



Mary Baldwin College
Institutional Review Board

Policies and Procedures

The Mary Baldwin College Institutional Review Board (IRB) is responsible for the oversight of all research activities at the College that involve human subjects. The MBC IRB is registered with the Department of Health and Human Services (DHHS) (IRB00004838 and IOR0004078). Mary Baldwin has a Federal Wide Assurance (FWA # 00008717) from the Office of Human Research Protection at DHHS.

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 the academic freedom of the constituents of Mary Baldwin College. To that end, it does not evaluate proposed research on the basis of the quality of the research design or protocol.

Applicability and Overview of Procedures. Any member of the MBC community – faculty, staff, or student - who is planning to conduct a research project that may involve the collection of data or specimens from human participants must review the following policies and procedures to determine whether IRB review is required. Student researchers should then consult with their faculty advisors and departmental reviewers to clarify the appropriate procedures. Faculty and staff members should consult with the departmental reviewer and/or IRB Chair.

If the consultation determines that the proposed project does involve human subjects research, the researcher must submit information about his or her project for review. On the basis of this review, the project will be designated as one of the following: **exempt**; **expedited**; or requiring **full IRB review**. **Researchers must obtain IRB approval, indicated by a letter signed by the chair of the IRB, PRIOR to beginning data collection.** Most external funding agencies require that IRB approval be in place prior to the submission of a grant proposal.

In all cases, researchers are advised to submit their materials at least three weeks before the planned project start date to allow time for possible revisions to the protocol. The IRB Chair will respond to the researcher within ten business days of **receipt of all relevant forms and associated materials** regarding the status of the review process.

Training. Proof of satisfactory completion of appropriate training is required prior to commencing work on an IRB-approved research project. Contact the Office of Sponsored Programs and Undergraduate Research for details.

Thank you very much for your continued help in implementing these policies and procedures. If you have questions or comments, please send them to the IRB Chair or to the Office of Sponsored Programs and Undergraduate Research.

1.0. Procedures for Researchers. A flow chart summarizing the procedures for obtaining IRB approval appears in Appendix 1; review the procedures listed in this section for more detailed guidance.

1.1 Determine whether your project involves human subjects research. Students should consult with their faculty advisor and departmental reviewer. Faculty and staff should consult the departmental reviewer and/or IRB Chair. If your faculty advisor and departmental reviewer (students) or your departmental reviewer and IRB chair (faculty/staff) determine that your project does not involve human subjects research, it does not need to be reviewed by the IRB, and you are free to begin data collection.

Frequently Asked Questions: Does IRB Review Apply to My Project?

What constitutes human subjects research? "Research" is defined as "systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalized knowledge" (45 CFR 46.102d).

Independent projects, including pilot studies, senior theses, and class projects aimed for publication, that involve the primary (first-time) collection and analysis of human data or specimens are typically considered to be human subjects research. Educational evaluation projects that are conducted solely for the purpose of program improvement are generally not considered to be human subjects research. Educational research that has the intent of systematic inquiry such as found in a thesis may be considered human subject research. Oral histories and other such memoir-gathering projects have not traditionally been considered to be human subjects research, but faculty advisors and departmental reviewers should be aware of and assess cases in which risks to informants may warrant IRB review.

What is the point of IRB review? In addition to assuring compliance with federal regulations, IRB review is designed to help researchers minimize foreseeable risks to participants' physical and mental health, financial standing, employability, and/or reputation as a result of voluntary participation in research activities.

Does research site or funding status matter? No. Both funded and unfunded human subjects research must be reviewed, as must research that takes place on or off the Mary Baldwin campus, including work done outside of the United States.

What about class-based or lab projects whose primary focus is to teach students how to do research rather than to lead to publication or to the development of generalized knowledge? Faculty in charge of such projects should discuss them with the IRB Chair on at least a biannual basis to determine whether they fall within the category of human subjects research. Even when formal review is not required, it is important that the rights of participants participating in such projects are protected.

1.2 If your project *does* involve human subjects research, begin the completion of a Protocol Review Form. The form may be found on the website for the Office of Sponsored Programs and Undergraduate Research, www.mbc.edu/research.

1.3 Complete and submit the appropriate form and associated materials. Be sure to allow enough time for review.

1.3.1 All student research and external research requires MBC faculty and/or qualified staff sponsorship.

1.3.2 All submissions must include a completed and appropriately signed Protocol Review Form.

1.3.3 All submissions should include appropriate associated materials. **Associated materials** include consent forms; assent forms (if minors are involved), flyers, letters of introduction, permissions to access, all instrumentation, debriefing procedures and a description of relevant procedures. Sample templates of informed consent, audio/video release forms, guardian and assent forms, and information about research access permissions are provided in Appendix 2 and on the website for the Office of Sponsored Programs and Undergraduate Research, www.mbc.edu/research. **Please note that passive or “opt-out” consent is not acceptable** (e.g., a participant or parent signs a form only if participation is not desired).

1.3.4 All signature and initialing blanks must be completed on the Protocol Review Form.

1.3.5 Submit materials to the departmental reviewer to confirm all documentation is present, completed, and classification is determined for project status.

1.3.6 Submit (Principal Investigator or Department Reviewer) an electronic copy of the Protocol Review Form and associated materials to irb@mbc.edu and a hard copy of documentation and the Protocol Review to the Office of Sponsored Programs and Undergraduate Research.

1.3.7 Allow time for IRB review. You will be notified of the status of your project within seven to ten working days. Categories of review are described in Table 2. Please note that a higher level of review is required for research involving vulnerable populations, deception, non-anonymous collection of data, and/or elevated risks to participants.

1.3.8 Provide clarifications as requested by the IRB. If you are asked to submit a revised Protocol Review Form, provide a change matrix, as illustrated in Table 1. **Major changes** may require new faculty sponsor /departmental reviewer signatures.

Table 1: Sample Change Matrix to Accompany Requested Protocol Clarifications

Principal Investigator: _____ Date: _____

Clarification Item Number	Changes
<i>5.1 Selection of Participants</i>	<i>Clarified selection criteria for participants; participants under the age of 18 will be excluded.</i>
<i>6.2 Access</i>	<i>Clarified locations where data will be collected; all data collection will take place on the MBC campus.</i>
<i>12.3 Risks</i>	<i>Completed section and provided information about likelihood of embarrassment.</i>

Table 2: Categories of IRB Review

<p align="center">Exempt applies to research that is generally free of foreseeable risk to the subject and:</p>	<p align="center">Expedited review applies to research that presents no more than minimal risk to participants and:</p>	<p align="center">Full review is automatically required when research:</p>
<p>A) does not involve prisoners, fetuses, pregnant women, the seriously ill, or mentally or cognitively compromised adults as participants; and</p> <p>B) does not involve the collection or recording of behavior which, if known outside the research, could reasonably place the participants at risk of criminal or civil liability or be damaging to the participant's financial standing, employability, or reputation; and</p> <p>C) does not involve the collection of information regarding sensitive aspects of the participants' behavior (e.g., drug or alcohol use, illegal conduct, sexual behavior); and</p> <p>D) does not involve deception; and</p>	<p>A) does not involve prisoners, fetuses, pregnant women, the seriously ill, or mentally or cognitively compromised adults as participants; and/or</p> <p>B) involves the anonymous collection or recording of behavior which, if known outside of the research, could reasonably place the participants at risk of criminal or civil liability or be damaging to the participant's financial standing, employability, insurability, reputation, or be stigmatizing to the participant. (If names are recorded and attached directly or indirectly via codes to data, they are not considered anonymous); and/or</p> <p>C) involves the anonymous collection of information regarding sensitive aspects of the participant's behavior (e.g., drug or alcohol use, illegal conduct, sexual behavior); and/or</p> <p>D) involves scientifically justified deception AND de-briefing procedures are immediate and are outlined in detail; and/or</p>	<p>A) involves prisoners, fetuses, pregnant women, the seriously ill, or mentally or cognitively impaired adults as participants; and/or</p> <p>B) the non-anonymous collection or recording of behavior which, if known outside of the research, could reasonably place the participants at risk of criminal or civil liability or be damaging to the participant's financial standing, employability, insurability, reputation, or be stigmatizing to the participant. (If names are recorded and attached directly or indirectly (via codes) to data the data is not considered anonymous. <i>Note: participant names can be recorded for the purpose of verifying participation or awarding class credit without compromising anonymity, provided there is no way of linking specific names to data collected</i>); and/or</p> <p>C) involves the non-anonymous collection of information regarding sensitive aspects of the participant's behavior such as drug or alcohol use, illegal conduct, or sexual behavior; and/or</p> <p>D) involves scientifically justified deception AND full debriefing of the subjects is NOT carried out immediately; and/or</p>

<p>E) does not involve participants under the age of 18 (some projects involving minors may be considered exempt. See Form C for details); and</p> <p>F) will be conducted in established or commonly accepted educational settings and will involve normal educational practices; OR will involve the use of anonymously collected data from educational tests, survey procedures, interview procedures or observation of public behavior; OR will involve the collection or study of existing publically available, anonymous data, documents, records, pathological specimens, or diagnostic specimens; OR will involve taste or food quality evaluations or consumer acceptance studies and the tested products are wholesome foods without additives or foods which contain additives at or below levels found to be safe by the FDA or approved by the EPA of the Food Safety and Inspection Service of the US Department of Agriculture.</p>	<p>E) involves any interaction between the researcher and a child or children in studies of individual or group characteristics of children’s behavior; and/or</p> <p>F) involves the use of educational tests, survey procedures, or observation of public behavior that is not collected anonymously.</p>	<p>E) involves procedures which present more than minimal risk to the participants (e.g. the probability and magnitude of harm or discomfort anticipated in the proposed research is greater than that ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests); and/or</p> <p>F) research that does not fall into any of the categories explicitly identified as qualifying for exempt or expedited status.</p>
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2.0. Procedures for the Departmental Reviewer

All departments and graduate programs are requested to designate a primary and secondary reviewer, whether or not it is anticipated that any human subjects research will take place in the department/program (see Form A). If a department does not designate reviewers, the IRB Chair will serve as the primary reviewer and the Director of Sponsored Programs and Undergraduate Research as secondary reviewer. If a department names a primary reviewer but not a secondary reviewer, the IRB Chair will serve as secondary reviewer.

Departmental reviewers are responsible for the initial screening of research projects to determine whether and what type of human subjects review is required. Departmental reviewers are required to complete a brief on-line training program. Please note that in the event that the departmental reviewer is the investigator or faculty sponsor of the proposed project, the secondary reviewer or IRB Chair must be appointed to be the reviewer.

The major tasks of departmental reviewers are as follows.

2.1 Consult with student and faculty researchers to determine whether proposed projects involve human subjects research as Federally defined.

In consultation with the faculty advisor and/or IRB Chair, determine whether the proposed project falls within the designation of human subjects research.

2.2 When a researcher submits a protocol, confirm that the review category designated by the researcher is correct by signing off on the last page of the Protocol Review Form.

If the departmental reviewer does not accept the researcher's review category designation, he/she should consult with the researcher to reach agreement. If agreement is not reached, consult with the IRB Chair. Note that no research can proceed until agreement has been reached on the category designation of the research. If no agreement is reached, the IRB Chair will assign the proposal to the highest level of review being considered (e.g., if choosing between exempt and expedited, proposal will go to expedited).

2.3 If the project has been determined by the Departmental Reviewer to be EXEMPT from review, sign and forward the Protocol Review Form and associated materials to irb@mbc.edu along with a hard copy to the Office of Sponsored Programs and Undergraduate Research.

This ends the departmental reviewer's review process for this research project, unless the project continues longer than a year. Any additional questions will be directed to the researcher or the faculty supervisor.

2.4 If the project is determined to warrant EXPEDITED review, sign and forward the Protocol Review Form and all associated materials to irb@mbc.edu along with a hard copy to the Office of Sponsored Programs and Undergraduate Research.

This ends the departmental reviewer's responsibility for this research project. Further communication about the research will be between the IRB Chair and the researcher or faculty sponsor.

2.5 If the research is determined to require FULL IRB review, the departmental reviewer should return all materials, including the Protocol Review Form, which the departmental reviewer has signed, to the researcher.

This ends the departmental reviewer's responsibility for this research project. Further communication about the research will be between the IRB Chair and the researcher.

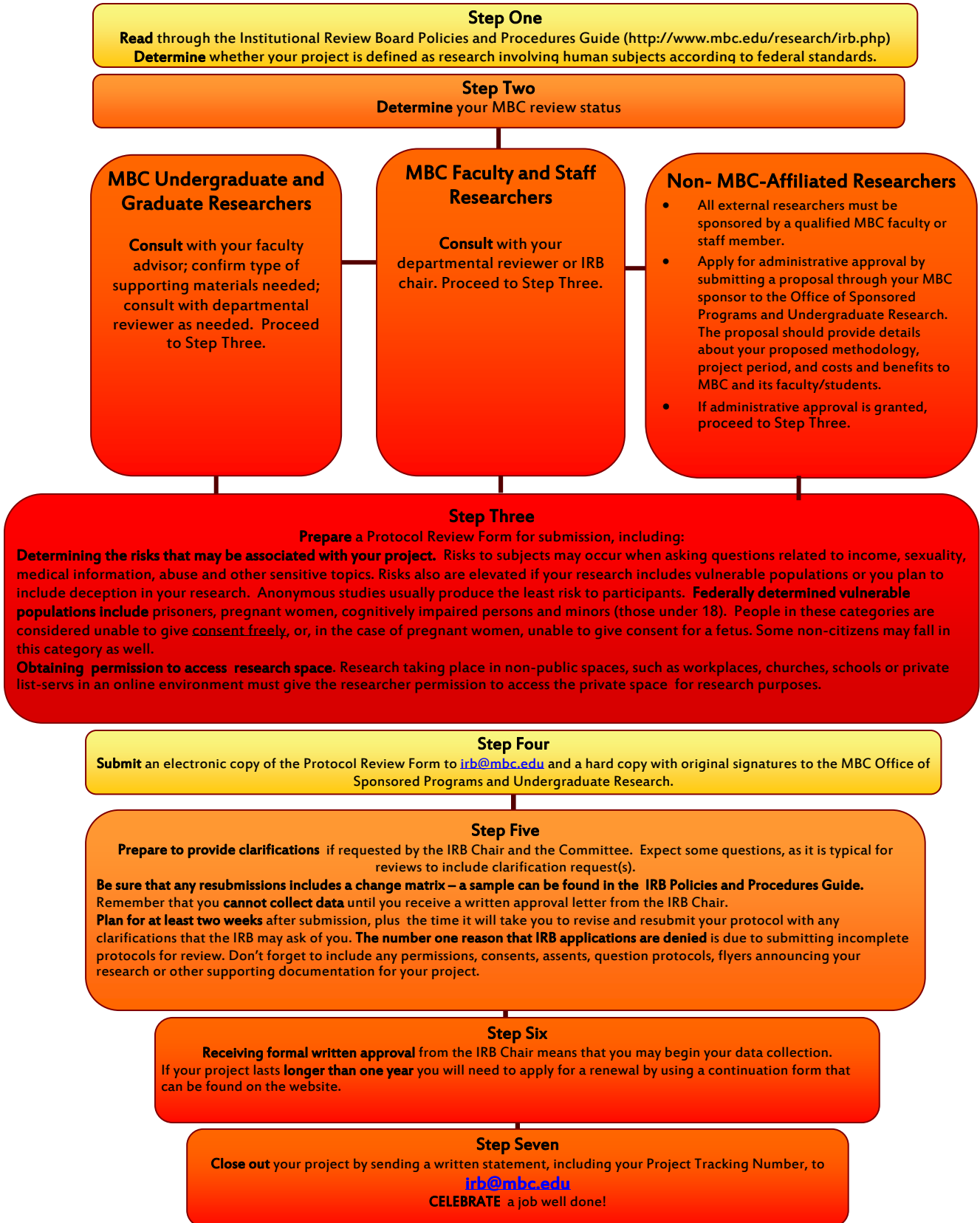
Once the departmental reviewer's signature has been obtained on the Protocol Review Form, it is the researcher's responsibility to the Protocol Review Form, the full proposal, and all associated materials

to irb@mbc.edu and send an email to the IRB chair indicating that a request for full review has been submitted.

3.0 Procedures for the Institutional Review Board

The Institutional Review Board will follow regulations and guidelines determined by the DHHS Office of Human Research Protection, as periodically updated.

Appendix 1: Seven Steps to a Perfect MBC Protocol





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Appendix 2

Obtaining Informed Consent and Access in Research Projects Involving Human Subjects

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Introduction: Components of Informed Consent

Informed consent to participate in a research project must be obtained from each individual participant aged 18 and older prior to data collection. For participants under 18, consent of a parent or guardian is required. ***This includes MBC PEG students and others enrolled in college who are under 18.*** In addition to obtaining parental consent, children between the ages of 9 and 17 must give written assent to participate. Children aged 7-8 may give written assent, but this is not required. Children aged 6 and younger are not required to give written assent to participate, although it is recommended that the research be explained to them in an age-appropriate manner and that they verbally assent to it.

Consent forms must include:

1. A statement that the study involves research, a readily understood explanation of the purpose(s) of the research and the expected duration of the participant's participation, a simple description of the procedures to be followed, identification of any procedures which are experimental, and if deception will be involved. If deception is involved, there should be an indication that the research cannot be fully described at this time, but that at the conclusion of the participant's participation an explanation will be provided.
2. A description of any reasonably foreseeable risks or discomforts to the participant. These include not only physical injury, but also possible psychological, social or economic harm, discomfort or inconvenience.
3. A description of any benefits to the participant or to others which may reasonably be expected from the research (if no direct benefit, this should be stated).
4. A statement concerning costs or compensation to the participant, if any.
5. An explanation of whom to contact for answers to pertinent questions about the research and research participant's rights, and whom to contact in the event of a research related injury to the participant. Phone numbers should be provided.
6. Description of the extent, if any, to which confidentiality of records identifying the participant will be maintained.
7. A statement that participation is voluntary, that refusal to participate will involve no penalty of loss of benefits to which the participant is otherwise entitled, and that the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.

Suggested consent form for ADULTS aged 18 and older
(adapt to your own needs: add information about purpose & risks as appropriate)

CONSENT TO PARTICIPATE IN HUMAN RESEARCH PROJECT

Mary Baldwin College

Project Title

Investigator's Name, Course and Course Number, Telephone Number

You have been asked to participate in a research study at Mary Baldwin College. The purpose of this study is to examine ***[explain the goals of the project in lay terms]***. The purpose of the study, terms of your participation, as well as any expected risks and benefits, must be fully explained to you before you sign this form and give your consent to participate. ***[If research involves deception, include the following language:*** the research cannot be fully described at this time, but at the conclusion of participation, an explanation will be provided.

[Insert paragraph here explaining what they will need to do and risk of pain, distress, etc., if any.]

[State here what compensation, if any (money, extra credit points) will be given for participation].

Participation in research is entirely voluntary. You may refuse to participate or may withdraw from participation at any time without penalty. The investigator may withdraw you from participation at his/her professional discretion.

If, during the course of this study, significant new information becomes available that may relate to your willingness to continue to participate, this information will be provided to you by the investigator. Any information derived from this research project that personally identifies you will not be voluntarily released or disclosed without your separate consent, except as specifically required by law.

If at any time you have questions regarding this research or your participation in it, you should contact the investigator or his/her assistants who must answer your questions. If, at any time, you have comments regarding the conduct of this research or if you wish to discuss your rights as a research participant, you may contact _____, the advisor to this research project at (540) 887 - _____.

You will be given a copy of this consent form to keep.

I have read and understand the above description of the research. Anything I did not understand was explained by _____ and all of my questions were answered to my satisfaction. I agree to participate in this research. I acknowledge that I have received a personal copy of this consent form.

Signature of Participant (age 18 and older) /Date

Signature of Investigator/ Date

Suggested GUARDIAN consent form for minors or others not able to consent for themselves.
(adapt to your own needs: add information about purpose & risks as appropriate)

CONSENT TO PARTICIPATE IN HUMAN RESEARCH PROJECT

Mary Baldwin College

Project Title

Investigator's Name, Course and Course Number, Telephone Number

You have been asked to allow your child to participate in a research study at Mary Baldwin College. The purpose of this study is to examine [*explain objectives of the study in lay terms*]. The purpose of the study, terms of your child's participation, as well as any expected risks and benefits, must be fully explained to you before you sign this form and give your consent.

[Insert paragraph here explaining what they will need to do and risk of pain, distress, etc., if any.]

[State here what compensation, if any (money, extra credit, snack) will be given to either parent or child]

Participation in research is entirely voluntary. You may refuse to allow your child to participate or may withdraw your child from participation at any time without penalty. The investigator may withdraw your child from participation at his/her professional discretion.

If, during the course of this study, significant new information becomes available which may relate to your willingness to continue to have your child participate, this information will be provided to you by the investigator.

Any information derived from this research project which personally identifies you or your child will not be voluntarily released or disclosed without your separate consent, except as specifically required by law.

If at any time you have questions regarding this research or your child's participation in it, you should contact the investigator or his/her assistants who must answer your questions.

If, at any time, you have comments regarding the conduct of this research or if you wish to discuss your rights as a research participant, you may contact _____, the advisor to this research project at (540) 887 - _____.

You will be given a copy of this consent form to keep.

I have read and understand the above description of the research. Anything I did not understand was explained by _____ and all of my questions were answered to my satisfaction I consent to for my child, _____ to participate. I acknowledge I have received a personal copy of this consent form.

Signature of Parent/Legal Guardian /Date

Signature of Investigator/ Date

[Sample Assent Form For Minors Ages 9-17. Guardian consent must also be obtained.]

Mary Baldwin College

[Name of Study]

I understand that I have been asked to participate in a research study about

I will be asked to _____, which will take about _____ minutes. I understand that I do not have to participate. If I do participate, I can quit at any time. I also understand that I do not have to answer any questions I don't want to answer or do anything I don't want to do. My parents, teachers, and others will not be told what I have said or done in the study. No one but the researchers will know.

This study is being done by _____ (name of researcher) at Mary Baldwin College. His/her phone number is _____.
If I have any questions or concerns about the study, I can call and ask him/her about them.

When I sign my name, this means that I agree to participate in the study and that all of my questions have been answered. I have also been given a copy of this form.

Name _____ Signature _____

Name of Witness _____

Witness Signature _____ Date _____

[Sample Audio/Video/Photographic Release Form]

[Project Title]

Audio/Video/Photographic Release Form

Please read this release form carefully before you decide whether to grant the permissions described.

During this study, *[describe recordings that will occur]*. With your consent, we would like to be able to use clips of these recordings for various educational purposes. Your name would *never* be associated with any of these uses.

You, of course, have the right to refuse to allow your recordings to be used in any of these ways. Furthermore, if at any time in the future, you change your mind about granting us permission to use your recordings for these educational purposes, simply notify us by contacting *[PI name, phone & e-mail; faculty advisor/sponsor name, phone, & e-mail, if applicable]* and we will stop using them (except in the case of photos already published in books or journals).

Please indicate below whether you **do** or **do not** give us permission to use your audio recording, video recording, or still photos in each of these ways:

In presentations to classes at Mary Baldwin College	Yes	No
In presentations of the research at professional meetings	Yes	No
In professional publications describing the research	Yes	No
On professional websites designed to make research results available for professional purposes only (NOT social media)	Yes	No
In newsletter reports of this research	Yes	No

Signature: _____ Date: _____

You will receive a copy of this form for your records.

Seeking Permission for Research Access

Permission to access private space for research purposes must be secured in writing. Private space includes physical locations for which public access is typically limited, such as workplaces, churches, or schools, and for private online sites, such as a professional listserv or other domain that requires membership and is not a public access site.

It is often helpful to make contact via phone or e-mail with the individual who is authorized to give permission to understand the process for securing permission in the particular institution, prior to submitting a formal request. Many online sites have web administrators who manage permissions for PIs.

Information to include when seeking permission to access a site for research are, at minimum:

- Principal Investigator's (PI) name and affiliation;
- PI's contact information;
- Title of study;
- Study purpose;
- Faculty Supervisor's/Sponsor's name and contact information, if PI is a student or non-affiliated researcher;
- IRB approval number (or state "approval pending") and contact information for the approving IRB.

You must submit written evidence of permission, signed by the individual authorizing your access and including his/her title and contact information, to the IRB, prior to approval/modification.