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Email: bor.regents@cmi.edu

Institutional Review Board

Date of Initial Policy: February 20, 2018

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CMI Policy No. 399

Institutional Review Board Policy

Policy Statement

All research involving human subjects that makes use of CMI resources or that is conducted by students, staff, or faculty on or off campus must be approved by the Institutional Review Board (IRB). The IRB may review other projects if requested, subject to a fee. The IRB is empowered to develop and revise procedures to ensure that all such research is conducted ethically and with regards for the rights and welfare of research subjects. These procedures must follow the rules set forth in the U.S. Department of Health and Human Services regulations for the protection of human subjects (45 CFR 46) as well as any relevant Republic of the Marshall Islands laws.

The IRB is an executive committee of the College and reports to the President of the College via the Vice President of Academic and Student Affairs.

Reason for the Policy

The purpose of the Institutional Review Board (IRB) is to protect the well-being and the rights of individuals participating in research activities, which are conducted under the auspices of the College of the Marshall Islands (CMI). The principles of respect for persons and justice are criteria to be considered for conducting research. College policy requires the IRB to review and approve all research conducted by faculty, staff, and students, on and outside of the campus, that involves human subjects. All research that uses CMI resources must also be approved by the IRB. Further, it is the responsibility of the IRB to review and approve any changes to a previously approved research project before it is finalized should the researcher wish to have the imprimatur of the college included with the research.

Definitions

From Section 46.102 of the U.S. Department of Health and Human Services regulations for the protection of human subjects (45 CFR 46).

Human subject means a living individual about whom an investigator (whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

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Intervention includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

Interaction includes communication or interpersonal contact between investigator and subject.

IRB means an institutional review board established in accord with and for the purposes expressed in this policy. The acronym for Institutional Review Board.

IRB approval means the determination of the CMI IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB, by other institutional and federal requirements, and by the RMI government.

Legally authorized representative means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).

Statements of Elaboration of the Policy

1. IRB approval does not preclude further review by College administrators, but any such review is not authoritative, and any concerns should be raised with the IRB. No College representative may approve research that has not been approved by the IRB.
2. The IRB will post a list of all approved projects to the CMI website.
3. Research carried out under the auspices of CMI must abide by the Declaration of Helsinki.
4. Researchers in all fields must also make every effort to understand the culture of the Marshall Islands in order to avoid causing culture-dependent social harms to research subjects. The Marshallese people should share in the benefits of research conducted in the Marshall Islands, and results should be made available to the community. Researchers are encouraged to report multiple interpretations in cases in which the academic and traditional interpretations of results vary. We encourage researchers to report results to the community.

5. Ensuring that all research meets the requirements of all applicable local and national laws, as well as the requirements of any sponsoring agencies or institutions, is ultimately the responsibility of each researcher.
6. External research and research funded through grants will be subject to a fee. External research in this case means any research that is conducted by an entity that is not affiliated with the College.

Relevant Policies

None

Key Office to Contact Regarding this Policy and its Implementation

The IRB is responsible for the oversight and implementation of this policy.

Links to Procedures or Forms

Procedures

A. IRB Membership

The IRB will have five regular voting members. All voting members of the committee must have, at minimum, a graduate research degree, or else have completed both a taught master's degree and a recognized research and research ethics training course such as that provided by CITI.

An ordinary term for a standing IRB member will be two years with the exception of the Director of Institutional Research and Assessment who serves ex officio as Chair. For the initial appointees, two will serve a one-year term and two a two-year term so that, in the future, new appointments will be staggered.

In addition to the regular voting members, a roster of alternate members will be maintained; this roster must have a minimum of two members to allow regular voting members to recuse themselves should a particular research project present a conflict of interest. Alternates may be called upon as consultants at any meeting but are only able to vote when they are called upon to replace a regular voting member. At no point may

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an IRB panel consider an application for approval with fewer than five voting members present.

The regular voting members, as well as the combined regular and alternate voting membership at any given meeting, must include all of the following:

1. The Director of Institutional Research and Assessment or designee
2. at least one member whose primary expertise is in a scientific area
3. at least one member whose primary expertise is in a non-scientific area
4. members of more than one gender
5. at least one member who is not otherwise affiliated with the institution and whose immediate family is not affiliated with the institution. Immediate family is here defined as a spouse, child, child-in-law, parent, parent-in-law, grandparent, sibling, sibling-in-law, grandchild, or other person who occupies such a position in the family, or a person living in the same household

One member may fulfill more than one of the above requirements.

Members will ordinarily be drawn from qualified members of the CMI faculty, CMI staff, and the surrounding community. If it is not possible to meet the above requirements otherwise, IRB members who reside off island may be appointed with the understanding that they will attend meetings using Skype or another form of telepresence. For off-island members, the preference will be to appoint individuals residing in the Pacific region, individuals who have previously resided in the RMI, or individuals of Pacific Islander heritage. All efforts should be made to include qualified Marshallese individuals on the IRB.

B. Role of the College President and Academic Officers

The College President and any administrative academic officers, including the Vice President of Academic and Student Affairs and the Dean of Academic Affairs, are considered ex officio non-voting members of the IRB.

C. Selection of IRB Members

The initial voting membership of the IRB, excluding the Director of IRA, will be selected by the IRB formation committee following recruitment efforts that shall include but not be limited to emails sent to the CMI community and discussion in Faculty Senate. Following the initial formation of the IRB, new members will be chosen by existing members.

Ordinarily, when possible, regular voting members of the IRB should have first served as alternate members.

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D. IRB Officers

Chairperson
The Director of Institutional Research and Assessment is the Chair of the IRB.

The responsibilities of the chair are as follows:

1. Receive applications and appeals from researchers
2. Assign IRB members to present research projects
3. Assign IRB members to review research projects for exemption
4. Confirm status of exempt applications
5. Maintain a list of IRB regular voting members and alternate members, including the following information about each member (adapted from 45 CFR 46.103):
    a. name
    b. earned degrees
    c. representative capacity
    d. indications of experience such as board certifications, licenses, relevant publications
    e. any employment or other relationship between each member and the institution, or between the member's immediate family and the institution
    f. any known potential conflicts of interest
6. Assign expedited applications to members for review and confirmation
7. Call IRB panel meetings
8. Invite alternate members as needed
9. Facilitate meetings
10. Update or renew registration with HHS

Responsibilities that the chair may carry out or assign to another regular voting member are as follows:

1. Register the IRB
2. Maintain a list of experts in community issues or academic fields who may be called upon as IRB consultants without voting privileges
3. Maintain any required records not otherwise assigned

Co-Chair

A co-chair will be selected by the IRB members. The Co-Chair should be a member of the CMI faculty. In the absence of the Chair, the Co-Chair will call and facilitate IRB meetings. The Co-Chair will also invite alternate members when the Chair is unable to do so. Finally, the Co-Chair will carry out other duties as assigned by the Chair.

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Secretary

A secretary will be selected by the IRB members. The Secretary is a non-voting member. The Secretary will take and maintain meeting minutes and be responsible for all reporting.

E. IRB Registration

Registration of the IRB with the U.S. Department of Health & Human Services (HHS) is to be maintained. Following the initial registration, the IRB registration must be renewed or updated:

- Every three years
- Within 90 days of a change to the IRB's contact information or Chair
- Within 30 days of deciding to review a type of FDA-regulated product not previously reviewed by the IRB

Should the IRB decide to disband for any reason, HHS must be notified within thirty days.

Should the IRB at any point consider non-exempt human subjects research conducted or supported by HHS, it will be the responsibility of the Chair to work with the President of the College to submit a Federalwide Assurance (FWA) for the approval of the Office for Human Research Protections (OHRP).

F. Procedure for Applying for Approval

Researchers must complete the relevant form and submit it together with any required evidence, such as draft consent forms, to the IRB Chair.

G. Procedure for IRB Deliberations and Decisions

The IRB will meet ordinarily on a monthly basis. Meetings will be canceled in the event that there are no applications requiring approval of a full IRB panel and no approved expedited applications to be accepted. They may also be rescheduled at the discretion of the IRB Chair. Additional meetings may also be called by the Chair.

Due to the confidential nature of materials discussed during these meetings, the sessions are not open to the public. In special circumstances, however, certain groups may be granted permission to attend. For research involving CMI resources the relevant heads of department should be invited to take part in deliberations, though they will not

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have a vote unless they are ordinarily members of the IRB. The IRB also has the right to invite outside experts.

The Project Checklist form will be used to document IRB's review and decision on the application.

Exempt Applications

Research that involves human subjects but meets the requirements listed under 45 CFR 46.101.b may be considered exempt. Exempt applications will be confirmed as such by the IRB Chair. The Chair may also determine that the project requires IRB approval, in which case the researcher will be directed to complete the appropriate application.

Expedited Applications

Projects that involve only minimal risk may qualify for the expedited applications procedure. Expedited projects must meet the requirements listed under OHRP Expedited Review Categories.

Expedited applications will be assigned to a single IRB member to verify expedited status and approve the application. The Chair must make this assignment within fourteen days of receipt of the application, and the member assigned the application will have fourteen days to reach a decision and communicate to the researcher that the research has been approved or that it has been referred for the full consideration of the IRB. In the latter case, the researcher will need to complete the full IRB form. The IRB member assigned to review the application will also notify the Chair of this decision. All approved expedited applications will be recorded in the minutes of the following ordinary IRB meeting.

In the case of exempt and expedited applications, only the Chair and assigned IRB member reviewer sign the Project Approval form.

Full Deliberations

Research requiring full IRB panel deliberation should be reviewed at the next ordinary meeting. No fewer than five voting members must be present at this meeting. A member assigned by the Chair will formally present the research proposal, including a thorough consideration of risks and benefits, to the panel. If the panel determines that further deliberations or information from external sources are required, they may delay their decision until the following meeting. Otherwise, a member may move to vote for any of the below possible outcomes. A simple majority will suffice to determine the outcome.

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Possible Outcomes

1. Approved: the project meets all requirements for approval and may proceed as written. The researcher must submit a final report to the IRB and, if the project is longer than one year in duration, must submit an annual report for review until the conclusion of the project. The committee may also request reports more often than annually depending on the degree of risk presented.
2. Approved, subject to minor revisions: the panel requires a limited number of minor, specific changes to the project. The researcher shall make the changes, file the paperwork with the IRB Chair, and proceed with the project in accord with outcome one or two, depending on the determination of the panel. So long as the researcher agrees to abide by the revisions required by the panel, the project does not have to go through the IRB process again.
3. Revise and resubmit: projects that have serious flaws but can, in the opinion of the panel, be revised to meet the requirements for approval. The panel may, if appropriate, refer the researcher to an expert in the field for assistance. Upon revising the project, the researcher will be required to reapply and go through the full IRB process.
4. Not approved: projects that are fundamentally flawed and cannot, in the opinion of the panel, be revised to meet the requirements for approval. In the case of an application being rejected, the researcher may apply again to the IRB with a new project, but the IRB will not consider the same project again, unless the researcher initiates the appeals process.

H. Revision Requests

Requests for revisions may include, but are not limited to, the following categories:

1. Contravention of cultural norms
2. Misinterpretations of traditional expectations and practices
3. Violation of local, national, and international laws and practices
4. Data gathering, analysis, and reporting issues
5. Violation of research ethics
6. Failure to follow appropriate procedures for submitting a research project or update to the IRB
7. Unforeseeable or unacceptable risks to participants

Researchers have the right to request clarification of a revision request or to provide an explanation of why they believe a revision request is not applicable. However, the IRB has sole discretion as to whether to reconsider its requests.

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I. Extend an approved IRB

Extension of previously approved protocols needs IRB approval to ensure the research continues to fall within the originally approved project. If there are no or minor changes to an existing protocol, requests for extension can be submitted through an email to CMI IRB explaining the basis of the request and confirming that the research continues to adhere to the protocols of the originally approved project. Extensive changes are best addressed by submitting a new application.

However, once a research project no longer involves human subjects (i.e., once the researchers have finished obtaining data through interaction or intervention with subjects or obtaining identifiable private information about the subjects), the protocol may be closed rather than extended.

J. Guidelines for Approval

Guidelines will be reviewed by the IRB annually. Queries or suggestions for changes to guidelines may be addressed in writing by any concerned individual to the Chair.

In order to receive approval, research involving human subjects must meet the following requirements adapted from "The Common Rule," the U.S. Department of Health and Human Services Policy for the Protection of Human Subjects (45 CFR 46, Subpart A).

Risks to subjects must be minimized.

1. The risks to subjects must be reasonably proportional to the potential benefits. Only those risks and benefits that result directly from the research and that affect the subjects, as opposed to society at large, should be considered.
2. Subjects must be chosen equitably. Special care must be taken on this point when research involves vulnerable populations.
3. Informed consent must be obtained from the subjects or their legal representative as defined by RMI law. This consent must be documented and the record maintained. Researchers must submit sample consent forms with their applications and are encouraged to use the forms provided by the IRB as a starting point.
4. If relevant, data collected is monitored for the ongoing safety of the research subjects.
5. The privacy and anonymity of subjects must be maintained where possible and appropriate. Appropriate safeguards must be in place to avoid the accidental or incidental revelation of a subject's identity.

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6. There must be a plan to share findings with the community.
7. All researchers involved in the project must have completed NIH's Protecting Human Research Participants certification via https://phrp.nihtraining.com/index.php.

In addition to the above requirements, for non-expedited projects, at least one member of the research team, ordinarily the Principal researcher, must have received appropriate research ethics training through the completion of a relevant degree or a program such as that provided by the Collaborative Institutional Training Initiative (Miami University)

K. Informed Consent

In order to comply with the informed consent requirements in Title 45 Part 46 of the US Code of Federal Regulations, all researchers working with human subjects must obtain consent from the subjects themselves or their legally authorized representatives. This consent is not considered adequately informed unless the prospective subject or representative has sufficient opportunity to consider, free from coercion, whether to participate based on information presented in language understandable to the subject or the representative. Informed consent may not include any language that waives the subject's legal rights or releases the researcher, the sponsor, the institution, or its agents from liability for negligence.

In all circumstances, informed consent requires that the subject or representative be provided with the following information:

1. A statement that the study involves research
2. The purpose(s) of the research
3. The expected duration of the subject's participation
4. The procedures to be followed, with any experimental procedures identified as such
5. Foreseeable risks or discomforts for the subject
6. The potential benefits of the research to the subject or others
7. Any alternative procedures or courses of treatment that might be advantageous to the subject, if relevant
8. The extent to which confidentiality of records identifying the subject will be maintained
9. If the research involves more than minimal risk, what compensation and/or medical treatment is available in case of injury, and how further information may be obtained
10. Contact information should the subject or representative have any questions regarding the research and research subjects' rights, or in case of a research-related injury

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11. 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.

The following information may also be required if appropriate:

1. Acknowledgement that procedures may involve unforeseeable risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant)
2. Circumstances under which the subject's participation may be terminated unilaterally by the researcher
3. Any additional costs to the subject that may result from participation in the research
4. Consequences should a subject decide to withdraw from the research and procedures for orderly termination of participation
5. Affirmation that any new findings which may relate to the subject's willingness to continue participation will be provided to the subject
6. The approximate number of research participants

Research involving minor-age participants requires a greater degree of rigor with regards to the review process and greater consideration as it pertains to the consent process for the participants. Minor age participants are considered vulnerable persons and as such substitute and/or third-party consent – from a parent or guardian - is required. Further, in recognition of a participant's fundamental right to consent to participate in research regardless of age or capacity, informed consent from the participant is required. The consent form and/or script should utilize age-appropriate, accessible language.

The committee has established the following guidelines for research involving minor-age participants:

1. For minimal-risk research involving participants 16 years of age and older, parental /third-party consent is not required;
2. For more than minimal risk research involving participants 16 – 17 years of age, parental/third-party consent may be required;
3. For participants under the age of 16, parental/third-party consent is required. In this case, the researchers must submit the consent form for participants and the parental/third-party consent form.

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Only the third party – parent or guardian – may consent on their behalf to participate. Similarly, it should be noted that should a parent or guardian consent to allow the minor-age participant to participate but the participant him/herself does not *assent* to participate, then consent has not been obtained for that participant.

Informed consent means that the minor understands and comprehends the research or evaluation invitation. Consent must be linguistically accessible to the minor and orally explained clearly. A third-party witness must verify that the minor has consented to participate.

Without prejudice to the progress of science, any type of scientific experimentation that is detrimental to the child's life, health, or personal development shall be prohibited even if the child and/or her/his parents or guardians consent to the procedure. ~~(RMI Law????)~~

As there may be contexts in which the guidelines may not be appropriate, it is advised that when utilizing participants under the age of 18, it is best that the Vice President of Academic and Student Affairs be contacted for advice and direction where needed as to the applicable consent processes or to seek additional requirements.

L. Appeals

Researcher appeals should be made in the first instance to the IRB Chair in writing within thirty days of the initial decision. The IRB will consider the appeal at the following regular meeting. Appeals shall be granted only under at least one of the following conditions:

1. An IRB member with an undisclosed conflict of interest is found to have participated in the decision.
2. A fundamental misunderstanding of the project on the part of the IRB panel can be demonstrated.
3. An external expert is found to have misadvised the IRB panel in a manner that had a material influence on the panel's decision.
4. In the event that an appeal is granted, every effort should be made to convene a new panel that consists of members who were not involved in the initial decision. At a minimum, any members shown to have an undisclosed conflict of interest will not be permitted to participate in the new panel.

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If the appeal is not granted, there is no further recourse for the researcher. An IRB decision can only be appealed to the IRB; the decision cannot be overridden by another party.

M. Research Misconduct

If the IRB Committee learns of any research misconduct such as revealing the identity of a research subject knowingly or unknowingly, the committee shall meet to determine an appropriate consequence which may include termination of approval. Any concerned member of the public may report misconduct to the Chair.

N. Post-Approval Reports

Adverse Events

All adverse events shall be reported immediately to the IRB Chair using the adverse events reporting form. Adverse events include but are not limited to:

1. Damage to physical property
2. Physical injuries to participants or affected third parties
3. Negative psychological reactions such as panic attack
4. Any incidents requiring emergency aid
5. A subject or other party experiencing an unexpected harm as a result of the research
6. Incidents or allegations of non-compliance with legal requirements, funding body requirements, the IRB-approved protocol, or other IRB determinations
7. Breaches of confidentiality

The Chair will inform the IRB of any adverse events at the next regular meeting. At the discretion of the chair, in cases of major adverse effects, the Chair may require that the research be paused until the full panel may consider the implications of the event.

Changes in Protocol

Changes in protocol shall be reported to the IRB Chair either within seven days in the case of a change in study protocol to eliminate an immediate hazard, or prior to making the change in any other case. The IRB Chair will determine whether to consider the changes via the expedited procedure or through the full panel. Expedited review is appropriate only if the changes are minor and represent either no change to the level of risk involved or ameliorate risk.

Periodic Reviews

Annual reports or reports at any other time as required by the IRB must be, in the first instance, made in writing to the IRB Chair. Periodic reviews shall include evidence of

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informed consent and any results. This report will be shared with the full IRB panel prior to the next regular meeting at which the panel will vote to reaffirm or reconsider approval.

Final Report

At the conclusion of a research project, a report of findings, documentation of informed consent if not provided in an earlier periodic review, and publications should be shared with the IRB via the Chair.

O. Student Research

The instructor for a class that is conducting research that falls under the Expedited category may complete a single form to cover all student-led projects in that class so long as the results will not be externally published.

P. Research for Assessment of Teaching and Learning

Studies of learning and teaching conducted only for ordinary, internal purposes, such as outcomes assessment, performance management, and improvement of teaching, do not require IRB approval so long as they pose no or minimal risk to students, no data or other information is shared externally, and internal sharing of data or other information is consistent with FERPA.

Q. Conflict of Interest

If an IRB member, or their immediate family, have a potential or perceived conflict of interest related to research coming under IRB consideration, that member must report the conflict in writing to the IRB Chair. The Chair will then make a determination as to whether it is an actual conflict of interest, in which case the IRB member will not be able to vote on the research and shall be replaced by an alternate member. Members with an established conflict of interest may still contribute to deliberation, but in this case, their position will be similar to that of an outside expert. In the case that the IRB Chair has a conflict of interest, this will be reported to the Co-Chair who will take responsibility for all related proceedings. IRB members may not contribute to deliberations related to their own research except to the extent all researchers are ordinarily involved.

R. IRB Records

All records shall be maintained in the Office of Institutional Research for a minimum of three years, or three years following the completion of the related research project, whichever is later. Record keeping does not affect the intellectual property rights of the researcher unless otherwise agreed.

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The following documents will be made publicly available:

1. Approved summary minutes of IRB meetings which shall include attendance at meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; and any details deemed suitable for public consumption.
2. A list of IRB members with all details as described under the responsibilities of the Chair.
3. Statements of significant new findings provided to subjects.

The following documents will be held in confidence, to be released only to appropriate department heads, researchers, or researchers:

1. Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, progress reports submitted by researchers, and reports of adverse events.
2. Copies of all correspondence between the IRB and researchers.
3. Approved full minutes of IRB meetings which shall include attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.

S. IRB Review Fees

The number and complexity of human research protocols at the College of the Marshall Islands is increasing in recent years. Each of these studies requires review and ongoing oversight by the Institutional Review Board (IRB).

CMI IRB charges an administrative fee for all external research i.e. conducted by an external member of the CMI community and research funded by grants. Fees are due in full at the time of submission and are assessments of real costs associated with the IRB's protocol reviews. These fees are non-refundable, regardless of whether the study is: assigned for IRB review; approved; withdrawn after submission; terminated before study milestones are met; has or has not enrolled participants, and/or has a finalized research contract. 70% of fees collected will be paid to IRB members involved in review of a project, regardless of the outcome of that review. 30% of the fees will go to the college's general fund to cover overhead.

Fees for external research that are funded personally by the principal investigator:

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	Exempt Review	Expedited Review	Full Review	Continuing Review	Modifications
External research funded personally by the principal investigator	No Charge	No Charge	$ 100	$100	$50
External research funded by private industry	$1000	5% of the project's indirect costs or $1500 whichever is lower	10% of the project's indirect costs or $2000 whichever is lower	5% of the project's indirect costs or $1500 whichever is lower	3% of the project's indirect costs or $1000 whichever is lower
External research funded by RMI government agencies	$500	5% of the project's indirect costs or $1000 whichever is lower	10% of the project's indirect costs or $1500 whichever is lower	5% of the project's indirect costs or $1000 whichever is lower	3% of the project's indirect costs or $500 whichever is lower
External research funded by grants	$500	5% of the project's indirect costs or $1000 whichever is lower	10% of the project's indirect costs or $1500 whichever is lower	5% of the project's indirect costs or $1000 whichever is lower	3% of the project's indirect costs or $500 whichever is lower
CMI research funded by grants	No Charge	5% of the project's indirect costs or $500 whichever is lower	10% of the project's indirect costs or $1000 whichever is lower	5% of the project's indirect costs or $500 whichever is lower	3% of the project's indirect costs or $200 whichever is lower

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Forms

IRB Project Approval Application Form
Periodic Update Form
Change of Procedure Form
Change of Personnel Form
Adverse Event Reporting Form
Project Checklist for IRB – IRB Members Use

Date of Initial Policy: February 20, 2018

Irene J. Taafaki — March 13, 2023

Dr. Irene J. Taafaki, President **Date**