University of Massachusetts
Boston
Institutional Review Board (IRB)
Instructions and Guidelines

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Federal Wide Assurance No. FWA00004634
About the Institutional Review Board

The IRB is a federally mandated administrative body established to protect the rights and welfare of human research participants recruited to participate in research activities conducted at the university. The IRB has authority to approve, require modifications in, or disapprove all research activities that fall within its jurisdiction as specified and approved by both the federal regulation and local institutional policy.

Any investigator proposing to initiate a project that involves the use of human participants must submit an application to the IRB for review. The IRB will then review your application and determine approval status. The agreement in place between this campus and the federal government (our Federal Wide Assurance # FWA00004634) prohibits any UMass Boston investigator (faculty, staff or student) from initiating any research project (funded or unfunded) involving human participants prior to receiving approval from the IRB. The following guidelines will assist you in applying, and maintaining your IRB submission.

If you have questions regarding this application, please call or e-mail the IRB Administrator (ext 7-5374; human.subjects@umb.edu) for further information.

Instructions for those conducting Human Subject Research at the University of Massachusetts Boston

Prior to completing the application:

   This document is the code of regulations for carrying out human participants’ research.

2. Collateral Site Approval
   If you plan to recruit participants or otherwise carry out research activities at an institution (e.g., school, hospital, etc.) other than UMass Boston, you will need to gain permission from that site as well as UMass Boston. If you have not already contacted the collateral site, it is recommended that you do so immediately to inquire about the possibility of conducting research there. You do not need to have approval from the collateral site before beginning the review process at UMass Boston. You, however, will need to document approval and submit any modifications stipulated by the collateral IRB before receiving final approval from the UMass Boston IRB. It is possible for one IRB to defer to another. This is called an Authorization Agreement and can be found on the IRB website. This document must be filled out completely and then signed by the Signatory Officials from each institution; each institution then receives a copy for the IRB to file.

   **Boston Public Schools (BPS) exception:** Please note that if your research involves children recruited through the Boston Public Schools, it is recommended that you gain approval from their IRB prior to submitting an application at UMass Boston. This recommendation is made because some investigators have completed IRB review at UMass only to find that BPS declined to give them access to their students.

3. Health Related Data
   If you plan to collect health-related information, other than directly from the subjects themselves, you are required to comply with the HIPAA Standards for Privacy of Individually Identifiable Health Information Regulations (45 CFR 160-164). These regulations were effective as of April 14, 2003. You will be required to either verify that any health-related data meets regulatory criteria for being de-identified or that your procedures for accessing private health information are HIPAA compliant. This application will assist you in maintaining HIPAA compliance. For more questions, see http://www.hhs.gov/ocr/privacy/

4. Training
   All PIs and co-investigators are required to provide evidence of their understanding of federal rules and regulations, as well as UMass Boston policies and procedures concerning research with human subjects
before the IRB will consider the approval of submissions. In addition, the release of university funds, whether from external or internal sponsors, that support research with human subjects requires similar evidence. For students engaged in research with human subjects, both the student and his or her faculty or staff sponsor must provide the required evidence.

UMass Boston has contracted with the University of Miami to provide free online training on issues related to the protection of human subjects in research for members of the university community through the Collaborative IRB Training Initiative (CITI). The CITI modules span a variety of areas including assessment of risk, informed consent, and research involving special populations such as children or prisoners. All UMass Boston researchers engaged in research with human subjects are required to complete the CITI training course. The required modules can be completed in more than one sitting at the researcher’s convenience.

The website is www.citiprogram.org. The trainings offered are below. Please choose the modules that would suit your needs below. Faculty should assign to students which modules would suit the classes needs.

- Social & Behavioral Research Investigators and Key Personnel
- Biomedical Research
- Biomedical Data or Specimens Only Research
- IRB Members
- Students - Class projects

The Application:

1. On the cover sheet, complete information about PI, the Co-investigator (if applicable) and/or Study Coordinator. Include contact information (name/dept., address for students, CITI Training completion date; this would be on your completion form you printed after passing the test, etc.).

2. Students must have the name of their advisor and their advisor’s contact information on the application form.

3. In Section 2, include the title of the study, a short summary, information regarding the study subjects. The PI will also choose which type of review she/he is seeking. (link to DHHS review categories is provided)

4. Section 3 regards funding and Financial Conflict of Interest. Here the PI will certify whether there is or is not a financial conflict of interest.

5. Section 4 regards HIPAA and PHI. The PI must clarify whether or not PHI will be collected from the subjects.

6. The end of the application requires signatures from the Principal Investigator, Co-investigator, Departmental Head/Chair, and if applicable, the Student Advisor. The statements prior to each signature line should be read carefully as they refer to the key responsibilities each signatory is accepting in conducting human participant research at the UMass Boston. **The IRB will not review any protocol that does not include the required signatures.**

Relevant supporting materials:

1. Recruitment materials, informed consent and assent, scripts, advertising text, measures, letters to subjects, screening tools and surveys. All recruitment materials MUST use these words “Research” and “Volunteer”, must have UMass Boston logo or mention affiliation with the University, and must have the PI’s contact information including department. After receiving the IRB approval stamp on the recruitment materials, the PI must go to Student Activities and receive their approval stamp before posting anything on the UMB campus. If recruitment
materials are posted on the UMB campus without the approval stamps from the IRB and Student Activities offices the materials will be taken down and the PI will need to submit a protocol violation form.

2. Submit your application to the IRB Administrator, (Quinn Administration Building, 2nd floor, Room 080).

3. The PI, student advisor and department head/chair are responsible for the entire submission to the IRB. It is their responsibility to make sure the all documents are in order. This includes grammatical errors, spelling errors, and quality of over the research overall. The IRB will table, reject and return without review submissions that are substandard.

   **Deadlines:**
   - **EXEMPT** and **EXPEDITED** reviews are ongoing (no deadline). Submit two copies of all materials.
   - **FULL BOARD** review applications have a specific monthly deadline. Please refer to http://www.umb.edu/research/policies_procedures/research_compliance/institutional_review_board_irb for meeting dates and submission deadlines. You must submit 13 copies of all protocol documents. **Please note that if you miss the submission deadline for IRB review, your application will be held for the following month’s IRB meeting.** The IRB will review a maximum of 4 new protocols per meeting (meetings may also include modifications and annual review submissions) and the agenda is filled in the order in which applications are received. Once meeting agenda is full, additional submissions will be reviewed on the next meeting date.

   **PAGENATE THE ENTIRE SUBMISSION, INFORMED CONSENT, PROTOCOL, SCREENS, and TOOLS, This will assist in the review process.**

   **YOUR APPLICATION SHOULD BE SUBMITTED TO THE IRB ADMINISTRATOR, DO NOT DELAY THE REVIEW PROCESS BY SUBMITTING YOUR APPLICATION DIRECTLY TO THE IRB CHAIR OR BOARD MEMBERS. THEY CANNOT ACCEPT A PROTOCOL ON BEHALF OF THE IRB FOR REVIEW. ALL APPLICATIONS MUST BE LOGGED INTO THE DATABASE BY THE IRB ADMINISTRATOR. THE IRB ADMINISTRATOR WILL ALSO PROVIDE PRELIMINARY REVIEW.**

Research with Students:

Faculty may want to conduct research with their students for pedagogical reasons; this will fall under the exempt category and must be submitted to the IRB for review and approval. The IRB requires the PI to show in the protocol how the student subjects may decline without feeling coerced or obligated to participate. If the getting the names of the students is not necessary to the research the IRB recommends keeping the study anonymous.

Class Project Research:

A class project is an academic project or student assignment that may involve collection of data from human subjects when the data is used solely for the purpose of teaching course content and is not intended to be used to develop or contribute to generalizable knowledge. This type of “research” is considered exempt, but MUST be submitted to the IRB for review. The IRB will send the PI a letter approving the research upon its review and approval.

Once something is classified as a class project, it is always a class project. In other words, retroactive approval for data collected during or after a class cannot be added to ongoing data collection or for previously collected data.

All projects where human subjects may be involved must have the explicit approval of the course instructor. Course instructors who require such assignments are encouraged to undergo CITI IRB (as well as their students) training in order to ensure that their assignments and the work their students do comports with federal rules and guidelines.

Instructions and FAQ’s 10/31/2014
After Submission:

1. You will be notified in writing of the IRB’s decision to approve, request revisions (or additional information), or disapprove your protocol. The majority of applications require revision or additional materials; this will add additional time to the review process. **You may not begin recruitment or any other interactions with potential participants until you receive written notification of approval from the IRB.** The general timeframe for feedback regarding IRB submissions follows:

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<th>Time frame for IRB Submissions</th>
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<td>Please note the following time frame for receipt of initial feedback from the IRB. The majority of applications require at least one round of revision prior to approval. Please plan your project so that it allows sufficient time for review. After turning in your application, you should anticipate:</td>
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<td>• Within 7 business days: the IRB Administrator will contact you if application materials are missing or inadequate.</td>
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<td>• After initial review by the Administrator: Exempt and Expedited submissions will be sent to the Chair or Vice Chair of the IRB for official review.</td>
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<td>• After official review: If the study was approved the PI will receive an approval letter and stamped consent/assent forms and stamped recruitment materials. (only stamped copies of forms may be used) If you study requires revisions the letter will have an itemized list of required changes.</td>
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<td>• Within 1 week following the full board review: the IRB Administrator will contact you with feedback from the IRB meeting.</td>
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2. Duration of Approval

   Initial protocol approval is granted for one year. Approximately three months before the expiration of the approval, the IRB Administrator will send a reminder to complete the Continuing Review Form. Please keep in mind that the submission must not expire. If the study expires the University will be out of compliance with our Federal Wide Assurance (FWA) with OHRP. Approval of the continuing review extends the approval period for the project. **Exempt protocols are not subject to annual review.**

   **SHOULD YOU LET YOUR IRB APPROVAL LAPSE, YOU WILL BE REQUIRED TO RESUBMIT A NEW APPROVAL APPLICATION. THE IRB HAS THE RESPONSIBILITY TO SUSPEND YOUR PROJECT IF THE REQUIREMENT IS NOT FULFILLED IN A TIMELY MANNER.**

Modifications:

Any time you change any aspect of your project (e.g., recruitment process, administering materials, collecting data, gaining consent, changing participants) you will need to submit a Request for Modification. Make sure to address all of the information requested on the request for modification form(s). If approval of the modification must be done quickly please remember that the time frame for review of an application is the same for a modification.
Completion of the Project:

Upon completion of your project, you will need to submit a Final Report to the IRB. If the final report form is not submitted the research will expire in the IRB system and will be out of compliance with our FWA.

Unanticipated Events Involving Risk to Human Subjects or Others:

Unanticipated events involving risk to human subjects (including a breach of confidentiality) or others refers to any experience that has taken place during the course of a research project that, in the opinion of the Investigator(s), was harmful to a participant or others, increased the risks of harm in the research, or had an unfavorable impact on the risk/benefit ratio for the participant(s). Such events must be reported to the IRB as soon as possible after their occurrence. Any event that is life threatening must be reported to the IRB immediately. The IRB will determine if any modification to the approved protocol or consent process is required.

Protocol Violations

Violations generally do not have a major impact on subject welfare or data integrity. Examples of a protocol deviation may include:

- Scheduling a required procedure outside of the time frame specified in the protocol
- Increase in subject recruitment without a modification being submitted
- Implementation of unapproved recruitment procedure