Investigator Responsibilities:

The researcher(s) named in the protocol application will be responsible for the oversight of the study involving human subjects. Responsibilities include (but are not limited to):

- Obtaining IRB approval, prior to starting work on any project with human subjects
- Mentoring and monitoring students working on human subjects research
- If applicable, requesting extensions to protocols approved under expedited and full board review
- Notifying the IRB of any proposed changes to approved protocol materials
- Reporting to the IRB any adverse events involving human subjects that take place during the course of a study

Additional Resources:

U.S. Department of Health and Human Services (DHHS):
www.dhs.gov

45 CFR Part 46:

For any additional questions or concerns, please contact:

Stefanie Hamberger, IRB Coordinator
shamberger@ubalt.edu
410 837-4057

UB Institutional Review Board
Full Board Submission Deadlines and Meeting Dates

<table>
<thead>
<tr>
<th>Submission Deadline</th>
<th>Meeting Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sept. 16, 2019</td>
<td>Sept. 23, 2019</td>
</tr>
<tr>
<td>Oct. 14, 2019</td>
<td>Oct. 21, 2019</td>
</tr>
<tr>
<td>Nov. 11, 2019</td>
<td>Nov. 18, 2019</td>
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<tr>
<td>Dec. 2, 2019</td>
<td>Dec. 9, 2019</td>
</tr>
<tr>
<td>Jan. 27, 2020</td>
<td>Feb. 3, 2020</td>
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<tr>
<td>Feb. 10, 2020</td>
<td>Feb. 17, 2020</td>
</tr>
<tr>
<td>Mar. 9, 2020</td>
<td>Mar. 16, 2020</td>
</tr>
<tr>
<td>Apr. 13, 2020</td>
<td>Apr. 20, 2020</td>
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<tr>
<td>May 11, 2020</td>
<td>May 18, 2020</td>
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</tbody>
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*For protocols submitted for full board review - it is recommended that the researcher be present at the IRB meeting.*

For Questions/Protocol Submission:
irb@ubalt.edu
(410) 837–4057

IRB Website:
www.ubalt.edu/irb

IRB Coordinator:
Stefanie Hamberger, Office of Sponsored Research
shamberger@ubalt.edu
(410) 837–4057
IRB Quick Reference Guide

What is the IRB?
The UB Institutional Review Board (IRB) is a committee established in accordance with the Federal regulations put forth in 45 CFR 46, to ensure the protection of human subjects in research. The IRB has sole authority to review, approve, modify, disapprove, suspend, or terminate research protocols involving human subjects. The IRB is committed to providing timely and high quality review, education, and monitoring of human research projects while facilitating excellence in research.

Who are the IRB members?
The IRB is comprised of seven UB faculty members from all academic areas at UB, one external member from the community, and an IRB Coordinator from the Office of Sponsored Research. The IRB is currently chaired by Dr. Gabriela Wasileski in the School of Criminal Justice, the IRB Coordinator is Stefanie Dwyer, in the Office of Sponsored Research.

Submission
All UB faculty, staff, and students, who anticipate using human subjects in a research project should complete an online Kuali Protocols IRB Application available at https://ubalt.kuali.co/protocols/portal/protocols or in the tools section of MyUB.
You must attach sample study instruments (surveys, interview questions, etc.), and applicable consent documents in your Kuali application.

Timeline (for applications to be considered by the UB IRB and a decision rendered)
For exempt protocols/renewals/ modifications – allow (2) weeks.
For expedited protocols - allow (3) weeks.
For full board review – allow (5) weeks.
*If the protocol is approved, the researcher will receive a formal determination letter.
**IRB approval must be granted prior to commencement of any project activities involving human subjects**

When Does a Project Require IRB Review and Approval?
Any project that includes the study of, an intervention or interaction with, human subject participants may require review and approval by the IRB. IRB review and approval is required when the definitions of both “human subject” and “research” are satisfied within the project scope. The regulatory definition of each is as follows [45 CFR 46.102(f)]:

“Research” – a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

“Human subject” – a living individual about whom an investigator (whether professional or student) conducting research (1) obtains data through intervention or interaction with the individual, or (2) identifiable private information.

Key Terms to Note:

Develop or contribute to generalizable knowledge – means the research is designed to draw general conclusions, inform policy, develop theories, principals or relationships and interpretations that can be widely applied. If the intent is to disseminate the results beyond an individual or internal group, the research is generalizable. Dissemination activities include publication, presentation, thesis or dissertation work. However, just because a project is not published or presented, does not mean it is not research.

Intervention – means both physical procedures by which data are gathered (i.e. behavioral studies) and manipulations of the subject or the subject’s environment that are performed for research purposes.

Interaction – means communication or interpersonal contact between investigator and subject.

Private/Identifiable Information – Any data element or combination of data elements that would allow for identification of a study participant. Examples: name, address, UB ID, telephone number, work address, social security #, etc.

Research Categories:
There are (3) categories of research:

“Exempt” – A project that is determined to be “exempt” from IRB review does not require further regulatory review, including continuing review.

“Expedited Review” – Expedited review can be carried out by the IRB Chair or by one or more experienced reviewers. The reviewers exercise all of the authorities of the IRB. The review process involves the same criteria as full board review. *Expedited review no longer requires continuing review (no expiration) unless IRB documents a rationale for requiring it.*

“Full Board Review” – The IRB determination requires a majority vote by a quorum of the full IRB committee with continuing review at least annually.

IRB Application Requirements:
All researchers who intend to utilize human subjects for research purposes must submit an online Kuali Protocols IRB Application available at https://ubalt.kuali.co/protocols/portal/protocols or in the tools section of MyUB.
You must attach sample study instruments (surveys, interview questions, etc.), and applicable consent documents in your Kuali application.

• Informed Consent Document. A template is available at www.ubalt.edu/irb
• Sample study questionnaire(s) or interview questions (if applicable)
• Any other materials to be used by researcher for work with human subjects.