University of Mary Washington

# INSTITUTIONAL REVIEW BOARD

# Manual of Policies and Procedures

**Approved September 2021**

# Institutional Review Board
# Manual of Policies and Procedures

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# SECTION I

# Introduction: Research Ethics

## A. Purpose of the Institutional Review Board

According to the University of Mary Washington's Statement of Community Values (2018), the University community "holds all of its members to the highest standards of conduct, scholarship, integrity, inclusiveness, respect, and engagement." The Institutional Review Board (IRB) at the University of Mary Washington (UMW) plays an essential role in meeting these commitments. The UMW IRB is federally mandated to ensure that research involving human participants conducted by bona fide members of the University community meets, to the fullest extent, the ethical and legal requirements for such research as set forth in federal regulations.

The IRB at UMW exists to oversee the conduct of research involving human participants. Its primary responsibility is to protect the rights and welfare of human participants in research and, to this end, the IRB reviews and monitors all research involving humans conducted at the University. The role of the IRB is to ensure that researchers meet current standards and regulations regarding ethical treatment of research participants and to report any problems to the Office of the Associate Provost for Academic Affairs.

This document (*University of Mary Washington Manual of Policies and Procedures for the Institutional Review Board*, hereafter "Manual") sets forth the policies and procedures of the UMW IRB to be followed by University researchers, IRB members, and the administrators who oversee and support the functions of the IRB.

## B. Ethical Treatment of Human Participants

The University supports fully the ethical principles set forth by the Nuremberg Code and the Belmont Report. Some of the main points of these guidelines are outlined here, and links to the complete documents are below.

### 1. Basic Precepts of the Nuremberg Code

- The voluntary consent of the human participants is absolutely essential.
- The research should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.
- The research should be so conducted as to avoid all unnecessary physical and mental suffering and injury.
- No research should be conducted, where there is an a priori reason to believe that death or disabling injury will occur.
- The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the research.

- Proper preparations should be made and adequate facilities provided to protect the research participant against even remote possibilities of injury, disability, or death.
- The research should be conducted only by scientifically qualified persons.
- During the course of the research, the human participant should be at liberty to bring the study to an end.
- During the course of the study, the scientist in charge must be prepared to terminate the research at any stage.

**2. Basic Precepts of the Belmont Report**

**a. Respect for Persons:** The principle of respect for persons acknowledges the autonomy of human beings and provides for protections for persons with diminished autonomy (e.g., children, prisoners, and people who are limited in their ability to make conscious decisions). The IRB seeks to ensure respect for persons by requiring informed consent by research participants.

**b. Beneficence:** Beneficence requires researchers to avoid bringing harm to research participants and to take steps to maximize the benefits of research and minimize risks. The IRB assesses the risks and benefits of human research.

**c. Justice:** Justice requires fairness in the selection of participants in research. The IRB reviews applications to make sure that the inclusion or exclusion of people in proposed research is fair and equitable.

## C. State, Federal, and Professional Codes

Research involving human participants at UMW must be conducted in accordance with mandates set forth by the Code of Federal Regulations (45 CFR 46, as revised 2018, also known as the "Common Rule"), the Code of Virginia (Title 32.1, Ch. 5.1 and other relevant sections), and any applicable codes set forth by a researcher's professional organization.

## D. Resources

**1. The Nuremberg Code in Full**
https://history.nih.gov/research/downloads/nuremberg.pdf

**2. The Belmont Report in Full**
https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html

**3. Code of Federal Regulations, Revised Common Rule in Full (45 CFR 46)**
https://www.hhs.gov/ohrp/regulations-and-policy/regulations/revised-common-rule-regulatory-text/index.html

**4. Office of Human Research Protections**
https://www.hhs.gov/ohrp/

5. **Code of Virginia, Human Research**
   https://law.lis.virginia.gov/vacode/title32.1/chapter5.1/

6. **UMW IRB Instructions and Forms**
   https://provost.umw.edu/irb/instructions-and-forms/

# SECTION II

# Policy Guidelines for Researchers

## A. Definitions

### 1. Research

Federal regulations define *research* as " . . . a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge" (45 CFR 46.102(l)). (See details in Section II.B below.)

### 2. Human Subject

Federal regulations define *human subject* as " . . . 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" (45 CFR 46.102(e)(1)).

### 3. Identifiable Private Information

Federal regulations define *identifiable private information* as "private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information" (45 CFR 46.102(e)(5)).

### 4. Minimal Risk

According to federal regulations, *minimal risk* means 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" (45 CFR 46.102(i)).

### 5. Vulnerable Populations

In 2018 the categories of vulnerable populations were updated in the federal regulations to include: children, prisoners, individuals with impaired decision-making capacity, and economically or educationally disadvantaged persons. Pregnant women and individuals with physical disabilities are no longer considered vulnerable under current regulations.

According to federal regulations, *vulnerable populations* are those individuals "vulnerable to coercion or undue influence" in making decisions regarding participation in research (45 CFR 46.111(b)). Therefore, special care is required with these populations in recruiting, obtaining informed consent, and designing research protocols with these populations.

## B. Covered and Excluded Research Activities

### 1. Covered Types of Research

The IRB must review and approve all human subjects research in which any UMW employee, student, or agent is engaged, either in the course of their University responsibilities, or when using the University's name, symbols, property, or services in connection with the research. For the purpose of this policy, *engagement* in research means performing activities that involve researchers' interactions with study participants or their data or biospecimens. These include such activities as recruitment, obtaining informed consent, collecting data, and analyzing data.

No research involving information from or about human participants may be initiated at UMW without prior approval by the IRB (including research conducted at UMW by external researchers). Research covered by this policy is research that is systematic in method and designed to contribute to generalizable knowledge. This includes, for example, case study research on a single individual, as well as pilot studies. As a rule of thumb, the IRB considers research to be "generalizable" if the results will be or have the potential to be publicly released for scholarly purposes; for example, presented at a conference or published in print or online.

### 2. Excluded Types of Research

The federal definition of research excludes the following types of investigations from IRB review; these fields of research have their own codes of ethics: "Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focuses directly on the specific individuals about whom the information is collected" (45 CFR 46.102(e)(1)). This may include, for example, research designed to hold specific elected or appointed public officials up for scrutiny. Other investigatory activities excluded from IRB review include those legally required by or for public health agencies, criminal justice agencies, and national security and defense agencies. The IRB has no jurisdiction over research conducted by members of the University community which is not related to their assigned roles and responsibilities at UMW.

### 3. Faculty and Staff Research

Research involving human subjects designed to contribute to generalizable knowledge that is conducted by UMW faculty and other employees, or by faculty who enlist their students' assistance in conducting the research, must be approved by the IRB, whether or not the research receives funding from external sources. However, when faculty undertake research projects on their own as private contractors, such research will be deemed independent of their University roles and responsibilities and not subject to IRB review if: (1) the research is conducted on their own time and not reimbursed by the University or through University accounts; (2) the research is conducted without the use of University space, materials, supplies, or staff support; and (3) any research publications, reports, or presentations will not list the faculty member's position and affiliation with the University of Mary Washington. Furthermore, IRB approval is not required for members of the University who act solely as consultants on human subjects research that involves participants not affiliated with UMW.

## 4. Student Projects: Research vs. Pedagogy

Some research conducted by students that is used to fulfill course or degree program requirements must be approved by the IRB. This includes all generalizable research, which means research reported publicly, whether sponsored by the University or not, including conferences and other forums such as Research and Creativity Day, the UMW Libraries digital archives, etc. Student projects in some courses are subject to IRB review if they are designed at least partially to provide data for generalizable research. For example, instructors may enlist students to assist in data collection or analysis for their own research or may design seminars in which a goal is for students to collaborate on research that will be submitted for publication. These projects constitute research and must be approved by the IRB before any engagement in research activities commences.

On the other hand, some courses at UMW require students to complete projects as a way of teaching them research methods and skills. If research for such pedagogical purposes is to be presented only within the classroom, the IRB does not require it to be reviewed, since it would not be intended to provide generalizable knowledge. Although the IRB does not require review of such projects, it assumes that instructors in these courses provide close supervision of students, teach students the ethics of human research, and ensure that students conduct these projects in a manner consistent with the precepts of the Nuremberg Code and the Belmont Report (see Manual, Section I). Any human subjects data collected in research conducted for pedagogical purposes may not later be used in a generalizable study, unless the subjects gave prior informed consent for the collection and use of their data for such purposes.

## 5. Internal Evaluations

Internal evaluations are subject to IRB review if they fit the definition of research provided above: i.e., a systematic investigation designed to contribute to generalizable knowledge. Not all internal evaluations fit this definition. Evaluations conducted exclusively for quality assurance, quality improvement, or accountability are not considered research for IRB purposes and do not require IRB review. In these evaluations, there is no intention to share knowledge and information with external audiences. By way of example, a faculty member conducting a routine course evaluation or an administrative department surveying the satisfaction of graduates to improve program quality would not be required to go through the IRB. However, a faculty member or administrator evaluating a program or teaching strategy with a view towards reporting the results professionally would be required to have the study approved by the IRB. Use of information from the University's records and databases, whether for generalizable research purposes or not, should be cleared by the Associate Provost for Institutional Analysis and Effectiveness.

## 6. International and Out-of-State Research

The UMW IRB does not have to capacity to ensure that research complies with the legal and ethical requirements for research in other states and countries. Therefore, researchers are responsible for understanding and complying with the laws and regulations of states or countries where they conduct research. In an international setting, investigators must also understand the cultural and ethical aspects of conducting human

research. This also pertains to research conducted in Native American lands under tribal laws.

### 7. Research by Investigators from Other Institutions

Investigators at other institutions who wish to collect research data at UMW should contact the IRB Chair for determination of whether the research will be subject to review by the UMW IRB or not. In general approval of the UMW IRB is not required if researchers merely wish to inform members of the University community about the research, or if UMW faculty agree to distribute surveys to their students, for example. However, external studies that involve university student data, facilities, or personnel, etc., are likely to require IRB approval. For information on research at UMW involving collaboration with external researchers or institutions, see Sections III.H-J below.

### 8. Recruitment and Screening

Procedures and documents used in identifying and recruiting participants conducted before their involvement in research are considered an integral part of the research and must be reviewed by the IRB. This includes obtaining identifiable data or biospecimens for screening, and any invitations or requests for individuals to participate in the study, such as advertisements, press releases, posters, email messages, social media posts, etc.

### 9. Pilot Studies

Work preparatory to research, such as getting feedback from colleagues or friends on research materials, does not require IRB approval. However, pilot studies involving human participants typically require IRB approval. A pilot study (sometimes called a feasibility study, mock study, or dry-run study) is a preliminary investigation of the feasibility of a larger study, is usually done on a small scale, and is exploratory in nature. It is designed to help the investigator refine data collection procedures and instruments or prepare a better, more precise research design. Although data collected through pilot studies may not ultimately be used in research reports and publications, pilot studies (regardless of sample size) represent part of the research process that leads to the development of, or contribution to, generalizable knowledge. Therefore, pilot studies of this nature that involve collection of data or biospecimens from human subjects require IRB review and approval and the subjects' informed consent before they are conducted.

## C. General Investigator Responsibilities

All human subjects research at the University of Mary Washington must be carried out under the guidelines set forth in this Manual, and in relevant federal, state, and professional codes. When planning and engaged in such research, all University employees, students, and agents (including but not limited to principal investigators, student research aides, faculty advisors on student research, and staff) must adhere to the policies outlined in this Manual. It is the responsibility of each UMW researcher to apply for and obtain IRB approval of research involving human subjects prior to engaging in any research activities, using the forms and accompanying instructions on the Forms page of the UMW IRB website (see Section III below). It is also the responsibility of researchers to conduct research

strictly according to the protocols approved by the IRB and to follow instructions on the official IRB approval letter. Any alterations to research affecting the approved application form or its attachments must be submitted to and approved by the IRB before they can be implemented.

## 1. Principal Investigators

When a study involves more than one researcher, the IRB will communicate with one principal investigator on the research team. The principal investigator will be responsible for ensuring that materials submitted to the IRB are accurate and complete, for communicating IRB matters to other researchers in the project, and for seeing that the research is conducted according to the protocols approved by the IRB and the policies and procedures in this Manual, as well as other University policies, such as those involving use of student records. The principal investigator is also responsible for reporting changes to the research application, for cooperating in continuing reviews, if any, and for reporting adverse events, if any.

When one or more UMW students participate in conducting research, there must be a faculty member serving as research supervisor. The faculty research supervisor may serve as the principal investigator or assign a student on the research team to coordinate communication with the IRB. In either case, the IRB will communicate with the faculty supervisor as well as the assigned student, if any.

## 2. Ethics Training

Before applying for IRB review of a study, all individuals engaged in human subjects research, as well as faculty who supervise student research, are required to successfully complete approved training on research ethics, policies, and procedures. This training is to be documented by submitting an up-to-date training certificate as an attachment to any application for IRB review. The training for researchers is brief, is conducted online, and is provided without charge to UMW faculty, staff, and students. Instructions for accessing the online training module are on the IRB website at https://provost.umw.edu/irb/irb-training/

## 3. Academic Integrity

The University Faculty Handbook (Section 4.8) establishes procedures for reporting, investigating, and deciding on allegations of academic misconduct by faculty. Although these procedures are outside the scope of IRB involvement, relevant records of the IRB may be submitted to appropriate University officials as part of inquiries into such matters.

## 4. Informed Consent

Investigators on all research involving human subjects as participants must obtain participants' informed consent prior to their participation in the research. According to federal regulations, *informed consent* means providing prospective study participants "the information that a reasonable person would want to have in order to make an informed decision about whether to participate" (45 CFR 46.116(a)(4)). Prospective participants or their legally authorized representatives must be provided this information in writing and individually give their consent to participate. Detailed information about informed consent

requirements and related procedures and documents is in Section III.F below and on the Forms page of the UMW IRB website.

### 5. Cooperative Multi-Site Research

Current federal regulations require that any U.S. institution engaged in non-exempt cooperative research must rely upon approval by a single IRB (45 CFR 46.114). Therefore, researchers involved in cooperative multi-site research must follow the procedures for obtaining the official reliance agreements required before the study can begin, as covered in Sections III.H-J of this Manual.

To request that the UMW IRB rely upon another IRB of record for review of a cooperative multi-site study, the lead researcher at UMW must submit the Reliance Authorization Agreement form and consult with the IRB Chair. To request that the UMW IRB serve as the IRB of record for a cooperative multi-site study, the UMW researcher acting as the principal investigator for the study must complete and submit the UMW as IRB of Record Request form with their IRB application. Instructions and forms are on the Forms page of the UMW IRB website.

### 6. Grant Applications

If an external funding agency requires research to be approved by an IRB at the time of application for the grant, UMW researchers must submit IRB proposals sufficiently in advance of the grant application deadline. Otherwise, the research does not undergo review until a grant has been awarded. According to federal regulations (45 CFR 46.118), no human subjects may be involved in any project supported by agency grants until the project has been reviewed and approved by the IRB.

### 7. Adverse Events and Unanticipated Problems Associated with Research

Researchers are required to report to the IRB Chair any adverse events or unanticipated problems affecting participants and arising from their research. An *adverse event* is defined as "any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign ..., symptom or disease, temporally associated with the subject's participation in the research ..."[1] An *unanticipated problem* is an incident, experience, or outcome during the research, or apparently resulting from the research, that was not foreseen by researchers as indicated on the approved IRB application and consent form, including physical, psychological, economic, or social harm to participants or others, or which suggests such harm is possible.

In case of an unanticipated problem or adverse event during or as an apparent result of the research, the principal investigator at UMW or a student researcher's faculty supervisor must notify the IRB Chair immediately. If an affected participant contacts the IRB chair directly about a problem or adverse event, the Chair will notify the principal investigator or responsible faculty member. To report such an event, use the official Adverse Events Reporting Form on the Forms page of the UMW IRB website and follow the accompanying instructions (see additional instructions in Section IV.J).

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[1] Office of Human Research Protections, 2007. For detailed definitions, visit https://www.hhs.gov/ohrp/regulations-and-policy/guidance/reviewing-unanticipated-problems/index.html

# SECTION III

# IRB Application Forms and Procedures

## A. General Application Guidelines

### 1. Application Forms

All research involving human subjects must be approved by the IRB before the research or contact with the subjects can begin. The appropriate application form, along with all required attachments, should be completed by the principal investigator, and, in the case of student research, a supervising faculty member must approve the contents of the application form and attachments before submission to the IRB. There are two basic application forms UMW researchers use to apply for IRB review and approval of a prospective study. The ***Exempt Status Review*** form should be used when a study meets the criteria for this level of review (see Section III.C below). Applications for studies that do not meet the criteria for Exempt Status Review should be submitted on the ***Expedited Review*** form (see Section III.E below). Both forms with detailed instructions are available on the Forms page of the UMW IRB website.

### 2. Informed Consent Forms

All applications for IRB review of research must be accompanied by the appropriate forms for providing participants information about the research and requesting their consent to participate in the research (see Section III.F below).

### 3. Submission of Forms

Completed application forms with attachments, or any questions about filling out the forms, should be submitted to the IRB member responsible for reviewing applications from the principal investigator's academic department, as indicated on the Members page of the UMW IRB website. Forms should be submitted at least two to four weeks prior to the planned date of beginning research activities, in order to allow sufficient time for the review to take place. This means before any interaction with human subjects or their data, including before circulation of participant recruitment materials. To avoid delays in the review process, applicants should submit forms that are complete, accurate, and clearly explained. The information submitted must be consistent across all parts of the application form and attachments. Reviewers will follow policies and procedures for review of applications described in Section IV below.

### 4. Changes in Research After IRB Approval

Any changes made in a study after initial approval must be approved by the IRB before they can be implemented. The principal investigator should notify the IRB Chair or designated reviewer in writing of any changes to be made in a study. If a change is minor (such as changing a question on a survey), a description of the change may be submitted. If the changes are more extensive, a revised application form with attachments will be required. The researcher will be notified in writing upon approval.

## B. Application for Exempt Status Review

Exempt Status Review is a level of review in which an individual member of the IRB reviews a research proposal with limited or no subsequent review at an IRB meeting. Researchers are required to indicate on the application form which category of exemption they believe their research qualifies for (as described in Section III.C below). Investigators who believe their study meets these criteria can apply for this level of review by completing the Exempt Status Review application clearly and accurately according to the instructions available on the Forms page of the UMW IRB website.

The form requires applicants to provide a brief rationale for the study that explains why they believe it meets the criteria for this level of review, and to briefly describe the research setting and participant population, the data collection and intervention procedures, the privacy and confidentiality measures, and the risks and benefits to participants. All required attachments to the application form (see Sections III.F-J below) must be submitted for IRB review.

Exempt Status Review applications should be submitted to the IRB Chair or to the IRB member designated as reviewer for the primary investigator's academic department, as indicated on the Members page of the UMW IRB website.

## C. Exempt Status Review Categories and Criteria

### 1. Research in Educational Settings

This category involves research on adults or children that is conducted in established or commonly accepted educational settings and specifically investigates normal educational practices that are not likely to adversely impact students or teachers. To qualify for this category the educational practices must not be likely to adversely impact students' opportunity to learn required educational content and not likely to adversely impact the assessment of educators who provide instruction.

An *established or commonly accepted educational setting* is a space used for teaching and learning in or by a public or private educational organization. Examples of places that would *not* be established or commonly accepted educational settings would include spaces used for home-schooling or spaces used for occasional training in a business or other noneducational organization.

Research to investigate *normal educational practices* may involve regular or special education instructional strategies or the effectiveness of instructional or assessment techniques, curricula, or classroom management methods, etc. Any research design that withholds instruction from participants entitled to it would not be normal. The IRB does not consider research involving collection of audio, video, or digital recordings or photographic images of children used as data to qualify for this category of Exempt Status Review; an application for Expedited Review will be required.

### 2. Research Involving Tests, Surveys, Interviews, or Observation

This category involves research on adults (or in limited cases children) using only these procedures, involving no more than minimal risk, and only if adequate privacy and confidentiality measures are in place. To qualify for this category, the research protocol

may not include procedures under any other Exempt Status categories. Research on adults in this category may include voice, video, digital or image recordings only when the subjects know they are being recorded. At least one of the following criteria must be met for research in this category:

a. **Data collection:** Information obtained is recorded in such a manner that human subjects cannot be identified, directly or through identifiers linked to the subjects;
b. **Risks:** Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation; or
c. **Privacy and confidentiality:** The IRB determines that privacy and confidentiality measures are in place if any information obtained about subjects is recorded in such a manner that they can be identified directly or through identifiers linked to the subjects.

Research on children can qualify for Exempt Status Review under criteria (a) and (b) of this category only if there is no interaction between the researcher and the child (*interaction* includes communication or interpersonal contact between investigator and subject). Research on children cannot qualify for Exempt Status Review under criterion (c) of this category. However, no research on children may qualify for Exempt Status Review in this category if it involves voice, video, digital, or image recordings; an application for Expedited Review will be required.

### 3. Research Involving Benign Behavioral Interventions

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. A *benign behavioral intervention* is defined as an activity that participants undergo which is brief in duration, harmless, painless, not physically invasive, and not likely to have a significant adverse impact on the subjects; and the investigator has no reason to think the subjects will find the intervention offensive or embarrassing (45 CFR 46.104(d)(3)(ii)). The criteria for IRB approval in this category also include having adequate privacy and confidentiality measures in place. If all of these criteria are met, the following would be examples of benign behavioral interventions: having subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of money between themselves and someone else.

This category is only for the collection of information from adult subjects and only includes protocols in which subjects give informed consent before the intervention. Research in this category may occur in conjunction with the collection of data from subjects through verbal or written responses (including visual or auditory recording or data entry). If the study involves deception, subjects must give **prior consent** that they will be unaware of or misled regarding the purpose of the study or intervention, and also be debriefed following the procedure. This category does not apply to any research involving medical interventions, including medical tests, procedures or devices.

To qualify for exemption under this category, the research must meet at least one of the following criteria:

a. **Data collection:** Information obtained is recorded by the investigator in such a manner that the identity of the subjects cannot readily be ascertained directly or through linked identifiers;
b. **Risks:** Any disclosure of the subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
c. **Privacy and confidentiality:** The IRB determines that privacy and confidentiality measures are in place if any information obtained about subjects is recorded in such a manner that they can be identified directly or through linked identifiers.

## 4. Secondary Research for Which Consent is Not Required

*Secondary research* refers to use of data not collected by the researcher for the proposed study. It means reusing identifiable information and identifiable biospecimens from adults or children that were originally collected for some purpose other than the proposed study, such as information found by the investigator in a record or specimen repository (e.g., a hospital database). However, research on children does not qualify for Exempt Status Review in this category if the data includes any voice, video, digital, or image recordings.

Secondary research may include data collected by the researcher for a previous study for which consent was obtained. Secondary research data or specimens do not all have to exist prior to beginning the proposed research; some may be placed in the data repository after the proposed research begins. If the research uses data from students' private school records, the researcher and the institution that provides the data are responsible for ensuring that it meets the requirements of the federal Family Educational Rights and Privacy Act (FERPA) and applicable state laws. Use of data from the University's records and databases should be cleared by the UMW Office for Institutional Analysis and Effectiveness, following instructions on their website.

To qualify for this category the research must meet at least one of the following criteria:

a. **Data availability:** The information or specimens are publicly available;
b. **Identifiability:** The information is recorded by the investigator so that the identity of the human subjects cannot be ascertained by the investigator directly or through identifiers linked to the subjects, the investigator does not contact the subjects at any time, *and* the investigator will not re-identify the subjects;
c. **Health purposes:** The research involves collection and analysis of identifiable health information only for health care or public health activities and purposes; or
d. **Agency data:** All of the identifiable private information is collected or maintained by a federal department or agency in compliance with all applicable privacy laws.

## 5. Research and Demonstration Projects for a Federal Agency

This Exempt Status Review category covers projects which are designed to study public benefit or service programs and are conducted under contracts or consulting arrangements, cooperative agreements, or grants with a federal department or agency, or research otherwise subject to the approval of a federal agency. This category applies to

research on adults or children. However, research on children will not qualify for Exempt Status Review in this category if it involves voice, video, digital, or image recordings; an application for Expedited Review will be required. This category covers projects which are designed to study, evaluate, or otherwise examine:

- Public benefit or service programs;
- Procedures of obtaining benefits or services under those programs;
- Possible changes in or alternatives to those programs or procedures; or
- Possible changes in methods or levels of payment for benefits or services under those programs.

**6. Research on Taste and Quality of Foods**

This category involves research to investigate taste and food quality or consumer acceptance, involving wholesome foods with no additives, or involves foods with the type and amount of ingredients that meet federal safety standards. If the food contains additives, researchers must verify for the IRB that the food meets standards of the Food and Drug Administration, the Environmental Protection Agency, or the Food Safety and Inspection Service of the Department of Agriculture (e.g., by providing package labeling or product website). This category applies to research on adults or children. However, research on children will not qualify for Exempt Status Review in this category if it involves voice, video, digital, or image recordings; an application for Expedited Review will be required.

**7. Storage or Maintenance of Data for Secondary Research**

This is not a category of research per se, but relates to the process for storage of identifiable private information or identifiable biospecimens for potential secondary research use (see definition of *secondary research* under Subsection III.C.4 above). For example, collection and maintenance of identifiable data for potential use in future research by the original applicant or others, then this category would apply. Broad consent is required, and the IRB must verify that informed consent procedures meet federal requirements. The IRB must also verify that adequate privacy and confidentiality measures are in place (see definition of *broad consent* in Subsection III.C.8 below).

**8. Secondary Research Requiring Broad Consent**

This category involves use of identifiable private information from adults or children not collected by the researcher for the current study, when adequate privacy and confidentiality measures are in place and Broad Consent has been obtained (see definition of *secondary research* in Subsection III.C.4 above). *Broad consent* refers to prior consent given by participants for unspecified future research use of their identifiable private information or identifiable biospecimens. For example, broad consent for use of medical information may be provided through use of HIPAA forms (Health Insurance Portability and Accountability Act). To qualify for this exemption, *all* of the following criteria must be met: Broad consent from subjects was obtained;

**a. Consent:** Signed informed consent was obtained from participants, or waiver of such documentation was obtained from the IRB;

***b.*** **Scope of consent:** The IRB determines that the proposed research is conducted within the scope of broad consent and approves the procedures used to obtain broad consent; *and*

**c.** **Results:** The research plan does not include returning individual research results to the subjects.

## D. Application for Expedited Review

Researchers who believe that their study does *not* meet the criteria for Exempt Status Review should submit an application for Expedited Review, following the instructions on the Forms page of the UMW IRB website. All policies and procedures in this Manual for adherence to the federal regulations for human subject research must be addressed in writing on the IRB application for Expedited Review.

The application for Expedited Review requires applicants to provide a rationale for the study that includes a brief review of relevant prior research. Other information required includes descriptions of: the research setting and methods of recruiting and identifying participants; the data collection and intervention procedures; the privacy and confidentiality measures; and the risks and benefits to participants. All required attachments to the application form (see Sections III.F-J below) must be submitted for IRB review.

Applications for Expedited Review should be submitted to the IRB Chair or to the IRB member designated as reviewer for the primary investigator's academic department, as indicated on the Members page of the UMW IRB website.

## E. Expedited Review Categories and Criteria

Research activities that do not qualify for Exempt Status Review (Section III.C above) are eligible for Expedited Review if they present no more than minimal risk to human participants, and if they involve research listed in one or more of the categories of research listed below.[2] The seven categories apply regardless of the age of participants, except as noted. These seven categories also pertain to continuing IRB review if required as a condition of IRB approval.

The activities in these seven categories are not deemed to be of minimal risk simply because they are included on this list; rather, inclusion on this list means that the activity is eligible for Expedited Review. The IRB Chair or designated IRB reviewer will determine if the specific circumstances of the proposed research are seen to involve no more than minimal risk to human participants and otherwise qualify for expedited review. If determined to be of greater than minimal risk, the proposal will be referred for Full Board

[2] In 2018, changes in the federal regulations for human subjects research permitted some research in these categories to qualify for Exempt Status Review (45 CFR 46.104). The categories of research eligible for Expedited Review listed here have not been revised since they were promulgated by the Department of Health and Human Services in 1998 (http://www.hhs.gov/ohrp/policy/expedited98.html). Under the 2018 regulations, HHS "will evaluate the list at least every 8 years and amend it, as appropriate" (45 CFR 46.110(a)).

Review (see Section IV.F below). For a detailed description of each of the expedited categories, with examples, see the guidance on the HHS website.

**1. Clinical Studies**

This category pertains to research in clinical settings of drugs and medical devices only when at least one of the following conditions is met:

- Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for Expedited Review); *or*
- Research on medical devices for which (i) an investigational device exemption application (21 CFR 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

**2. Collection of Blood**

This category includes collecting samples by finger stick, heel stick, ear stick, or venipuncture only if taken from:

- Healthy, nonpregnant adults who weigh at least 110 pounds, when the amounts drawn meet certain criteria; *or*
- Other adults and children, considering the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected.

**3. Noninvasive Collection of Biospecimens**

This category includes such things as hair and nail clippings, extracted teeth, excreta, saliva, and dental plaque.

**4. Noninvasive Collection of Data**

This category includes collection of data using procedures routinely employed in clinical practice, excluding procedures involving general anesthesia, sedation, x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.

**5. Secondary Use of Data**

This category involves use of data, documents, records, or specimens that have been collected, or will be collected solely for nonresearch purposes, such as medical treatment or diagnosis.

**6. Recordings**

This category involves collection of data from voice, video, digital, or image recordings made for research purposes.

### 7. Characteristics or Behavior

This category involves research on individual or group characteristics or behavior, including, but not limited to, perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior; or generalizable research employing survey, interview, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

## F. Informed Consent Policies and Forms

According to federal regulations, all materials that inform potential research subjects about the study, including recruitment materials, are considered part of the informed consent process and are subject to IRB review (45 CFR 46, Preamble, XIV.G.4). An informed consent notice is required as an attachment to the IRB application. The informed consent notice must provide prospective subjects with the information a reasonable person would want to have in order to make an informed decision about whether to participate in the study. Any changes to the informed consent materials are considered changes to the IRB application and must be submitted to the IRB for review prior to implementation. Detailed instructions with informed consent templates and samples are available on the Forms page of the UMW IRB website.

The procedures required for obtaining informed consent are explained in the following subsections. All research participants or their legally authorized representatives must receive the informed consent notice in writing and voluntarily sign the form prior to their involvement in the study. Only the IRB can waive these requirements, as explained in Subsections III.F.3-4 below.

### 1. Informed Consent Notice for Adult Participants

All adult research participants must give prior consent, and the consent form is a required attachment to the IRB application. All information about the proposed research that is provided in the consent form must be consistent with the corresponding information given on the IRB application form. The form must be written in language the prospective subjects will understand. In drafting the informed consent notice, researchers should follow the detailed instructions and sample template provided on the Forms page of the UMW IRB website. Informed consent notices will be reviewed by the IRB to ensure that they provide all of the information required according to those instructions. Only the IRB can waive any requirements for informed consent, and researchers who consider such waivers necessary must request the appropriate waiver in their IRB application (see Subsections III.F.3-4 below). At a minimum, the following information is required on consent forms:

- **a. Opening summary:** A concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate
- **b. Voluntary nature of participation:** A statement that refusing to participate will involve no penalty or loss of benefits, and that one who consents to participate may later withdraw from the study
- **c. Purpose of the research:** Scientific or investigatory goal of the research

d. **Description of subject's involvement:** What participants will do and/or what procedures they will undergo to provide study data, and identification of any procedures that are experimental
e. **Alternatives to participation:** Disclosure of alternative interventions or treatments available
f. **Privacy:** Description of measures that will be taken, as appropriate, to maintain individual subjects' privacy
g. **Confidentiality:** Description of measures that will be taken to maintain the confidentiality of participants' data, and a statement regarding secondary use of the data
h. **Risks:** Foreseeable risks or discomforts to the subjects related to their participation
i. **Benefits:** Direct benefits to the subjects or indirect benefits to the public that may reasonably be expected from the research or participation in it
j. **Contact information:** How to obtain answers to questions about the research and about subjects' rights, and how to report adverse events or complaints; and
k. **Signatures:** Both the researcher administering informed consent and the consenting participant or legally authorized representative must sign and date the form prior to involvement in the study; a copy of the form signed by the researcher must be provided to the subject or legally authorized representative.

**2. Storage**

The signed informed consent forms for a study should be kept in a secure location by the researcher or the researcher's department for a minimum of three years.

**3. Waiver of Signatures**

Certain types of research cannot be conducted practicably when signatures on consent forms are required, such as research involving online or telephone surveys. If all other requirements for informed consent are met, the IRB may waive the requirement for signatures under any of the following circumstances if justified on the IRB application:

- The only record linking the subject and the research would be the consent form, and the principal risk would be due to a breach of confidentiality (in this case, the researcher administering informed consent must ask each prospective subject if they want to sign or not);
- The research presents no more than minimal risk and the procedures would not require signed consent outside of the research context; or
- The subjects or legally authorized representatives are members of a cultural group or community in which signing forms is not the norm, the research involves no more than minimal risk to participants, and there is an appropriate alternative for documenting that informed consent was obtained.

**4. Requests for Alteration or Waiver of Consent**

A request for waiver of informed consent or for alteration in the contents of the informed consent notice can only be approved by the IRB if all of the following requirements applicable to the study are met:

- The research involves no more than minimal risk to participants;

- The research could not practicably be carried out without the waiver or alteration;
- If the research involves using identifiable private information, the research could not practicably be carried out without using the information in an identifiable format;
- The waiver or alteration will not adversely affect the rights and welfare of subjects; *and*
- When appropriate the participants or legally authorized representatives will be provided with additional information after participation (see Subsection III.F.8 below)

**5. Assent Notice for Child Participants**

When children under the age of 18 are research subjects, their parents or legally authorized representatives must give informed consent prior to their participation, using a modified version of the informed consent notice for adult participants described above. Additionally, children who are capable of making a voluntary decision whether or not to participate in research must be asked for their assent to be research subjects. Children under the age of 7 (or under second grade) are considered by the IRB to be too young to make a voluntary decision about participating in research. The assent forms must be written in age-appropriate language the children will understand. Sample templates for the parental consent and child assent forms, along with detailed instructions on conducting research with children, are available on the Forms page of the UMW IRB website.

All children are defined by federal regulations as "vulnerable to coercion or undue influence" in making decisions regarding participation in research (45 CFR 46.111(b)). Therefore, IRB reviewers will ensure that researchers do not appeal to those vulnerabilities in the assent notice or the participant recruitment literature.

The recommended consent procedure for research involving children is to obtain the parental consent first and then the assent of the child. The parental consent form should state that the child will also be given an opportunity to volunteer for study participation, and the assent form should be attached to the parental consent form. In order for the child to be a research subject, both the parent and the child must agree to the child's participation using the appropriate forms. These procedures may be altered if approved by the IRB as necessary to protect the well being of the child.

**6. Translations**

Informed consent notices, including child assent forms, should be written in language the prospective research participants will understand. Therefore, if participants need to receive the informed consent notice in a language other than English, both the English version of the consent form and the translation must be attached to the IRB application. However, researchers may delay submitting the non-English translations until an IRB reviewer has determined that the English language versions are satisfactory. The IRB requires that the translation be made by a reliable translator, so the source of the translation must be provided. Detailed instructions are provided in the Adult Informed Consent Instructions on the Forms page of the UMW IRB website.

### 7. Recruitment and Screening

Procedures and documents used in identifying and recruiting participants conducted before their involvement in research are considered an integral part of the research and must be reviewed by the IRB. This includes any invitations or requests for individuals to participate in the study, as well as obtaining identifiable data or biospecimens for screening. The following conditions apply:

a. **Data collection:** Certain data collection activities conducted prior to the beginning of the research do not require informed consent, but must be described on the IRB application. An investigator may obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without prior informed consent, if either of the following conditions are met:
   - The investigator will obtain information through direct oral or written communication with the prospective subject or legally authorized representative, or
   - The investigator will obtain identifiable private information by accessing records or stored identifiable biospecimens

b. **Recruitment materials:** Participant recruitment materials such as posters, advertisements, social media posts, email messages, etc. are considered part of the informed consent process if they provide information about the study to potential participants or their legally authorized representatives. Although recruitment materials do not have to contain all the information required in Subsection III.F.1 above, the IRB must review such materials to ensure that the recruiting appeal is not coercive and that the information provided is consistent with the description of the study contained in the IRB application form and consent form.

### 8. Debriefing Materials

Debriefing means providing information about the research to participants after they have given their informed consent to participate, and usually after their participation is completed. If the research involves deception of the participants, debriefing is required in order to fully inform participants about the research and enable them to withdraw from the study. The only exception is on research under Exempt Status Review Category 3, Behavioral Interventions, (see Section III.C.3 above).

Even if there is no deception, debriefing may be used to educate participants by providing useful information or resources not provided in the original Informed Consent materials. Debriefing is also used to notify participants of any risks discovered by researchers after the informed consent process. Regardless of its specific purpose, a copy of the debriefing form should be given to participants to keep for future reference. Detailed instructions and sample templates for debriefing materials are available on the Forms page of the UMW IRB website.

### 9. Broad Consent for Secondary Use of Data

The term *broad consent* refers to prior consent given by participants for unspecified future research use of their identifiable private information or identifiable biospecimens. Broad consent is an alternative informed consent procedure that may be used on certain

categories of Exempt Status Review research (see Section III.C above) and on the Forms page of the UMW IRB website.

Researchers who expect to use subjects' confidential data for future studies or share it with other researchers after completion of the proposed study may rely on the consent procedures of a data storage facility (such as the Health Insurance Portability and Accountability Act notification of a hospital database). Alternatively, the informed consent notice should include the following statement of broad consent: "After this research is complete, all participant identifiers will be removed and the data will be stored and distributed for use in future research studies without additional informed consent from participants." Use of information from the University's records and databases should be cleared by the UMW Office for Institutional Analysis and Effectiveness, following instructions on their website.

### 10. Oral Consent Procedures

According to federal regulations, oral consent does *not* mean merely reading a written consent notice aloud to potential research participants; this is considered written consent (45 CFR 46. 117(a)(1)). Rather, oral consent is a complex procedure that requires the presence of a witness to sign a written version of the consent notice (45 CFR 46.117(b)(2)). Researchers who believe this oral consent procedure may be necessary for any participants in their study should first consult with the IRB Chair about details of the procedure and the required documentation of informed consent if this procedure is used. An alternative suitable in some situations would be to request that the IRB waive requirement for signatures on consent forms (see Subsections III.F.3-4 above).

## G. Attachments to IRB Applications

### 1. Signature Page

The UMW IRB requires that all individuals engaged in the research sign the signature page that is part of each application form. Engagement in research includes activities such as recruiting human subjects, administering informed consent, collecting data, and analyzing data. If any research activities are to be performed by UMW students, the supervising faculty member must also sign the signature page to verify that they take responsibility for the conduct of the research according to IRB instructions and policies.

Each signature on the signature page should be authentic, not typed. An authentic signature may be hand written on a hard copy of the signature page, or an image of an authentic signature may be embedded on a digital copy of the signature page. In case of a physical disability, injury, etc. that prevents a researcher from providing their authentic signature, they should explain to the IRB reviewer and seek advice from the UMW Office of Disability Resources.

### 2. Data Collection Materials

Researchers will be required to provide with their IRB applications all materials to be used for collection of data from the human subjects in their studies. These include survey questionnaires, tests, interview questions, observation forms or protocols, instructions to be given to participants for behavioral interventions, etc. These are considered part of the IRB application and undergo review by the IRB before the research

begins. If a published standardized test or questionnaire will be used, it is sufficient to provide the name of the instrument and publicly available online or bibliographic source.

### 3. Documentation of Ethics Training

Each individual who engages in research and signs the signature page of the IRB application form is required to submit official, up-to-date documentation of successful completion of ethics training. The document should be an accurate copy of the actual training certificate or completion report from the training provider, and must include the expiration date. If the training expires before the IRB application is approved, the researcher will be required to resubmit an updated training certificate. Updated ethics training may also be required as part of continuing review (see Section IV.H below).

### 4. Confidentiality Agreements

Individuals who are not affiliated with UMW but are performing certain tasks in research reviewed by the UMW IRB may submit a confidentiality agreement in lieu of signing the signature page or documenting ethics training. This includes persons who have access to identifiable information about subjects, such as those who ask scripted questionnaires by phone, transcribe interview recordings, perform translation or interpretation services involving participant data, perform data entry tasks, etc. Such service providers are not considered engaged in the research if all of the following conditions are met:

- The services performed do not merit professional recognition or publication privileges;
- The services performed are typically performed by those providers for non-research purposes; and
- The the service provider's employees or agents do not administer any study intervention being tested or evaluated as part of the research

The application form must describe the service provider and the functions they will perform, and the confidentiality form must verify the conditions above. Signed confidentiality agreements must be submitted to the IRB prior to allowing such service providers access to the identifiable data.

## H. Single IRB Requirement for Cooperative Multi-Site Studies

### 1. Definitions

A *cooperative multi-site study* is one in which research is conducted according to a single protocol and in which researchers from more than one institution are engaged. For the purpose of this policy, *engagement in research* means activities that involve researchers' interactions with study participants or their data. These include such activities as communication with potential subjects for recruitment purposes, obtaining informed consent, collecting data, and analyzing data. Research is *not* considered cooperative multi-site research under this policy if researchers from different institutions are presenting or publishing together but are conducting different protocols at distinct sites, or if research at multiple locations is conducted only by UMW researchers.

### 2. Regulatory Background

In the conduct of cooperative research projects involving more than one institution, each institution is responsible for safeguarding the rights and welfare of human subjects. However, under current federal regulations, any U.S. institution engaged in non-exempt cooperative research involving one or more other institutions must rely upon approval by a single IRB (45 CFR 46.114). The IRB of record, which conducts the review, will be identified by the lead institution, or by the federal department supporting the research. The only exceptions to this policy are 1) if review by more than a single IRB is required by law (including tribal law), or 2) if a supporting federal department determines that a single IRB is not appropriate for the research. Under this policy, cooperative multi-site studies that meet the criteria for Exempt Status Review (see Section III.C above) are not required to be reviewed by a single IRB, but the lead institution may agree to serve as the IRB of record and seek the reliance of cooperating IRBs.

## I. Requesting the UMW IRB to Rely on an External IRB of Record

### 1. Initiating the Request

To request that the UMW IRB rely upon another single IRB for review of a cooperative multi-site study involving researchers at UMW, the research must first be approved by another qualified IRB. The lead researcher at UMW must then complete the relevant portions of UMW IRB's Reliance Authorization Agreement form and submit it, along with required attachments, to the UMW IRB Chair. The form and the instructions to be followed are available on the Forms page of the IRB website.

### 2. Purpose

When fully executed, the UMW Reliance Authorization Agreement form is a formal agreement between the UMW IRB and the designated IRB of record. It acknowledges that the UMW IRB approves the research to be conducted at UMW and cedes authority for review and approval of the research to the IRB of record. The Reliance Authorization Agreement form itemizes the responsibilities of both the IRB of record and the UMW IRB.

### 3. Finalizing the Agreement

When the UMW IRB Chair receives the Reliance Authorization Agreement form, he or she will ensure that it is complete and then forward it to the UMW Provost or the Provost's designee for signature. The Chair will then send it to the IRB of record to be signed by that institution's signatory official, who will return it to the UMW IRB. The fully executed Reliance Authorization Agreement form with attachments will be be kept on file with the IRB records in the UMW Office of the Provost. A copy will also be provided to the lead researcher at UMW indicating approval that the UMW-based research may begin.

### 4. UMW Lead Researcher's Responsibilities

When the UMW IRB relies on another IRB, the lead researcher at UMW is the member of the multi-site research team who assumes responsibility for that part of the study in which UMW researchers are engaged. This role should be taken by a full-time faculty member or a qualified administrator who is willing and able to maintain close communication with the principal investigator at the lead institution and to ensure that

that the approved research protocols are followed by all researchers at UMW involved in the project. In addition to initiating the request for UMW to rely on an external IRB of record, other key responsibilities of the lead researcher at UMW include the following in relation to engagement of UMW researchers in the study:

- Ensure that no research activities begin until the Reliance Authorization Agreement form has been fully executed
- Ensure that the IRB of record obtains documentation of ethics training for each member of the research team at UMW, and that no member of the UMW research team has a conflict of interest
- Ensure adherence to the requirements of the IRB of record as specified in the approved research protocol and in the IRB approval notice
- Ensure that all relevant policies and procedures are adhered to throughout the research, including UMW IRB policies, relevant Virginia laws, and relevant local policies
- Communicate with the IRB Chair about the progress of the research and cooperate in continuing review and post-review monitoring of the study by the IRB of record
- Notify the UMW IRB Chair of any changes in the research materials, protocol, etc. approved by the IRB of record
- Report to the IRB Chair any adverse events and unanticipated problems related to the research at any site that affect participants
- Notify the UMW IRB Chair and the principal investigator of the cooperative study when the research at UMW is completed

**5. Responsibilities of the UMW IRB**

The Chair of the UMW IRB will ensure that the IRB meets the following responsibilities necessary for reliance upon another IRB for review of multi-site research in which UMW researchers are engaged.

- Ensure that the Reliance Authorization Agreement form is properly completed and signed by the signatory officials representing both UMW and the IRB of record
- Ensure that the UMW IRB meets its obligations according to the Reliance Authorization Agreement
- Communicate with the lead researcher at UMW about the reliance agreement and other IRB matters
- Ensure that reports of adverse events and unanticipated problems with the research are made as required by the IRB of record
- Provide the Office of the Provost complete records of the reliance agreement and related IRB actions
- Inform the IRB of record when the research being conducted by UMW researchers is complete, and, when the Reliance Authorization Agreement is terminated, record the termination in the minutes of the UMW IRB

## J. Requesting the UMW IRB to Serve as the IRB of Record

### 1. Considerations Prior to Request

The IRB of record for a multi-site study, also known as the sIRB (single IRB), may be identified by a federal department supporting the research, or if the research is not federally funded, the IRB at one of the cooperating institutions may agree to serve. The the ultimate decision for the UMW IRB to serve as the single IRB of record on a cooperative multi-site study must be made by the UMW IRB, if not pre-assigned by a grant funding agency. Individual researchers, therefore, should not make any commitments about the UMW IRB taking this role prior to its decision to do so.

When submitting a federal grant application or conferring with cooperating researchers, the lead researcher at UMW should understand the requirements of serving as principal investigator on the study (see Subsection III.I.4 below), as well as what the UMW IRB will consider in making a decision to serve as the single IRB of record, as follows:

a. **Federal guidance:** According to the federal advisory committee on human subjects research, "the IRB selected [as the IRB of record] should have the appropriate expertise for the research being reviewed, and the capacity to act as coordinator, receiver and dispenser of critical study-related data to the sites, their research teams, their IRBs and their institutions."[3] For the UMW IRB to serve as the single IRB of record for a cooperative multi-site study, the research must be within the expertise and capacity of the UMW IRB to review and conduct ongoing monitoring of the research at multiple sites throughout the duration of the study, and to manage record-keeping.
b. **UMW exclusions:** The UMW IRB has determined that it does not have the resources or expertise to serve as the IRB of record for multi-site studies if they involve biomedical interventions or involve research activities at any sites outside the United States. Because multi-site studies that qualify for Exempt Status Review are not required under federal regulations to have a single IRB of record (45 CFR 46.114), the UMW IRB will not normally agree to serve as an IRB of record for such studies.
c. **Other considerations:** Additional factors related to the UMW IRB's monitoring and record-keeping capacity that may impact its decision to serve as an IRB of record include, but may not be limited to:
    - the number of institutions engaged in the study
    - the number of protocol variations at different sites
    - the level of risk to study participants, the duration of the study, and/or
    - the number of other cooperative studies for which the UMW IRB is committed to serve as the IRB of record

### 2. Procedures and Forms for Identifying the IRB of Record

a. **Grant application:** If the study is being conducted under a grant requiring the funding agency to name a single IRB as the IRB of record, the grant applicant should

[3] The HHS Secretary's Advisory Committee on Human Research Protections; https://www.hhs.gov/ohrp/sachrp-committee/recommendations/2016-january-5-recommendation-nprm-attachment-a/index.html

not volunteer or offer the services of the UMW IRB for this responsibility without first consulting the IRB Chair or requesting that the funding agency do so. Researchers are advised to consult with the IRB at the time they prepare a grant proposal involving cooperative multi-site research.

b. **Recommendation of cooperating researchers:** If the multi-site study does not have a single IRB of record assigned by a grant funding agency, the researchers at each institution would normally reach a consensus on which IRB they think would be most appropriate to serve as the IRB of record and then submit a request to that IRB with the IRB application. The IRB selected by the researchers would then make its decision whether or not to serve as the IRB of record.
c. **Submission of request for UMW IRB to serve as IRB of record:** To request that the UMW IRB serve as the IRB of record on a cooperative multi-site study, the principal investigator at UMW should submit the IRB application form with attachments and the UMW as IRB of Record Request form to the IRB Chair or designee. The forms with detailed instructions are available on the Forms page of the IRB website. The UMW as IRB of Record Request form should have the following attachments, as appropriate:
    - The appropriate IRB application, complete with attachments
    - A list of the relying institutions with contact information
    - Any site-specific attachments such as recruitment and consent materials
    - Official documentation from the grant funding agency assigning this responsibility to the UMW IRB

### 3. Review Criteria and Procedures

The IRB application and request for the UMW IRB to serve as the IRB of record must be reviewed and approved before any research activities for the study may begin. The IRB member who receives the initial IRB application will conduct a preliminary review to ensure that it provides sufficient information for the IRB to make a determination about whether or not to serve as the IRB of record. There are two different IRB procedures for review depending on the level of risk to participants in the study:

a. **Greater than minimal risk:** If the IRB reviewer believes the study involves greater than minimal risk to participants, the reviewer should refer it to the IRB Chair, who will call a convened meeting of the full IRB to review the application and the request for UMW to serve as IRB of record. The decisions of the full board will be communicated to the applicant by the IRB Chair.
b. **Minimal risk:** If the IRB reviewer believes the study does not pose greater than minimum risk to subjects, the reviewer should consult with the IRB Chair about whether the request for UMW to serve as IRB of record is within the capacity of the UMW IRB. If the designated IRB reviewer is also the IRB Chair, he or she should consult with at least one other IRB member about the IRB's capacity to serve as the IRB of record on the study.

**4. IRB Decisions**

The UMW IRB's decision of whether or not to serve as the IRB of record will be indicated on the UMW as IRB of Record Request form and communicated to the lead researcher at UMW.

a. **Decision to serve as IRB of Record:** If the decision is that the UMW IRB *will* serve as the IRB of record, the Chair or designee should first ensure that the IRB application is properly completed. The IRB Chair will then complete the UMW as IRB of Record Request form indicating the decision, attach the completed IRB application, and return it to the applicant with the appropriate IRB approval letter and instructions for obtaining reliance authorization agreements from each cooperating institution. The IRB will follow procedures for review of the IRB application as appropriate for Exempt Status Review, Expedited Review, or Full Board Review.
b. **Decision not to serve as IRB of Record:** If the decision is that the UMW IRB will *not* serve as the IRB of record, the IRB Chair will complete the UMW as IRB of Record Request form indicating the reasons for the decision, and instruct the applicant to secure a different IRB of record for the project. The lead researcher at UMW should then follow the procedures in Section III.I above to request that the UMW IRB rely on a different IRB for review of the project.

**5. Agreement of Relying Institutions**

If the UMW IRB decides it will serve as the IRB of record and has approved the IRB application, the IRB will request signed reliance authorization agreement forms from the cooperating institutions in the study in order to formalize the decision. Each relying institution normally uses its own version of the agreement form. When requesting the form from a cooperating institution, the request must include the IRB application form, the IRB approval letter, and all attachments. When submitting its signed agreement form, the relying institution should provide all site-specific research materials to be used at the cooperating institution, such as consent forms, ethics training certificates, etc., which must be reviewed and approved by the UMW IRB. Then the IRB Chair will have the agreement form signed by the UMW Provost or designee. The IRB will send the fully executed reliance authorization agreement forms with attachments to the IRB at the cooperating institution with a copy to the principal investigator at UMW. When this procedure is complete, the research at the cooperating institution may begin.

**6. Principal Investigator Responsibilities**

On cooperative multi-site studies for which the UMW IRB serves as the IRB of record, the principal investigator will be a full-time UMW faculty member or qualified administrator who is willing and able to maintain close communication with researchers at cooperating institutions and to ensure that that the approved research protocols are followed at all sites. In addition to following the the steps above to request that UMW serve as the IRB of record, other key responsibilities of the principal investigator include the following:

- Ensure that no research activities begin at any cooperating institution until the reliance authorization agreement form has been fully executed

- Ensure that no members of the research team have conflicts of interest
- Ensure adherence at each cooperating institution to the protocols on the approved IRB application
- Ensure that all relevant policies and procedures are adhered to at each site throughout the study, including UMW IRB policies, relevant state laws, and relevant local policies
- Submit for IRB approval any changes in the cooperating institutions, research protocols, instruments, consent materials, etc. before such changes are implemented
- Communicate with the IRB Chair about the progress of the research at each site and cooperate in continuing review and post-approval monitoring of the study
- Apply for IRB approval of any changes in the research materials, protocol, etc.
- Report to the IRB Chair any adverse events and unanticipated problems related to the research occurring at any site
- Notify the UMW IRB Chair when the research at any site is completed

**7. IRB Responsibilities**

In addition to reviewing the IRB application and following the procedures for deciding to serve as an IRB of record for a study, the IRB performs all the other duties of an IRB related to research conducted by each cooperating institution, including, but not limited to:

- Maintain regular communication with the principal investigator at UMW
- Ensure that all responsibilities of the IRB of Record, as listed on the signed reliance authorization agreement forms, are carried out
- Keep appropriate records of all reliance authorization agreements and decisions regarding review of the IRB application, any post approval changes, adverse events or unanticipated problems, continuing review, and/or post-approval monitoring
- Ensure that when any reliance authorization agreement is suspended or terminated, the decision is formally communicated to the cooperating IRB and recorded in the IRB minutes (See Section IV.I.2)

# SECTION IV

# IRB Meetings and Review Procedures

## A. Meeting Guidelines and Schedule

IRB members are required to attend meetings which are scheduled in advance by the IRB Chair in consultation with members. The Chair may invite guests to attend meetings and serve as consultants on review of proposals or for other informative purposes. However, only members may be present during deliberation and voting on decisions regarding approval of IRB applications.

### 1. Role of the IRB Chair

The IRB Chair presides at meetings, prepares meeting agendas and notifies members in advance of the date, time, and location of the meeting. In the absence of the Chair, the Chair will designate a temporary Chair or the IRB will select a member to act as temporary Chair. A designee of the Provost will serve as IRB secretary and take minutes of the meeting, or in the absence of the designee, the IRB Chair will appoint a temporary secretary (see Subsection V.G.4 below).

### 2. Conflicts of Interest

No IRB member may participate in the initial or continuing review of any project (Exempt Status Review, Limited Review, Expedited Review, or Full Board Review) in which the member has a conflicting interest, except to provide information requested by the IRB (45 CFR 46.107(d)). A conflicting interest includes, but is not limited to, being a member of the research team or acting as supervisor of student research on a project under review. When a member has a conflict of interest on a proposed study, the review should be conducted by the IRB Chair or other designated member.

### 3. Quorum

Federal regulations require that a majority of members be present at IRB meetings, and that at least one member whose concerns are not scientific be present and voting. Actions of the IRB require approval by a majority of members present and voting (45 CFR 46.108(b)). IRB decisions must receive the approval of a majority of those members present at the meeting where a quorum is in attendance. If recusal of a member for conflict of interest causes lack of a quorum, the vote should be postponed to another meeting.

### 4. Meeting Schedule

IRB meetings are scheduled monthly during the academic year, and the schedule is published on the Meetings page of the IRB website. Except for the annual business meeting, scheduled meetings may be cancelled by the Chair within one week prior to the meeting date if there are no proposals to review or other IRB business to conduct.

a. **Annual Business Meeting:** At the beginning of Fall semester each year, the IRB Chair will work with the Office of the Provost to select a date, time and place for the

opening IRB meeting. The purpose of the meeting is to conduct general IRB business, including orientation and updating of members, discussion of review procedures and other IRB policies, and establishment of the meeting schedule for the remainder of the year.

b. **Expedited Review Meetings:** At the end of Fall and Spring semesters each year, IRB meetings will be held to complete the expedited and limited review of proposals that have undergone preliminary review and approval by a member since the previous review meeting (see Sections IV.C-E below).
c. **Full Board Review Meetings:** When proposed research poses greater than minimal risk to participants, the application will be reviewed at a scheduled meeting of the IRB. The procedures for review and conduct of the meeting are detailed in Section IV.F below.

## B. IRB Reviewer Responsibilities

### 1. Goals of Review

Each IRB member is designated to review IRB applications from one or more academic departments including their own, according to the listing on the Members page of the IRB website. The purpose of the review is to determine the acceptability of proposed research, which includes an evaluation of a researcher's capability for conducting the research safely and ethically according to the approved protocol and all IRB policies and instructions. Therefore, IRB members must ensure that approval is given only to applications that completely and clearly explain the research protocols consistently throughout. Reviewers should use the instructions for completing application forms and informed consent forms, which are available on the Forms page of the IRB website, to guide them in providing feedback on the applications. Reviewers must consult with the IRB Chair to resolve any questions they have relating to review of applications. One of the Chair's responsibilities is to work with IRB members, institutional officials, and investigators to make sure that applicable requirements are met.

### 2. Criteria for Approval

Current regulations require that, at a minimum, each application meets the following criteria for approval (45 CFR 46.111):

a. **Selection of subjects:** Measures are in place to ensure that procedures for recruitment and selection of subjects are equitable.
b. **Informed consent:** All prospective subjects in the research or their legally authorized representatives will be fully informed about the conditions and extent of their involvement in the research prior to their involvement according to instructions on the Forms page of the IRB website; informed consent will be obtained in writing or appropriately waived (see Section III.F above).
c. **Vulnerable populations:** Recruitment and informed consent materials do not make specific appeals to populations vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons; additional safeguards have been included in the study to protect the rights and welfare of vulnerable subjects.

d. **Research procedures:** Principles of sound research design are implemented to ensure that participants are not unnecessarily exposed to any risks.
e. **Privacy and confidentiality:** Provisions are in place as appropriate to protect the privacy of subjects and the confidentiality of data.
f. **Risks and benefits:** Measures to minimize risks to subjects are described; the risks to subjects are reasonable in relation to anticipated benefits to subjects and/or the importance of the knowledge that may result.

## C. Exempt Status Review Procedures

### 1. Qualifications

The IRB Chair or designated member will evaluate application forms to determine if the research is appropriate for Exempt Status Review. If the proposed research is of minimal risk to participants and qualifies for one of the categories of exemption described in Section III.C above it should reviewed following procedures for Exempt Status Review. Research involving pregnant women or children may be approved under Exempt Status Review, as long as all other criteria for this level of review are met. However, research involving prisoners or wards of the state is not eligible for Exempt Status Review, unless such subjects are included only incidentally in a broader subject population. A proposal may qualify for Exempt Status Review even if it is submitted on the form for Expedited Review. However, if the proposal does not meet the qualifications for Exempt Status Review, the principal investigator should be instructed to submit an application for Expedited Review.

### 2. Completeness and Clarity of Application

Once the reviewer determines that the application qualifies for Exempt Status review, the reviewer will ensure that all information required on the application form and on all attachments is provided clearly and completely following all relevant instructions on the Forms page of the IRB website. The reviewer must obtain revisions to the application and all attachments from the principal investigator as necessary to meet requirements for approval.

### 3. Approval Letter

Once the IRB reviewer determines that the application form is clear and complete with all attachments, the letter of approval should be sent to the principal investigator (and the faculty supervisor for student research if different), following instructions on the approval letter template provided by the IRB Chair. The approved IRB application form with all attachments must accompany the approval letter.

### 4. Record Keeping

The IRB reviewer must retain a file containing the approval letter and the approved IRB application form with all approved attachments. This file is to be submitted at a convened meeting of the IRB, when it will be entered into the official records of the IRB maintained by the Office of the Provost. The file may also undergo Limited Review at that time (see Section IV.D below).

## D. Limited Review Procedures

Research approved under Exempt Status Review in categories 2, 3, 7 and 8, as defined in Section III.C above, will undergo further limited review during a convened meeting of the IRB. Limited Review is conducted at a review meeting of the IRB following the procedures for Expedited Review (see Section IV.E below). This part of the review procedure is to verify that certain specific criteria are met in the IRB application (45 CFR 46.111).

### 1. Exempt Categories 2 and 3

For research involving tests, surveys, interviews or observation, or research involving benign behavioral interventions, the Limited Review ensures that adequate provisions are in place to protect the privacy of subjects and the confidentiality of data.

### 2. Exempt Category 7

For research involving storage and maintenance of data for secondary research, Limited Review ensures that the requirements of broad consent are met, that consent is properly documented, and that adequate provisions are in place to protect the privacy of subjects and the confidentiality of data.

### 3. Exempt Category 8

For secondary research requiring broad consent, Limited Review ensures that the requirements of broad consent are met, that consent is properly documented, and that the investigator does not plan to return individual research results to subjects, unless legally required to do so.

## E. Expedited Review Procedures

### 1. Qualifications

Research that presents no more than minimal risk, qualifies for one of the categories for Expedited Review described in Section III.E above, and does not qualify for Exempt Status Review, will be reviewed following Expedited Review procedures. Determinations regarding level of risk and qualifications for Expedited Review are made by the IRB Chair or designated IRB member. If a reviewer determines that the application meets qualifications for Exempt Status Review, they should follow the procedures in Section IV.C above. If the reviewer determines that the application does not meet the qualifications of minimal risk or the criteria for Expedited Review, the application must undergo Full Board Review as described in Section IV.F below.

### 2. Completeness and Clarity of Application

Once the reviewer determines that an application qualifies for Expedited Review, the reviewer will ensure that all information required on the application form and on all attachments is provided clearly and completely following all relevant instructions on the Forms page of the IRB website. The reviewer must obtain revisions to the application and all attachments from the principal investigator as necessary to meet requirements for approval. As part of the review process, the IRB Chair or designated reviewer must

determine if the research is at a level of complexity and duration that would necessitate continuing review (see Section IV.H below).

### 3. Approval Letter

Once the IRB reviewer determines that the application form is clear and complete with all attachments, the letter of approval should be sent to the principal investigator (and the faculty supervisor for student research if different), following instructions on the approval letter template provided by the IRB Chair. The approved IRB application form with all attachments must accompany the approval letter.

### 4. Record Keeping

The IRB reviewer must retain a file containing the approval letter and the approved IRB application form with all approved attachments. This file is to be submitted at a convened meeting of the IRB to conduct the second stage of Expedited Review and entered into the official records of the IRB maintained by the Office of the Provost.

### 5. Review at IRB Meeting

IRB applications that have been approved for Expedited Review by a member of the IRB must go through a second stage of review at an IRB meeting convened for this purpose (45 CFR 46.110). The UMW IRB has established the following process for this stage of Expedited Review:

a. **Reviewer:** During the meeting, each proposal is reviewed by an IRB member, other than the member who approved it originally, who has no conflict of interest
b. **Discussion:** If the second reviewer questions the original approval, the question is brought to the floor of the IRB meeting for resolution, and entered in the minutes
c. **Approval:** The reviewer indicates approval by initialing the original approval letter
d. **Conditional Approval:** If the IRB determines that the proposal requires changes in order to be approved, the IRB may vote for conditional approval until the appropriate changes are made, and the changes will be reviewed following the procedures for Expedited Review described above.

## F. Full Board Review Procedures

### 1. Application and Preliminary Review

There is no separate application form for Full Board Review. The IRB Chair or designated reviewer will evaluate each application for Expedited Review to determine if the proposed research requires Full Board Review based on either of the following:

- The research poses greater than minimal risk to subjects, *or*
- The research does not qualify for any categories of Exempt Status Review or Expedited Review

The principal investigator for the study must be notified in writing, usually within 10 days, if the application requires Full Board Review and the rationale for the decision.

**2. Scheduling the Meeting**

The principal investigator must be notified by the IRB Chair in writing of the date of the meeting, and the reason for requiring Full Board Review. The meeting should take place at the next scheduled monthly meeting of the IRB posted on the Meetings page of the IRB website. The principal investigator may be invited by the IRB Chair to attend a portion of the meeting in order to answer questions, but is not permitted to be present during the IRB's deliberations or vote on the study. The same conditions apply to any IRB member who is involved in the research under consideration.

**3. Preparation for Meeting**

The Chair will notify members of the meeting and send the proposal to all members as part of the meeting agenda. A quorum of members must be present and voting, including at least one member whose primary concerns are in nonscientific areas.

**4. Presentation at Meeting**

The IRB Chair or designated member will present a summary of the proposal to include an overview of the project and the identification of major issues arising in the project. The Chair will then call for a motion for approval, provisional approval (stipulated changes), tabled pending further information, or disapproval. After a motion has been made and seconded, there will be an opportunity for discussion before a vote is taken. The primary investigator may be invited by the Chair as needed to answer questions. However, only members with no conflict of interest may be present during deliberations and voting.

**5. Voting**

Actions to be taken by the IRB regarding Full Board Review of a proposal must receive the approval of a majority of the voting members present. The minutes will record the number of members voting for, against, and abstaining. Members who are recused from the vote due to conflict of interest will also be identified in the minutes.

**6. Notification Letter**

The IRB Chair or designated reviewer will notify the principal investigator of the IRB's decision following Full Board Review. If the research proposal is approved, the notification letter should be attached to the approved application form and include the schedule for continuing review and the termination date of the current approval (see Section IV.H below). If approved provisionally, the principal investigator must submit the required changes to the IRB Chair or designated reviewer for approval before research activities may begin. If tabled, the notification letter will inform the principal investigator of the additional information required, or of recommended changes to be made, and of the date of the next IRB meeting when the revised application will be reviewed. If disapproved, the letter should provide the IRB's rationale for disapproval and give the investigator an opportunity to respond (45 CFR 46.109(d)). The notification letter with attachments will be kept on file in the Office of the Provost.

## G. Post-Approval Changes and Monitoring

### 1. Review of Post-Approval Changes

After initial approval, any changes to the application, no matter how minor, must be reviewed and approved by the IRB. Changes in approved research may not be implemented without IRB approval, unless necessary to eliminate immediate hazards to research participants, and then must be approved as soon as possible. The principal investigator must notify the IRB Chair or designated reviewer in writing of any changes, including changes in investigators, research instruments and procedures, research locations, recruitment and informed consent procedures, etc. If a change is minor (such as adding a question to a survey), a description of the change may be submitted. Otherwise, a revised IRB application form with attachments is required.

The review of changes will be conducted following the same procedure as the initial review of the application (Exempt Status Review, Expedited Review or Full Board Review). However, changes in an Expedited approval that result in greater than minimal risk to participants should be reviewed by the convened IRB. Additionally, minor changes in a Full Board approval that do not involve risks to participants, as determined by the reviewer, may be reviewed under the Expedited Review process.

### 2. Post-Approval Monitoring

Under its responsibility to review and monitor human research conducted at the University, the IRB has established procedures for monitoring of research following the initial review and approval. This monitoring may occur under the procedures for formal continuing review (see Section IV.H below). Additionally, any ongoing studies, whether or not continuing review is a requirement, may be subject to occasional post-approval monitoring by the IRB. Such post-approval monitoring may occur under any of the following circumstances:

- Random selection of projects for monitoring;
- Occurrence of an adverse event or unanticipated problem related to the research that affects the welfare of subjects;
- Previous approved changes in a project that may cumulatively have the effect of increasing its complexity, the vulnerability of participants, or the level of risk to participants;
- Evidence that researchers have made changes in the consent procedures or research protocol without prior IRB approval; or
- Evidence that researchers have not complied with applicable laws and regulations, relevant UMW policies, or IRB policies

Researchers will be notified by the IRB in writing at least 10 business days in advance about when the monitoring will occur, the reason or circumstance for the monitoring, and the procedure for the monitoring.

Possible monitoring procedures, to be determined by the IRB, may include: observation of the consent procedures, research protocol, confidentiality measures, etc.; verification from sources other than the primary investigator that no material changes have occurred since the previous IRB review; or review of a progress report from the principal investigator.

When the IRB concludes its post-approval monitoring, a written report of its findings and decisions will be sent to the principal investigator and entered into the IRB minutes (see Section IV.I below). The results of the IRB's post-approval monitoring, including continuing review, may be submitted to the Provost or other University official as part of inquiries in cases of academic misconduct (*University Faculty Handbook*, Section 4.8).

## H. Continuing Review Procedures

Continuing IRB review of research occurs at least annually, if required as a condition for initial IRB approval. The initial IRB approval letter will indicate if and when continuing review is required. Continuing review is required for any studies that pose greater than minimal risk to human subjects. Continuing review will often be required on cooperative multi-site studies for which the UMW IRB acts as the IRB of record. Under federal regulations, the requirement for continuing review depends on the type of initial review.

### 1. Exempt Status Review

For research initially approved under Exempt Status Review, continuing review will not be conducted on a regularly scheduled basis unless changes to an exempt study cause the level of review to change. If this is the case, the IRB letter approving the changes will also notify the principal investigator of any change in continuing review requirements.

### 2. Expedited Review

**a. Criteria**: For research initially approved under the Expedited Review procedure, the IRB reviewer, in consultation with the Chair, must determine during initial review whether continuing review should or should not be required. Criteria to consider in requiring continuing review include:

- The research protocol is of a level of complexity suggesting that continuing review will enhance the welfare of subjects;
- The research protocol involves a vulnerable population and is likely to last more than one year (according to 45 CFR 46.111(b), vulnerable populations include: children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons)
- The research is a cooperative multi-site study for which the UMW IRB serves as the IRB of record and which involves more than a few relying institutions; or
- The sponsoring or grant funding agency requires continuing review

**b. Alteration of initial requirement:** If the determination is made during the initial Expedited Review that continuing review will not be required, the IRB may later require continuing review based on findings of post-approval monitoring (see Section IV.G above). In such cases, the IRB must provide the principal investigator timely notice of the continuing review requirement and its date and enter it into the IRB minutes.

**c. Cancellation of initial requirement:** If the initial Expedited Review approval requires continuing review, the IRB may, in its judgment, cancel the requirement after a continuing review determines that the research protocol has reached the

data analysis stage and that adequate data confidentiality measures are in place. In such cases, the IRB will inform the principal investigator in writing of the cancellation decision and include it in the IRB minutes.

**3. Full Board Review**

Research approved under the Full Board Review procedure will undergo continuing review at a convened meeting of the IRB to take place within one year of initial approval, and at least annually after that. A rationale for a decision to conduct the review more frequently should be entered into the meeting records.

**4. Initial Approval Letter**

When continuing review is required, the initial approval letter to the principal investigator will, at a minimum, provide:

- Rationale for the requirement of continuing review (if undergoing Expedited Review)
- Responsibilities of the principal investigator, to include preparation of a progress report to be submitted to the IRB Chair
- Expiration date of initial approval (i.e., the date by which the continuing review must be completed to avoid termination of IRB approval)
- Due date for the progress report, sufficiently in advance of the expiration date to allow the IRB time to conduct the review, but not more than 30 days prior

**5. Progress Report**

When continuing review is a requirement of initial IRB approval, it is the responsibility of the principal investigator to submit a progress report about the study to the IRB Chair or designated reviewer by the required date and to notify the UMW IRB when the research is complete. The progress report must include the most recently approved IRB application with approval letter and all attachments. In addition, the following attachments to the progress report are required, as appropriate:

- If any changes were approved by the IRB since the most recently approved application, no matter how minor, include documentation of those changes and a revised IRB application reflecting those changes
- If additional changes in the application are needed or anticipated that have not been approved by the IRB, include a request for IRB approval of the new changes, no matter how minor, such as changes in: new members of research team with signature page(s); up-dated ethics certificates; changes in collaborators or institutions on multi-site studies; changes in informed consent materials; changes in data collection materials, data analysis, or confidentiality measures; changes relating to risks or benefits to participants, such as changes in the scholarly context of the research
- Include reports of any adverse events, unanticipated problems, or complaints related to study participants that have occurred since the most recently approved IRB application, whether previously reported to the IRB or not

### 6. Conducting the Continuing Review

Upon receipt of the principal investigator's progress report, the Chair or a designated reviewer will make a preliminary determination that the progress report is complete and will notify the principal investigator if additions or clarifications are needed in order to conduct the review. The review must then be conducted following the same procedure as for the preceding review, Expedited or Full Board Review. The reviewer will review the progress report and attachments, and obtain any other revisions from the PI necessary for IRB approval. For Full Board Review, the IRB meeting should be held at a scheduled IRB meeting prior to expiration of the previous approval of the research.

The goal of continuing review is to determine if the research continues to meet the criteria for IRB approval and is in compliance with appropriate laws, regulations, and University policies. To make these determinations, the review should include verification that changes to the previously approved IRB application are accurate and consistent across all parts of the application form and attachments. The continuing review should also consider whether any changes are needed in requirements for future reviews, such as in the frequency of the review or the level of review.

## I. Results of Post-Approval Monitoring and Continuing Review

### 1. Evaluation Report

The IRB Chair or designee will send a report of the findings of continuing review or post-approval monitoring and the IRB's decision to the principal investigator. The evaluation report should be dated on or shortly before the pre-established review date and include the date of the previous review approval. The evaluation report and current approved IRB application with attachments will be entered into the IRB minutes and kept on file in the Office of the Provost. If the project is a cooperative multi-site study for which the UMW IRB serves as the IRB of record, the evaluation report with attachments must also be sent to the relying IRBs. In the case of suspension or termination, the evaluation report should be sent immediately to the IRB Chair who will send a copy to the Provost.

### 2. IRB Decisions

As a result of continuing review or post-approval monitoring, the IRB may make one of the following decisions to be explained in its evaluation report.

a. **Completed research:** If the continuing review process demonstrates that the study has been completed since the previous review (i.e., no researchers are or will be interacting with any participants or their data), then the evaluation report will note completion of the research and cancellation of continuing review requirements.
b. **Approval:** If the IRB determines during continuing review that no changes in the submitted IRB forms and materials are needed, the evaluation report will be in the form of an approval letter sent to the principal investigator noting that the research may continue following the submitted protocols. Any changes to the research protocol or forms since the preceding review should be summarized in the approval letter. The approval letter should also indicate the date of expiration of the current approval and any changes in the continuing review process (e.g., a change in the level or frequency of review).

c. **Suspension:** A study may be temporarily suspended in order for the IRB to make further investigations as part of continuing review, or for the principal investigator to make protocol modifications required by the IRB as a result of its review. The evaluation report will provide the rationale for the decision and a timeline for the suspension. When the suspension period ends, a new evaluation report will be issued to the principal investigator indicating approval or termination of the study. The decision to suspend a study will be reported promptly to the principal investigator, the Office of the Provost, appropriate agencies, and to relying institutions for cooperative multi-site studies.
d. **Termination:** A study may be terminated due to continuing or serious noncompliance with: the protocols approved by the IRB, University or IRB policies, or relevant laws and regulations. Even without noncompliance, a study may be terminated if it has been associated with unexpected serious harm to individuals, or if the IRB finds that the study could impose unreasonable risks on participants or others. The decision to terminate a study will include the rationale for the decision and be reported promptly to the principal investigator, the Office of the Provost, appropriate agencies, and to relying institutions for cooperative multi-site studies.

## J. Reporting of Adverse Events and Unanticipated Problems

Upon receipt of an Adverse Event Report form, the IRB Chair will notify the UMW Provost and ensure that the information on the form and attachments is complete, including description of IRB actions, if any. Include any recommended revisions to IRB policy and procedures or other corrective actions to be taken by the IRB, and describe the IRB's decision-making method for actions taken. Any decision to suspend or terminate the research must be made by a vote of the full IRB. Any revisions of the IRB application and consent form may be approved following procedures for post-approval changes in Subsection III.A.4 above.

The IRB Chair will work with the Provost or Provost's designee to determine if the incident needs to be reported to the federal Office for Human Research Protections (OHRP). The report, if required, should be sent by the Provost to OHRP within 30 days of the event. All unanticipated problems need to be reported, but not all adverse events need to be reported. An *adverse event* is defined as any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign, symptom or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research. An *unanticipated problem* is an incident, experience, or outcome that meets all of the following criteria:

- Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;
- Related or possibly related to participation in the research (in this guidance document, *possibly related* means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and

- Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

An unanticipated problem to be reported to OHRP may be one that is not an adverse event. For example, some unanticipated problems involve social or economic harm instead of the physical or psychological harm associated with adverse events. In other cases, unanticipated problems place subjects or others at increased *risk* of harm, but no harm occurs. See detailed instructions on the OHRP website.

# Section V

# Institutional Administration of the IRB

Institutional administration and oversight of the UMW IRB is provided by the Office of the Provost. The UMW IRB reports directly to the Provost or to the administrator designated by the Provost to serve as the institutional official responsible for human subjects in research conducted at UMW. This responsibility includes supporting the IRB in numerous ways, as detailed below.

## A. Regulatory Responsibilities

### 1. IRB Registration

The UMW IRB is officially registered with the U. S. Department of Health and Human Services Office for Human Research Protections (OHRP). The Office of the Provost is responsible for updating and renewing the IRB registration, following procedures on the OHRP website. Updates must be done every three years or when any changes occur in the IRB membership roster or the contact information for the signatory official in the Office of the Provost.

### 2. Federalwide Assurance

Federalwide Assurance (FWA) is a document required from any institution engaged in non-exempt human subjects research which assures that the institution is committed to compliance with the federal regulations contained in the Revised Common Rule (45 CFR 46, 2018) and has a written statement of ethical principles and the procedures it follows for adherence to the regulations. This Manual serves as that written statement, and upon request, the Provost or designated administrator will provide a copy of this Manual to OHRP or any U.S. federal department or agency supporting research to which the FWA applies. The Provost or designated administrator is the University's human protections administrator listed on UMW's FWA, and is responsible for ensuring that the entire institution (including institutional officials, the IRB, research investigators, and all other employees or agents) is in full compliance with the Common Rule whenever the institution is engaged in human subjects research. The Provost is also responsible for updating and renewing the FWA on the OHRP website. Renewal takes place every five years, even if no changes have occurred. Updates on the FWA to the legal name of the institution or the contact information of the human protections administrator should occur within 90 days after changes are made.

## B. Appointment of Members

### 1. Membership Requirements

In order for the IRB to be in compliance with federal regulations (45 CFR 46.107), the Provost will ensure that the following requirements and conditions for IRB membership are met:

a. **Number:** The IRB will have at least five members.
b. **Disciplinary expertise:** The IRB will include members with varying backgrounds and disciplines, with at least one member having expertise in a scientific area and at least one member having expertise in a non-scientific area.
c. **Diversity:** The IRB will include members with a variety of racial, ethnic, and gender identities, with different cultural backgrounds, and with sensitivity to such issues as community attitudes.
d. **Institutional knowledge:** The IRB will include members able to ascertain the acceptability of proposed research in terms of institutional commitments, regulations, applicable law, and standards of professional conduct and practice.
e. **Knowledge of subjects:** If the IRB regularly reviews research that involves vulnerable subjects (including children, prisoners, individuals with impaired decision making capacity, or economically or educationally disadvantaged persons), there should be one or more members experienced in working with such individuals.
f. **External member:** The IRB will have at least one member who is not otherwise affiliated with UMW and is not an immediate family member of someone affiliated with the University.

### 2. Member Appointment Procedures

The UMW Provost appoints members to the IRB, fills member vacancies when they occur, and appoints a member to serve as IRB Chair. Members are appointed to staggered 3-year terms and are eligible for reappointment. To replace a member, the IRB Chair will recruit volunteers from the faculty to serve on the IRB and, upon consensus of the IRB, will forward the nominations to the Provost. In case of a temporary vacancy, the IRB Chair will work with the member being replaced to identify a qualified substitute and then submit the nomination to the Provost. To fill a vacancy in the position of IRB Chair, the outgoing Chair will poll IRB members to identify one or more volunteers, and, upon consensus from the IRB, will submit those nominees to the Provost. Chairs serve 3-year, renewable terms.

### 3. Appointment Letters

The Provost issues the formal appointment letters for the IRB Chair and for IRB members with copies to the IRB Chair. The appointment letters should include the following information, as appropriate for members and the Chair: duration of the appointment term, member responsibilities, and information about required member training.

## C. Institutional Support for the IRB

### 1. Regulatory Requirements

According to federal regulations, the IRB must have access to meeting space and sufficient staff to support the IRB's review and record keeping duties (45 CFR 46.108).

### 2. Budget

Expenditures in support of IRB activities will be charged against the budget of the Office of the Provost.

### 3. IRB Website

The IRB website (http://provost.umw.edu/irb/) is the main mode of communication with the University community about IRB policies and procedures. The Office of the Provost works closely with the IRB Chair and the University's technical support staff to keep the information and forms on the website up-to-date and to improve user-friendliness as needed. The IRB website contains separate pages for the following, which are updated at the beginning of every academic year and more often as needed:

- IRB Members https://provost.umw.edu/irb/board-members/
- Meeting Dates https://provost.umw.edu/irb/meeting-dates-for/
- Manual of Policies and procedures https://provost.umw.edu/irb/manual-of-procedures-and-policies/appendices/
- Instructions and Forms https://provost.umw.edu/irb/instructions-and-forms/
- IRB Training https://provost.umw.edu/irb/irb-training/

### 4. Additional Support

In addition to fulfilling its responsibilities as outlined above, the Office of the Provost also supports the IRB by:

- Assisting in the creation and revision of IRB forms and documents, and obtaining legal review as needed
- Providing IRB member training beyond the required ethics training, such as occasional attendance at conferences or seminars
- Ensuring that the IRB has the technical support from the University needed to conduct its meetings and other business in the most secure and efficient manner
- Serving as a resource to IRB members as needed on research-related areas such as grant policies and procedures, HIPAA and FERPA regulations, Virginia statutes and regulations, etc.
- Facilitating the sharing of information related to research between the IRB and other divisions or offices of the University, such as: Human Resources, Institutional Analysis and Effectiveness, Title IX, Disability Resources, etc.
- Printing and copying IRB meeting materials, including agendas and minutes, and assisting in determining the schedule of IRB meetings
- Providing IRB letterhead and other clerical supplies

## D. Review of Research

The University is required, under the FWA, to ensure that the IRB has established written procedures for conducting initial review and monitoring of research, for reporting its findings to the researcher(s) and the institution, and for ensuring that changes in approved research are not initiated without without IRB review and approval, following the policies and procedures in this Manual. According to federal regulations, research covered that has been approved by the IRB may undergo further appropriate review and approval or disapproval by a UMW official, who must inform the IRB of the results of the review. However, University officials, including those in the Office of the Provost, may not approve the research if it has not been previously approved by the IRB (45 CFR 46.112).

## E. Communication

### 1. Office for Human Research Protections

OHRP is the division of HHS that provides compliance oversight evaluations of institutions and human subjects research that are under its jurisdiction. The Provost is responsible for all communications with OHRP and for sharing all communications to or from OHRP with the IRB Chair.

### 2. Official IRB Reports and Agreements

a. **Adverse events and unanticipated problems:** If the IRB Chair notifies the Provost that an unanticipated problem in UMW research has occurred that must be reported to OHRP, the Provost will submit an incident report to OHRP within 30 days of the event and handle any subsequent communications with OHRP (see Section IV.J above). Under OHRP guidelines, the incident report must also be submitted to other appropriate institutional officials, to any U.S. federal department or agency supporting the research, and to the IRB. If the problem occurs in a cooperative multi-site study under a different IRB of record, a completed UMW Adverse Events Report form will be submitted to the IRB of record, which is responsible for reporting it to OHRP.

b. **Noncompliance, suspension, termination:** The Provost will submit an incident report to OHRP within 30 days of any serious or continuing noncompliance with IRB approved research protocols or with federal regulations (45 CFR 46, 2018), and in case of the IRB's suspension or termination of IRB approval of a study (see Section IV.I above). Under OHRP guidelines, the incident report must also be submitted to appropriate institutional officials, to any U.S. federal department or agency supporting the research, and to the IRB.

c. **Cooperative multi-site reliance agreements:** If the UMW IRB acts as the IRB of record for a multi-site study, each cooperating institution submits its signed reliance agreement to UMW, which must also be signed by the Provost at UMW in order for the agreement to be in effect. Similarly, when UMW relies on another IRB for review and approval of a multi-site study, the UMW Provost or designee must sign our Reliance Authorization Agreement form that will be sent to the IRB of record for their signature. When fully executed, the reliance agreement forms are kept on file as attachments to the approved IRB application. The Provost also serves as signatory for termination of the agreements, following procedures on the reliance agreement forms.

### 3. University Community

The Office of the Provost assists the IRB Chair in communicating with the University community about IRB matters. It also has responsibility for maintaining the UMW IRB website.

## F. Research Ethics Training

### 1. UMW Researchers

The standards for ethical research established in this Manual require that UMW researchers who interact with human subjects or their data be qualified to conduct the research following ethical principles. Therefore, the Office of the Provost is responsible for implementing the required training and providing UMW researchers access to it by keeping the relevant information on the Training page of the IRB website up to date.

### 2. IRB Members

Appointed IRB members will receive comprehensive reference materials including educational information from the Office for Human Research Protections and this Manual. At a minimum IRB members will complete training, available through OHRP or through an alternative program designated by the Provost, to train them to review research from an ethical and regulatory standpoint.

## G. Record Keeping

The Office of the Provost is responsible for maintaining the official records of the UMW IRB. IRB records are kept by the University for a minimum of three years. These records include the following:

### 1. Regulatory Documents

The Office of the Provost will maintain the *UMW Manual of IRB Policies and Procedures,* records of IRB registration and FWA, and copies of reports and correspondence to and from OHRP, and make them available to the UMW IRB as needed.

### 2. Official Roster of IRB Members

The roster of IRB members is a current list including members' names, earned degrees and credentials relevant to their IRB position, relation to the University (such as full- or part-time employee), duration of term, and representative capacity. Appointment letters will also be kept on file.

### 3. Records of Reviewed IRB Applications

Reviewed IRB applications will be submitted by the IRB to the Office of the Provost at the end of the Fall and Spring semesters each year (see Sections IV.C-F above). Files for each reviewed application must be kept by the University for a minimum of three years after the completion of an approved study or after the review of a non-approved study. The files will be numbered sequentially by calendar year in the order in which they are received (e.g., the first application in 2025 will be numbered 2025-001). The files will contain the following as appropriate:

- The approval letter indicating the level of review, or the letter denying approval based on Full Board Review
- The approved IRB application form
- All required attachments to the application, including informed consent materials (see Sections III.F-G above)

- Associated reliance agreement forms pertaining to cooperative multi-site research
- Documentation of all post-approval changes to the IRB application and/or attachments
- Reports of adverse events and unanticipated problems related to the research
- Continuing review or post-approval monitoring documents, if any
- Other official IRB correspondence related to the research project, if any

The Office of the Provost will also maintain a searchable database of IRB approvals that includes: the file number of the application, title of the research project, name of principal investigator and/or supervising faculty member, funding source (if any), dates of approval, date of continuing reviews (if any), date of expiration of approval (if any), and level of review (Limited, Expedited, or Full Board Review).

**4. Minutes of IRB Meetings**

The minutes of each meeting will be taken by a designee of the Provost or of the IRB Chair. The minutes shall include: date of meeting, attendance (names of IRB members, researchers, consultants, and guests present), actions of the IRB including decisions of the IRB on approval, revision, or disapproval of applications (including a list of projects approved under Limited and Expedited Review), the vote on these actions, and a written summary of discussion of controverted issues and their resolution. Any official actions of the IRB taken via electronic means will be included in the minutes. For IRB actions involving Full Board Review of an application, the minutes will include the basis for requiring changes to or disapproving research. The minutes will also include reports of any adverse events and unanticipated problems related to human subjects research, identifying those reported to OHRP.

**5. IRB Correspondence**

The IRB Chair will provide the Provost's Office with copies of any official IRB correspondence or other documents not included in the IRB minutes that should be archived in the IRB records.

**6. Records of Ethics Training**

The Office of the Provost will maintain up-to-date records of the required human subjects research ethics training for all IRB members and researchers affiliated with UMW.