC - Charleston, Mailbox #9.
7) **Be Patient**, while your proposal is “Out for Review”. Assuming that the proposals are complete and that no major revisions are requested, the timeline for processing applications is: 4 weeks for Exempt Review, 6 weeks for Expedited Review, and 8 weeks for Full Review.
8) **IRB Response** will be sent to you in the form of an email, stating that:
   a) Your proposal has been approved and issued your application number. *(Do not begin any work until you receive this letter.)*
   OR
   b) You will be requested to provide additional information, forms, or to alter your proposal in some way. *(Respond promptly to all requests, to avoid delays in approval.)*

**Follow-up:**

It is your responsibility to follow-up with renewals or closures.

- Your project, once approved, is good for one year and approval expires on your anniversary.
- You may not continue beyond your anniversary; unless, you have applied for Renewal and received written approval. Submit “Annual Renewal-Progress Report” 60 days before expiration.
- If you finish or terminate your project prior to the anniversary of your approval, you must submit a Closure Report and Summary of your findings to the IRB. This will be maintained in the IRB Files for a period of 3 years.
- The project must be closed or renewed, even if the student graduates. The project will not automatically close or renew.
- These forms can be located on the website at: [http://www.ucwv.edu/IRB/](http://www.ucwv.edu/IRB/)

**Questions or concerns, please contact Juliana Serafin, Chair at: x-4939 or irb@ucwv.edu**
Institutional Review Board (IRB)

Frequently Asked Questions

It is our goal that this will help guide you through the IRB process and give you an understanding the importance of the IRB and your compliance with the process.

What is the purpose of an IRB? The purpose of the IRB is to review projects involving human research to ensure that the subjects are treated humanely and fairly. Failure to comply with federal regulations by not having a functioning IRB or not notifying the IRB of such projects and obtaining approval prior to starting a project could cause UC to lose federal funding. Therefore, it is extremely important that these projects go through the proper approval process and you do not begin any human research until you receive a written approval from the IRB.

When do I need to have a project reviewed by the IRB? Anytime you have a project involving collection of data or samples from human subjects or research on human subjects. This includes surveys; unless they are only asking for opinions. (Refer to UC IRB website for more detailed guidelines.)

Who is the Principal Investigator? This must be a UC Faculty Member, normally the faculty member assigning the project.

How do I submit an application?
- Meet with your Professor/Instructor to discuss the type of application you need. Review the checklist on our site for more detail. Once you select the type of application, it will list the forms required.
- Complete the application in its entirety, attach any additional forms (survey’s, consents, questionnaires, tests, etc.) and sign the application under “Other Investigator”.
- Take the completed application packet to your Professor/Instructor and ask him/her to review it and sign it as the “Principal Investigator”.
- Take the completed application packet to the Chair of that Department/Division, ask him/her to review it and sign off on it.
- Forward your completed application to Marea Dodd in the School of Pharmacy either electronically or via interoffice mail.

What happens next? Upon receipt of your application packet, it will be checked for completeness, all required signatures, and all required documents. If it is acceptable, it will be forwarded for IRB Review. If it is not acceptable, it will be returned to your Principal Investigator for corrections.

Once your application has gone out for review, the reviewers normally have 2 weeks to review the material. If the reviewers accept your application as is, your application will be forwarded for an approval. If the reviewers do not accept your application as is, you will be notified to make modifications or clarifications. At that point, your response is required before your application can move forward.

How long does it take to get approval? This depends on how long it takes for the IRB to receive all required documents from you and how quickly you respond to requests for modification or clarification. If you have been thorough with your application, it should take around 2 weeks for an Exempt Review, 4 weeks for an Expedited Review, and 6 weeks for a Full Review. However, these are only estimates and a lot depends upon you.

How do I know when my application is approved? Once your application is approved, you will be issued an approval letter with your application number.

How long is my approval good for? Once approved, your approval is good for one year. If you expect your project to go beyond your 1 year anniversary, it is your responsibility to get with your PI and submit a “Renewal / Progress Report” 60 days prior to the expiration.

Other Reports? Once you have completed your project, you must formally close it. You will need to complete a “Closure Report” and have it signed by your PI, then attach a copy of your summary before forwarding to the IRB. If your project requires work beyond the expiration of approval, you will need to complete a “Renewal Application / Progress Report”.

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