Institutional Review Board Policies and Procedures

Authority. The Mary Baldwin University Institutional Review Board (IRB) is responsible for the oversight of all research activities at the University that involve human subjects. The MBU IRB is registered with the Department of Health and Human Services (DHHS; IRB: 00004838 and IORG: 0004078). Mary Baldwin has a Federal Wide Assurance (00008717) from the Office of Human Research Protection within the U.S. Department of Health and Human Services.

Mission and Purpose. The IRB is responsible for evaluating proposed human subjects research on the grounds of ethical responsibility and the protection of the rights of participants. The IRB is also committed to protecting academic freedom. To that end, it does not evaluate proposed research on the basis of the characteristics, methods, or quality of the research design, except to the extent that these affect the rights of participants and the protections extended to them.

Applicability. Any member of the MBU community – faculty, staff, or student – or outside researcher who is planning to conduct a research project that may involve the collection of data or specimens from human participants at Mary Baldwin University must review the following policies and procedures. All student research requires qualified MBU faculty to act as Principal Investigators (PI). Students will be listed on applications as Co-Principal Investigator (Co-PIs), working in partnership in the management, development, and/or execution of the project. This is to ensure and simplify research oversight by the IRB. All external research requires qualified MBU faculty as PI, Co-PI, or sponsorship.

Training. All PIs and CO PIs, must complete human subject research training prior to proposal submission. For more information on the training required, please refer to the human subjects training document on our IRB website (https://go.marybaldwin.edu/research/irb/).

Procedures for Proposal Submission. Individuals planning to collect human data or specimens as part of a proposed research project must submit a proposal/application to the IRB. The researcher may not begin data collection until he or she has received an approval letter from the IRB chair. Please note that most external funding agencies require that IRB approval be in place prior to the submission of a grant proposal.

Determining whether a proposed project involves human subjects research. Please use the "Checklist to determine if a project needs IRB approval and which proposal form to use" available on the IRB webpage (https://go.marybaldwin.edu/research/irb/). When it is not clear whether a proposed project falls within the covered definition of human subjects research, a determination will be made by the IRB Committee, in consultation with the Provost, according to the federal regulations (https://www.hhs.gov/ohrp/regulations-and-policy/index.html). Requests for determination should be submitted to irb@marybaldwin.edu. No research data may be collected from human participants until a determination has been made and conveyed by the IRB chair.

Completing and submitting a proposal. Researchers who are affiliated with Mary Baldwin University should follow the process required by the College of their primary affiliation. Outside researchers should submit the following documents to the MBU IRB (irb@marybaldwin.edu): 1. a written request for research access, 2. the proposal that was approved by their IRB, and 3. the letter of approval from their IRB. A Reliance Agreement may also be required.

Proposal submission forms. Submission forms and a checklist to determine which form to use can be found on the IRB website (https://go.marybaldwin.edu/research/irb/).

Required materials. Formal submission of materials requires submission of an electronic copy of the proposal form and all supporting materials. The materials can be in separate files.

Where to submit forms. Researchers affiliated with all MBU colleges, should submit materials to irb@marybaldwin.edu. When non-MBU affiliated researchers are PIs, they should copy their MBU faculty sponsors on the submission email. The faculty sponsors must then send an email stating that they: 1. Certify that he/she has reviewed the protocol and approves of the procedures described therein. 2. Agree to assume overall responsibility for the conduct of this investigator. 3 3. Agree to work with the investigator, and with the IRB as needed, in maintaining compliance with this agreement. 4. Assert that the Principal Investigator is qualified to perform this study.

Review procedures. Expedited proposals and requests for exemption will be reviewed by the IRB chair or one IRB member. Full proposals are reviewed by all members of the IRB. In reviewing proposals, the Institutional Review Board follows the current regulations and guidelines determined by the Office for Human Research Protections within the U.S. Department of Health & Human Services (https://www.hhs.gov/ohrp/regulations-and-policy/index.html). Three categories of action are possible:

- Approval. The proposal is approved without revisions. Upon receipt of an approval letter, the researcher may begin data collection. All protocols are approved for a period of one year.
- Approval pending revisions. Required revisions are conveyed in writing to the researcher and, as applicable, the faculty advisor, by the IRB chair. Revised proposals should be submitted to the IRB chair (irb@marybaldwin.edu).
- Proposal rejected. If, in the judgment of the IRB, the proposal does not meet federal standards for the protection of human subjects, the protocol is rejected. The researcher will receive a letter stating the reasons for rejection. The researcher can then submit a new proposal.

Project Extension. All projects are approved for a period of one year. If a researcher wants to continue the research after the one year of approval, then they should submit a continuing research form (available at https://go.marybaldwin.edu/research/irb/) to the IRB (irb@marybaldwin.edu). If a continuing review request has not been submitted and approved by the end of the approval period, the researcher must cease data collection immediately.

Seeking Permission for Research Access or Use: The researcher must seek permission in advance to conduct any research activities in private spaces and to use equipment that they or their department does not own. Private space includes physical locations for which public access is typically limited, such as workplaces, churches, schools, and private online sites, such as professional listservs or other domains that require membership and are not accessible by the general public. Permission to access private space for research purposes must be secured in writing. It is often helpful to make contact via phone or e-mail with the individual who is authorized to give permission in the particular institution, prior to submitting a formal request. Many online sites have web administrators who manage permissions. You must submit with your proposal written evidence of permission from the individual authorizing your access or use of equipment. The letter or email should include his or her title and contact information.

Components of Informed Consent: To determine if your research requires documentation of informed consent, please use the checklist to determine if a project needs documentation of informed consent from participants available on the IRB webpage. If your research does require documentation of informed consent and your research includes minors (anyone under the age of 18 years), then you must obtain parental consent. Research involving greater than minimal risk and no prospect of direct benefit to individual subjects must obtain consent from both parents. Additionally, all research involving minors must obtain a child's assent or justify why a child's assent cannot be obtained. A child's assent will depend on their age, maturity, and psychological state. When appropriate, the assent should include a written consent document at the child's reading level that is signed by the child.

There are sample consent forms available on the IRB webpage (https://go.marybaldwin.edu/research/irb/).

Consent forms regulations (46.116 at https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46): 4 “Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

(a) Basic elements of an informed consent document:

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
2. A description of any reasonably foreseeable risks or discomforts to the subject;
3. A description of any benefits to the subject or to others which may reasonably be expected from the research;
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
6. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
7. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and
8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

(b) Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

1. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
3. Any additional costs to the subject that may result from participation in the research;
4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
5. A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and
6. The approximate number of subjects involved in the study.”