MERRIMACK COLLEGE

Merrimack College IRB Guidelines

Guidelines for Review of Research Involving Human Subjects

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Institutional Review Board - Merrimack College

Guidelines for Review of Research Involving Human Subjects

1.0 Institutional Review Board Mission

The mission of the Merrimack College Institutional Review Board (IRB) is to safeguard the rights and well-being of human subjects in projects conducted at or sponsored by Merrimack College. All College sponsored projects involving research with "human subjects" are within the jurisdiction of Merrimack College's Institutional Review Board.

The Institutional Review Board (IRB) is an institution-wide committee certified by the US Department of Health and Human Service's Office of Human Research Protections whose job is to protect the rights of human participants in research conducted at the College. Any research involving human participants conducted either at Merrimack College or under its sponsorship at another location must be reviewed and approved by the College's IRB.

All College sponsored projects involving research with human subjects are within the jurisdiction of Merrimack College's Institutional Review Board It is the responsibility of all members of the Merrimack community to seek support from the IRB with their research.

Federal regulations stipulate "*each institution or agency which conducts or which proposes to conduct or authorize human research shall establish a human research review committee….No human research shall be conducted or authorized by such institution or agency unless…such committee has reviewed and approved the proposed human research project…"* Merrimack College's faculty, students, and staff are subject to these regulations.

Starting in Fall 2017, the IRB application process now requires that all IRB applications are submitted online through the **Cayuse IRB** software platform. Information on how to submit an application can be found on Merrimack's IRB website: https://www.merrimack.edu/about/offices_services/office-of-the-provost/institutional-review-board/

2.0 General Guidelines

Research involving human beings as subjects and having any of the following attributes shall not be initiated until it has been approved or exempted by the Merrimack College Institutional Review Board (IRB):

(1) The research is sponsored by Merrimack College;
(2) The research is conducted by or under the direction of faculty and staff of Merrimack College, or students under the direction of faculty or staff of the College, even if the research is conducted off campus;
(3) The research is conducted on the premises of Merrimack College.

The only exception to the above may be in the case of research that has already been reviewed and approved by an IRB in another institution. In such a case, the investigator is responsible to notify the Merrimack IRB, and submit a copy of the outside IRB approval. The Merrimack IRB has the discretion to accept or reject the approval of an outside IRB in lieu of a Merrimack review process.

Starting November 1, 2017 the IRB will only be accepting applications through the new online submission software, Cayuse IRB. Faculty, students and other researchers at the College now

have full access to Cayuse IRB software for both submitting and reviewing IRB applications. Using the software is the only way to submit an application to the IRB.

2.1 Scope and Purpose of IRB Review

The purpose of the IRB is to review each research plan and protocol, and, as appropriate, the process for obtaining informed consent, in order to safeguard the welfare and rights of human subjects of research. The Board's review is limited to the determination that each study conforms to various ethical standards including:

(1) A research design which minimizes risks to subjects;
(2) A reasonable balance of risks and anticipated benefits;
(3) As appropriate, adequate provision for informed consent, taking into account differences in research methodologies;
(4) An equitable selection of subjects, considering the methodology, purpose, and setting of the research; and
(5) As appropriate, the research plan makes adequate provision to protect the privacy of the subjects and to maintain the confidentiality of data. When the IRB lacks the required expertise in a given field, it may avail itself of the expertise of consultants from within or outside of the College.

Should the review of an application require a specialized body of knowledge or expertise not available from the current members of IRB, a special subcommittee will be formed for the initial review, continuing review, review of protocol changes, and/or review of reports of unanticipated problems or of serious or continuing noncompliance.

2.2 Basis of Guidelines

These guidelines are based primarily on regulations provided by the U.S. Department of Health and Human Services, as well as relevant professional and ethical guidelines. IRB members and researchers submitting proposals are encouraged to consult those regulations for further information (U.S. Department of Health and Human Services): www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm).

3.0 Human Subject Research

- Involves a living individual about whom an investigator (whether professional or student) conducting research obtains
- Involves data through intervention or interaction with the individual
- Involves identifiable private information.

3.1 More than Minimal Risk

More than minimal risk can be defined as risk that exceeds what would ordinarily be experienced in daily life or during routine physical or psychological tests.

3.1.1 Psychological Risks

The experience of participating in the study may cause anxiety, significant emotional disturbance, depression, or distress. Psychological risks may include the following:

- Subjects are asked about experiences or events that they are likely to have found traumatic (e.g., being the victim of an assault or abuse, experiencing an unwanted pregnancy, being involved in an accident or natural disaster, etc.).
- Subjects are presented material or asked questions that they are likely to find offensive, degrading, or threatening.
- The subjects' psychological environment is manipulated, e.g. through isolation, negative messages, etc.
- Subjects are deceived as part of the research in such a way that the participant might experience any undesired transitory, recurrent, or permanent changes in thought processes and emotion.

3.1.2 Legal, Economic, Academic, Professional, or Social Risks

The disclosure of the subject's information may cause civil or criminal liability, or damage the subject's financial standing, academic standing, employability, or reputation. This category of risk may include the following:

- Identifiable information is collected that, if disclosed, could place a subject at risk of criminal or civil liability, or disciplinary action by the College (e.g., information about a subject's illegal activities, such as illegal drug use or underage drinking, or about other activities that violate College policies, such as academic dishonesty).
- Identifiable information is collected that, if disclosed, could damage a subject's financial standing, academic standing, or employability (e.g., information about a subject's dismissal from a previous job; information about a subject's health history).
- Identifiable information is collected that, if disclosed, could damage a subject's reputation (e.g., information about a subject's sexual behavior).

3.1.3 Physical Risks

- Subjects may experience physical discomfort or injury, including physical exertion beyond the subject's normal activity.
- The subjects' physiological requirements, such as nutrition, sleep, or light, are manipulated.

3.2 Vulnerable Subjects

Additional safeguards shall be provided for the following categories of human subjects who may be vulnerable to coercion or undue influence:

- minors (persons less than age 18 who are not College students)
- incarcerated persons

- pregnant women
- mentally disabled persons
- fetuses
- physically disabled persons
- mentally disturbed persons
- residents of health care or long-term facilities
- economically or educationally disadvantaged persons

Investigators who wish to include human subjects from these categories in their research shall design their research projects taking into consideration the federal regulations, and IRB reviewers shall consult those regulations in such cases. (www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm)

3.3 External Dissemination

External dissemination includes the following:

- Findings will or may be disseminated beyond Merrimack College and/or the subjects themselves
- Findings may be posted on a website available to audiences outside Merrimack
- Findings may be shared in a poster, paper, report, or oral presentation for audiences outside Merrimack

3.4 Identifying Information

Information recorded about individual subjects includes identifiers that would permit persons other than the investigator to identify these subjects, such as names, student ID numbers, social security numbers, birthdates, etc.

3.5 Federally Defined Research for Scholarly Audiences

The main purpose of the project is twofold: to advance the investigator's knowledge and understanding and to develop or contribute to generalizable knowledge.

The project is a systematic investigation, rigorously designed to yield generalizable knowledge; findings are appropriately used to draw conclusions about populations beyond those who were eligible to participate in the study

The primary audience for project methods and finding includes professional scholars and researchers

3.6 Informed Consent

The process of obtaining informed consent from those participating in a research project is central to the protection of human subjects of research. Investigators must provide potential subjects with reasonable information about the study, its procedures, benefits, risks, and alternatives, to enable him or her to make an intelligent decision about participation. The format of informed consent may vary according to the research methodology.

A consent form is worded in the second person and written in a language which the prospective subject can be expected to understand. Use of the first person (e.g., "I understand that ...") can be interpreted as suggestive, may be relied upon as a substitute for sufficient factual information, and can constitute coercive influence over a subject. Use of scientific jargon and legalese is not appropriate. Think of the document primarily as a teaching tool not as a legal instrument. The consent form must not sound coercive. It must not include any language through which a subject is made to waive or appear to waive any legal rights or to release the College or its agents from liability for negligence.

A signed copy of all written consent forms should be placed in a research file. Participants must be given a copy of the consent form as well, though this need not be a signed copy.

3.6.1 Preparation of the Informed Consent Form

For adults, informed consent forms should be written at a 6-8th grade reading level. For children, the forms should be written at an age appropriate reading level. Each of the following points must be covered on all consent forms unless the specific point is irrelevant to the project:

- Introduction and Purpose: The purpose of the study should be expressed in lay terms (see also reading level above). It should be stated specifically that this is research.
- Description of Study Procedures: The subject must be told exactly what his/her participation will involve, with particular attention to the way it will be experienced by the subject. This should include length of time required, the number of times the subject will be contacted, the types of tests or procedures to be completed, and whether any videotaping or audiotaping will be included.
- Risks/Discomforts of Being in Study: Any reasonably foreseeable risks, discomforts, or inconveniences to the subject should be described. Participants should be informed of the availability of professional counseling in case they should experience discomfort due to the research.
- Benefits of Being in Study: Any benefits to the subject or to others which may reasonably be expected from the research should be described. Most often the expected benefit is the development of knowledge which it is hoped will be of value to other individuals at some time in the future. In some cases, however, there may be direct or indirect benefit to the individual participant. Both should be made clear.
- Confidentiality: Steps taken to assure confidentiality of records identifying the participant should be explained. If the data are to be published or discussed in a public forum, potential subjects must be informed. Procedures for ensuring the anonymity of data to be used in publications or any public forum should be explained.
- Payments or Compensation: The financial consequences of participation or any material inducements offered in return for participation should be stated. Any conditions related to these (e.g., payment based on complete participation only) should be stated.
- Right to Refuse or Withdraw: Subjects should be informed that they are free to decide whether or not to participate, and free to discontinue participation in the study at any time without penalty or loss of benefits to which they are otherwise entitled. They should be assured that a decision not to participate will not adversely prejudice future interactions with the investigator(s) or the College. This is especially important when a dependent relationship exists between the investigator and the subject (e.g., faculty-student).

- Right to Ask Questions and Report Concerns: Since potential subjects often need time to decide about participation, it is appropriate to encourage them to ask any questions about any part of the study that might be unclear to them. Also subjects should be assured that they may take as much time as necessary to think over the question of their participation. The consent form shall include telephone numbers and email addresses of the project supervisor and the IRB Chair, so that a subject can ask further questions about the research or his/her rights as a research participant, or in the event of any research-related problem.
- Signatures: Space is provided on the consent form for the signature of the subject or legal guardian. In the case of children, if the child is old enough to understand, the child is also invited to sign the form, in addition to the required signature of the parent or guardian. There is also space for the signature of the person who obtained the consent, and the dates of the signatures.

Templates for consent forms can be found in the Cayuse IRB application.

3.6.2 Exceptions or Alterations to the General Requirements for Written Consent Forms

In some circumstances, federal regulations allow for exceptions or alterations to the general requirements for written consent forms. In such cases, applicants and the IRB should consult those guidelines, and relevant professional guidelines. More information can be found on the OHRP website (www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm). The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

- That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or
- That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

4.0 Categories of Research

Persons intending to carry out research involving human subjects will submit to the IRB an online application. There are three categories of human subject research review:

- Exempt Research
- Expedited Research Review
- Full Research Review

The final determination of level for review is made by the Chair of the IRB in conjunction with the IRB. Applicants are encouraged to consult with any members of the IRB while preparing applications if they have any questions.

An investigator who believes his/her project is not research as defined by these guidelines must submit in writing a brief description of the project to the IRB Chair. The Chair will either: (1) certify in writing that the project does not fall under the purview of the IRB; or (2) affirm that the project must be submitted for IRB review under one of the three categories. However, even in cases determined not to be research under IRB guidelines, the IRB Chair will inform the principal investigator (PI) that s/he is responsible to ensure that the safety and rights of human subjects participating in the project are protected, and proper methods followed.

4.1 Research Qualifying for Exempt Status

Research that does not present more than minimal risk, does not involve vulnerable populations, and is not intended for external dissemination qualifies for exempt status. Exempt status will be determined after submitting an online application through Cayuse IRB.

4.2 Research Qualifying for Expedited Review

Expedited review of research projects may be employed in cases that: (a) involve no more than minimal risk to human subjects; and (b) involve only procedures listed in one or more of the following categories. The categories in this list apply regardless of the age of subjects:

- Research on individual or group characteristics or behavior, including, but not limited to: research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior.
- Research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.
- Collection of data from voice, video, digital, or image recordings made for research purposes.
- Collection of biological specimens by non-invasive procedures routinely used in research. (See the federal guidelines for specifics.)
- Research involving materials (data, documents, records or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).
- Moderate exercise by healthy volunteers.
- Review of revised applications approved contingent on modifications.
- Review of minor changes in approved applications. Examples of such minor changes include:
  - administrative changes
  - changes to recruitment materials or submission of new recruitment materials that are easily compared to the approved consent form
  - minor changes to study documents to be distributed to or seen by subjects (e.g., surveys, questionnaires, brochures)
  - new study documents to be distributed to or seen by subjects (e.g., surveys, questionnaires, brochures) that are similar in substance to those already approved by the convened IRB
  - changes in payment to subjects or the amount subjects are paid or compensated that are not so great as to affect the risk/benefit ratio of the study
- Reactivation of inactive, previously approved research projects.

NOTE: Some research in these categories may be exempt under the specifications listed above. This listing refers only to research that is not exempt.

The expedited review procedure may not be used where identification of subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, academic standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal. Research topics which may place human subjects at risk include sensitive aspects of the subject's own behavior, such as illegal conduct, drug or alcohol use, sexual behavior, or violent behavior.

4.3 Research Requiring Full Review

All research not covered in the exempt or expedited categories must undergo a full review process.

5.0 Procedures for IRB Review of Research

In order for the IRB to review an application (initial, continuing, and protocol changes), investigators must submit it through the Cayuse IRB software system (https://merrimack.cayuse424.com/). Investigators must include the proposed consent form(s), descriptions or copies of any stimuli or measures used the research, any recruitment materials (included flyers, e-mail, and project descriptions administered to groups) as attachments to the application or it cannot be submitted. Additionally, certification of ethics training need to be done through the Collaborative Institutional Training Initiative (CITI) https://about.citiprogram.org/en/homepage/. CITI certification must be uploaded for every member of the research team working on a project. Note, that starting July 1, 2018 only CITI certification will be accepted.

All faculty are expected to be familiar with these Merrimack Guidelines for Review of Research Involving Human Subjects and with the relevant U.S. Department of Health and Human Services regulations.

5.1 Procedure for Exempt Review

An application with exempt status will have been reviewed by one or more experienced reviewers designated by the IRB Chair from among members of the IRB. If the review will be done by a single IRB member, that member may not be a member of the Department which initiated the project, or have any other clear conflict of interest. Reviewers of applications for exemption may approve the exemption, require modifications in it (to secure approval), or request resubmission under a different category, but may not disapprove the research.

5.2 Procedure for Expedited Review

Under an expedited review procedure, the review may be carried out by the IRB Chair and one or more experienced reviewers designated by the Chair from among members of the IRB. In the event of a conflict of interest, the IRB Chair may be recused and the review will be

completed by designated member(s) of the IRB. Reviewers of expedited applications may approve the research, require modifications in it (to secure approval), or request resubmission for a full review, but may not disapprove the research. Applications eligible for expedited review may be referred for full review at the discretion of the IRB Chair, or at the request of a committee member. The IRB Chair shall inform all Board members the status of research proposals that have been determined to be exempt or expedited through the Cayuse IRB application tracking system.

5.3 Procedure for Full Review

Under a full review procedure, all members of the Board shall receive an electronic copy of the full application through the Cayuse IRB software system at least 10 days before the Board meets to review it. A majority of the Board must be present at the meeting, including at least one member from outside the College and one member whose primary concerns are in nonscientific areas.

5.4 Review Process

In accordance with HHS regulations at 45 CFR 46.108(b), initial and continuing reviews of research must be conducted by the IRB at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas (i.e., a quorum), except where expedited review is appropriate under HHS regulations. Proposed changes to approved protocols (that do not qualify for expedited approval) must also be conducted by the IRB at a convened meeting. Approval of research is by a majority vote of this quorum. Should the quorum fail during a meeting (e.g., loss of a majority through recusal of members with conflicting interests or early departures, or absence of a nonscientist member), the IRB may not take further actions or votes unless the quorum can be restored. The Board may approve the research, require modifications (to secure approval), or disapprove the research. In order for the research to be approved, it shall receive the approval of the majority of those members present at the meeting, excluding any members with a conflict of interest.

5.4.1 Application for Exemption from Review

The application process involves submitting the application through the Cayuse IRB software system (https://merrimack.cayuse424.com/). The IRB Chair or Vice Chair will review all applications after submittal to determine what category of research the application falls under. The PI, and the faculty advisor(s) when appropriate, will be contacted via email of the status of their application and the category of research the application falls under. If it is an exempt study, the applicant will receive a response typically within 10 days.

5.4.2 Application for Expedited Review

The application process involves submitting the application through the Cayuse IRB software system (https://merrimack.cayuse424.com/). The IRB Chair or Vice Chair will review all applications after submittal to determine what category of research the application falls under. The PI, and the faculty advisor(s) when appropriate, will be contacted via email of the status of their application and the category of research the application falls under. If it is an expedited

review, one or more members of the IRB will be assigned to review the application. The applicant will receive a response typically within 10 days that either approves the application, asks for minor changes or major changes. Revisions will all be done using the Cayuse online software system.

5.4.3 Application for Full Review

The application process involves submitting the application through the Cayuse IRB software system (https://merrimack.cayuse424.com/). The IRB Chair or Vice Chair will review all applications after submittal to determine what category of research the application falls under. The PI, and the faculty advisor(s) when appropriate, will be contacted via email of the status of their application and the category of research the application falls under. If it is a full review, the IRB will have to meet to review the application. The applicant will receive a response typically within 10 days that either approves the application, asks for minor changes or major changes. Revisions will all be done using the Cayuse online software system.

5.4.4 Application for Continuing Review

For research projects with duration of more than one year, an annual IRB review is required whether the project was reviewed via the exempt, expedited or full review process. If the research was reviewed via the expedited or full review process, researchers will be notified by email that their project is up for annual review. If the protocol for the study has remained the same as the previously approved IRB application, the application will still have to be re-submitted through the Cayuse IRB software system if it had not been uploaded previously. If it already in the Cayuse IRB system and the protocol is the same, only the dates will need to be updated.

If the protocol or other aspects of the study have been changed, that information will have to be updated using the Cayuse IRB system. You may also have to attach updated online training certification for all research personnel involved with the project along with new certifications for any new researchers. For continuous projects, the review process (exempt, expedited, or full) that was used for the initial project review will be followed assuming no substantive changes to the protocol have been made.

Continuing review of research previously approved by the convened IRB may qualify for expedited review if one of the following criteria is met:

1. The research is permanently closed to the enrollment of new participants; all participants have completed all research-related interventions; and the research remains active only for long-term follow-up of participants; or
2. Where no participants have been enrolled and no additional risks have been identified; or
3. Where the remaining research activities are limited to data analysis.

Those protocols which are determined by the IRB or an investigator to be of high risk or that have a high risk/potential benefit ratio shall be reviewed more often than annually. Additionally, projects conducted by investigators who have previously have failed to comply with requirements may have their projects reviewed more often than annually.

5.5 Criteria for IRB Approval of Research

In order to approve research under either the expedited or the full review, the IRB shall determine that all of the following requirements are satisfied:

- Risks to subjects are minimized.
- Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and to the importance of the knowledge that may be reasonably expected to result.
- Selection of subjects is equitable, considering the methodology, purpose and setting of the research.
- As appropriate, and taking into account differences in research methodologies, informed consent will be sought from each prospective subject. Such consent may be written, but in some circumstances may be oral or may be waived under the stipulations of the regulations from the U.S. Department of Health and Human Services. Applicants may consult the federal regulations at: www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm.
- As appropriate, the research plan makes adequate provision for securing the data collected to ensure the safety of subjects.
- As appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. In particular, faculty supervisors are responsible to make student researchers aware of the possibility of accidental harm to research subjects, and of the necessity to keep all data anonymous.
- When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects. In such cases the investigator and the IRB should consult the regulations of the U.S. Department of Health and Human Services and relevant professional guidelines.

5.6 Range of Actions Taken by IRB after the Review of a Protocol

After reviewing a protocol (including protocols undergoing initial or continuing review and requests for protocol changes), the IRB may approve the protocol, disapprove the protocol, defer the research activity to request clarification or modification from the investigator, or request that an individual with specialized expertise provide guidance to the IRB before the protocol is approved. The IRB Chair will inform the principal investigator of the decision of the Board via email no later than 10 days after the IRB meeting in which a protocol has been reviewed.

Should the investigator wish to appeal the decision of the IRB, the investigator must follow the protocol described in the reconsideration section of the guidelines. The investigator will have two weeks to respond to these requests from the IRB committee:

- If changes are recommended by the Board, the IRB Chairperson or designated member will communicate these requests to the investigator.
- The IRB Chairperson or designated member will be responsible for review and approval of the investigator's submitted changes.

- If the investigator deems it necessary to make further changes, these can be submitted to the Chairperson or designated IRB member for review and approval through the Cayuse IRB system.
- If there are changes in the study that the IRB Chair or designated Board member feels may change the level of risk to human participants, the investigator will be requested via email to submit the proposal to the full Board for further review during a convened meeting of the IRB.

5.7 Communication with Investigator

The Chair will draft a letter to the PI documenting the review. The Chair of the IRB will send the letter communicating the findings of the IRB to the PI via IRB email advising him/her of the outcome of the IRB review. The Chair will ensure that all IRB approved documents, including the Consent Form (if applicable) are provided to the Investigator at the same time the Letter to the PI is distributed. The Chair of the IRB will affix the approval and expiration dates to all approved informed recruitment and consent documents and stipulate that copies of these dated documents must be used in obtaining consent. No expired documents should be used to recruit or obtain informed consent from participants.

The IRB shall notify investigators in writing of its decision to approve or disapprove any proposed research activity, or of modifications required to secure IRB approval of the research. The investigator must respond to the request for modification of a project proposal within three months, by sending a revised proposal to the IRB. If the investigator does not respond, the study will be considered to be terminated without approval. If the IRB disapproves a research project, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

5.7.1 Approval

At a minimum the following information will be documented in an approved letter to the PI:

- Protocol identification (title, number)
- Investigator's name
- List of documents being approved (protocol, consent, advertisements, etc.)
- IRB approval date
- Statement of approval
- Expiration date of IRB approval
- Requests for continued online training for all research personnel in contact with data obtained from human subjects
- Protocol deviation/non-compliance issues and reporting expectations
- Procedure for investigator to follow in order to report any adverse or unexpected events

Procedure for submitting proposed changes in protocol to IRB for review as well as information regarding federal guidelines indicating that, during the period for which IRB approval has already been given, changes in protocol may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject.

5.7.2 Deferral

- The Chair will include the reason for deferment of the study in the letter to the PI.
- The letter shall state the clarifications that must be made to the protocol and/or informed consent documents before approval can be granted.
- The Chair will remind the Investigator to make the changes requested by submitting the response and documentation to the IRB for review.

5.8 Reconsideration Procedure

An investigator who disagrees with an IRB decision may request reconsideration by either appearing before the Board or by requesting an advisory review panel. This request must be made in writing within 10 business days of the investigator's receipt of the Board's notification.

5.8.1 Investigator Appears Before the IRB

An investigator may ask to appear before the IRB to request that the Board reconsider a decision. This meeting must occur no later than the next regularly scheduled meeting of the IRB. Within 10 business days of that meeting, the IRB will notify the investigator of its decision, and may affirm, modify or reverse its original decision. If the investigator is still dissatisfied, he or she may now have 10 business days to request in writing to the Office of Academic Affairs formation of an advisory review panel.

5.8.2 Advisory Review Panel

An investigator may request reconsideration by the IRB based on the report of an advisory review panel.

- Composition of Advisory Review Panel: The advisory review panel must be formed within 10 business days of the investigator's request for its formation. The panel shall consist of three persons, selected as follows:
  - One member chosen by the IRB Chair; this person may not be a current member of the IRB.
  - One member chosen by the principal investigator; this person may not be a member of the investigator's Department and may not have had any direct involvement in the activities in question.
  - One member chosen by the Office of the Vice-President for Academic Affairs; this person will serve as chair, may not be a current member of the IRB, may not be a member of the investigator's Department, and may not have had any direct involvement in the activities in question.
- Procedures of Advisory Review Panel
  - Purpose: The Panel's purpose is not to substitute its own judgment for that of the members of the IRB on the merits of whether the research should be approved. Instead, the Panel will focus on procedural questions such as the following: Was all available information bearing on the proposed research sought out and considered? Was there adequate deliberation by the IRB of the information in light of relevant professional standards? Were the standards applied relevant to the scope and purpose of the IRB as

defined in these guidelines, and to the criteria for IRB approval stated in the federal and/or these guidelines?

- Meeting: The members of the Advisory Review Panel will convene and hear statements from a representative of the IRB, the investigator, and other persons who might be called by the Panel, the IRB representative, or the investigator. The Panel may involve the College's general counsel or other legal assistance. The panel will meet in executive session to reach its decision. Within 30 calendar days of its formation, the panel will complete its investigation and transmit to the IRB Chair and to the Office for Academic Affairs a written report of its findings and recommendations.

- IRB Reconsideration based on report of the Advisory Review Panel
  - The IRB will consider the Advisory Review Panel's report at a regular or special meeting held within 30 calendar days of the chair's receipt of the Panel's report. A majority of the IRB, including at least one member from outside the College and one member whose primary concerns are in nonscientific areas, must be present at this meeting. The investigator and members of the Advisory Review Panel may be present at this meeting. Statements may be made by all parties. Then the IRB will meet in executive session and, by a simple majority vote of members present, may affirm, modify, or reverse its original decision. The IRB is under no obligation to accept the Panel's findings or recommendations.
  - Within 5 business days of that meeting, the IRB will provide written notice of its final decision to the investigator and to the appropriate Department Chair, the Office of the Vice-President for Academic Affairs, and members of the advisory review panel. This report will include a statement of the reasons for the Board's decision and a description of any action taken by the Board.

6.0 Procedure for Changing an Approved Research Project

To make changes in an approved research project, the investigator should submit the revised plan with the requested changes highlighted, a revised informed consent form if needed, and a letter explaining the requested changes. OHRP recommends that each revision to a research protocol be incorporated into the protocol. This practice ensures that there is only one complete protocol with the revision dates noted on each revised page and the first page of the protocol itself. This revision should be submitted through the Cayuse IRB software application. Revised projects may usually be reviewed by expedited review. However, a full review may be required by the Board. Any changes to the protocol may not be implemented without IRB review and approval except when necessary to eliminate apparent immediate hazards to the participant.

7.0 IRB Composition

The Merrimack College Institution Review Board shall have at least five members, appointed by the Provost and Vice President for Academic Affairs, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB Chair and members of the IRB are appointed to two-year terms, on a staggered basis, so that only one-half of the members' terms expire in a given year. The Chair of the IRB will be a member of the Merrimack faculty who has received tenure, and this person shall be given one course-release per academic year in order to complete the duties of the office.

The IRB shall be comprised of at least five members, and must have an odd number of members. In order to maintain the required expertise and diversity of viewpoints necessary for the IRB to provide adequate review of proposed research, each IRB shall include at least one member representing each of the College's academic areas: Education, Humanities, Social Sciences, Business, Health Sciences, and Science and Engineering. Typically there is no more than one member from any single Department. Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution, having no connections to the College. The IRB committee will consist of members with varying backgrounds to promote complete an adequate review of research activities commonly conducted by the institution. At Merrimack College, every nondiscriminatory effort will be made to ensure that no IRB consists entirely of men or entirely of women, including the institution's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. A majority of the Board, or at least three members, should have some familiarity with social scientific or scientific research. No IRB may consist entirely of members of one profession. Each IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.

The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If the IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.

When the IRB lacks the required expertise in a given field, it may avail itself of the expertise of consultants from within or outside of the College.

A Board member may be removed from service by the Provost, Vice President for Academic Affairs, on the recommendation of the IRB.

The IRB may NOT have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB. The IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

7.1 Conflict of Interest for Members of the IRB

A Board member who is from the same Department as the principal investigator(s) of a project under review shall be deemed to have a conflict of interest. Under certain other circumstances, for example if personal or professional relationships exist between an applicant and a member of the Board, the IRB Chair may rule that there is a conflict of interest. A Board member with a conflict of interest may be a consultant to the Board on the project, but may not vote on the project.

7.2 IRB Meetings

The IRB will typically meet once a month during the academic year. The meeting schedule will be posted at the beginning of each semester on the IRB website. All materials for consideration by the IRB will be due to the IRB two weeks prior to the meeting date, and those deadlines will be posted as well at the beginning of each semester. Members of the IRB will receive materials for primary review 10 days prior to the scheduled meeting date through access to the IRB website.

7.3 Minutes for Convened IRB Meetings

Minutes for convened IRB meetings will be taken by the Chair of the IRB and include all required findings of the IRB meeting, including protocol-specific information justifying each IRB finding. The minutes of the meeting will include:

- Separate deliberations, actions, and votes for each protocol undergoing initial or continuing review by the convened IRB.
- The vote on all IRB actions including the number of members voting for, against, and abstaining. In order to document the continued existence of a quorum, the minutes will be recorded in the following format: Total = 5; Vote: For-4, Opposed-0, Abstained-1.
- The minutes of IRB meetings will clearly reflect the determination regarding which protocols require continuing review more often than annually, as appropriate to the degree of risk regarding risk and approval period (review interval).
- The minutes will include documentation of four findings when approving a consent procedure which does not include, or which alters, some or all of the required elements of informed consent or when waiving the requirement to obtain informed consent. When approving such a waiver for research reviewed by the convened IRB, these findings will be documented in the minutes of the IRB meeting, including protocol-specific information justifying each IRB finding.

When the IRB votes on protocols involving the circumstances stated below, specific findings on the part of the IRB will be included in the IRB minutes of the meeting:

- approving a procedure which waives the requirement for obtaining a signed consent form [see 45 CFR 46.117(c)];
- approving research involving pregnant women, human fetuses, or neonates (see 45 CFR 46.204-207);
- approving research involving prisoners (see 45 CFR 46.305-306); or

- approving research involving children (see 45 CFR 46.404-407), the IRB should document such findings.

7.4 IRB Records

The IRB Chair shall supply documentation of all IRB activities to the Office of Academic Affairs at the end of each academic year through the Cayuse IRB system. That office shall retain an electronic copy of such records for a period of three years, or, in the case of approved projects, three years following completion of the research. Records shall be kept in the Cayuse IRB software system and shall include the following.

- Complete copies of all research proposals received, together with the Board's action taken thereon.
- For approved projects, progress reports submitted by investigators, and reports of injuries to subjects.
- Summary account of IRB meetings which shall include: attendance at the meetings; a copy of the minutes of the IRB meeting, actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; and, where relevant, the basis for requiring changes in or disapproving research.
- For research reviewed under an expedited review procedure, these findings will be documented by the IRB Chairperson or other designated reviewer elsewhere in the IRB.
- Copies of important correspondence between the IRB and investigators relevant to research applications and research in progress.
- The IRB Chair or designee will review and finalize the documentation of the expedited review procedure and will record the determinations of the expedited review procedures.

7.5 Procedures for Amendment of IRB Guidelines

These guidelines may be amended by a two-thirds vote of the Board. Amendments must be within the spirit of the regulations provided by the U.S. Department of Health and Human Services.

7.6 Training for Members of the IRB and Institutional Signatory

The Institutional Signatory, the Chair of the IRB, and each member of the IRB must complete:

Collaborative Institutional Training Initiative (CITI) training. CITI is available for all faculty interested in getting certification to work on human subjects. CITI provides a comprehensive and holistic training certification that is widely recognized. **It will be the required certification system starting on July 1 2018 for all Merrimack faculty, students and staff**. (https://about.citiprogram.org/en/homepage/)

8.0 Obligations of the Investigator

The investigator agrees to abide by the ethical guidelines outlined in the Belmont Report and by all the regulations described in the Merrimack College IRB guidelines. The investigator agrees to make changes to the protocol only after submitting an application to the IRB as described in the "Procedure for changing an approved research project" section of the guidelines.

Additionally, the investigator agrees to alert the IRB should any adverse events occur during the course of their work with human subjects. See https://www.hhs.gov/ohrp/regulations-and-policy/guidance/reviewing-unanticipated-problems/index.html for more details on adverse events. IRB approval will expire one year from the date of the letter of notification. If the research is to continue beyond that date, the investigator must submit a Continuing Review Form, prior to the expiration of IRB approval.

In order to ensure that investigators do not implement any protocol changes without prior IRB review and approval (except when necessary to eliminate apparent immediate hazards to subjects), the IRB requires that all personnel working on an approved research protocol receive training every three years from CITI. Investigators must provide certificates for all research personnel working on a program (including the investigator) with initial and ongoing applications for review. Before new personnel are allowed to work on a research project involving human subjects, they must complete this online training and the certification must be uploaded into the Cayuse IRB software as part of a project update. The email letter informing the investigator that the protocol has been approved instructs the investigator that he or she is responsible for adhering to the approved protocol without making changes (except as necessary to eliminate apparent immediate hazards to subjects). Additionally, the IRB reserves the right to perform random audits of research records to ensure that no changes have been made to the protocol without IRB approval.

If necessary, the IRB will require that a project provide verification from sources other than the investigators to determine that no material changes have occurred since previous IRB review. Those projects which will need these verifications include:

- complex projects involving unusual levels or types of risk to subjects;
- projects conducted by investigators who previously have failed to comply with the requirements of the HHS regulations or the requirements or determinations of the IRB; and
- projects where concern about possible material changes occurring without IRB approval have been raised based upon information provided in continuing review reports or from other sources).

Additionally, the IRB will require verification from a source other than the investigators for a randomly selected project on occasion.

HHS regulations do not permit human subject research activities to be started, even in an emergency, without prior IRB review and approval. When emergency medical care is initiated without prior IRB review and approval, the patient may not be considered a research subject. Such emergency care may not be claimed as research, nor may any data regarding such care be included in any report of a prospectively conceived research activity.

9.0 Reports of Adverse Events or Unanticipated Problems

Any adverse or unanticipated events involving human subjects in a research project must be reported to the IRB by the principal investigator or the faculty supervisor in the case of a student project. The form can be found on the Cayuse IRB site.

Adverse events include all unanticipated (not mentioned in the consent form or application) occurrences of physical or psychological harm and unexpected threats to privacy (e.g., lost records) or safety of subjects. Minor adverse consequences should be reported only if they were either unanticipated in the consent form or if the original application substantially underestimated their probability or magnitude.

Upon receipt of an Adverse Event Report, the IRB will decide if further investigation of the event is required. In some cases, investigators may be required to discontinue a study pending the outcome of the IRB review. Where required by other agencies, investigators must fulfill additional obligations to report adverse events to government agencies, funding agencies, or other institutions.

10.0 Noncompliance

If an investigator fails to abide by the guidelines listed in the Merrimack College IRB Guidelines for Review of Research Involving Human Subjects, he or she will be considered to be in noncompliance. Noncompliance to the Common Rule or to the requirements of the IRB increases risks to participants in human research. Investigators are encouraged to report to the IRB Chair or administrators situations in which agreed upon procedures have not been implemented as expected. Noncompliance may also come to light during continuing reviews, or through monitoring of research activities. In many cases non-compliance that is neither serious nor ongoing will be corrected through an agreement between the investigator and the IRB Chair.

The IRB shall expeditiously process all reported instances of noncompliance. Upon receiving information indicating possible non-compliance, the IRB Chair shall make a determination if the non-compliance involves Human Research, and if so, whether the non-compliance is serious or continuing. If the non-compliance is neither serious nor continuing, the IRB Chair shall take steps to correct the non-compliant behavior with the investigator and shall report the incident to the Dean, Department head, and the Provost, Vice President for Academic Affairs. If the noncompliance appears to be serious or ongoing, and does not extend beyond the IRB's jurisdiction for human research, then the Chair refers the issue to the IRB for its determination and oversight.