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# The IRB Process: A Guide for Student Researchers


University of Michigan
IRB - Health Sciences and Behavioral Sciences
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## Chapter 1 – Introduction to Human Subjects Research Protection

This guide is designed to help student investigators at the University of Michigan (including those conducting an undergraduate honors thesis, master's thesis, or doctoral dissertation) understand their ethical and regulatory obligations in the conduct of human subjects research, as well as relevant University policies and procedures. Student investigators and their faculty advisors must be aware of their responsibility to seek IRB review. Failure to obtain IRB approval for research with human subjects may preclude the use of previously collected data and could result in other institutional sanctions.

**What is an Institutional Review Board?**
Institutional Review Boards (IRBs) provide review and oversight of research protocols to (a) promote informed consent, voluntary participation, and safety among research participants, and (b) ensure that investigators adhere to ethical standards, federal regulations, and institutional policies governing human subjects research.

IRB Health Sciences and Behavioral Sciences (IRB-HSBS) serves the central Ann Arbor campus of U-M. For a list of units and schools under the jurisdiction of IRB-HSBS, please see: http://research-compliance.umich.edu/units-supported-irb-hsbs The IRB-HSBS consists of two boards: IRB Blue and IRB Maize.

The IRB-HSBS staff conduct regulatory review of applications and manage application workflow and communications between investigators and reviewers (designated members of the board who conduct expedited review of applications on a rolling basis). In addition, the IRB-HSBS staff provide the following services for faculty, staff, and students involved in human subjects research:

- Educational programming (http://research-compliance.umich.edu/irb-hsbs-education)
- In-person consultation at "IRB-on-the-Road" sessions, which are like office hours held at academic units throughout campus (http://research-compliance.umich.edu/irb-hsbs-road-schedule)
- Assistance with general questions or study-specific questions about IRB review procedures

Board members include university faculty, qualified staff, and community members. Each board meets once each month to review applications. Meetings are also attended by legal consultants and data security consultants.

**Why does research with human subjects require review?**
The University of Michigan is responsible for ensuring that the rights and welfare of human subjects are adequately protected in studies conducted by its faculty, staff, and students. Federal regulations require this protection, and, in order for the University to fulfill its responsibility, all research involving human subjects must receive appropriate review and approval. The federal regulatory framework governing human subjects research (http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm) codifies key ethical principles found in the Belmont Report (http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm). The Belmont Report indicates that, in order for research to be ethical, the following conditions must be met:

1) Subjects must choose to participate voluntarily after being fully informed about the research study (respect for persons)
2) The benefits of the research out-weigh the risks associated with the research (beneficence)
3) The selection of subjects is equitable (justice).

Please see Appendix I for more information.

## Chapter 2 – Am I required to submit an IRB application?

The first question that must be considered is whether your project fits the regulatory definition of *research*, and, if so, whether it involves *human subjects*. If your project constitutes human subjects research, you are required to submit an IRB application.

**Is my project research?**
The federal regulations and U-M policy define research as "a systematic investigation, including development, testing, and evaluation, designed to develop or contribute to generalizable knowledge".

- A **systematic investigation** is an activity designed to test a hypothesis and permit conclusions to be drawn. The research is described in a formal protocol that sets forth an objective and procedures to reach that objective.

- **Generalizable knowledge** is information expressed in theories, principles, and statements of relationships that can be widely applied. A plan to publish findings or present at a professional conference generally, but not always, indicates an intention to contribute to generalizable knowledge.

**Does my project involve human subjects?**
The federal regulations define a human subject as "a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable private information".

- **"Living individual"** refers to data (information or specimens) collected from living subjects.
- **"About whom"** refers to the fact that the information collected must be personal information about an individual.
- **"Intervention"** includes physical procedures, manipulations of the subject or the subject's environment for research purposes.
- **"Interaction" r**efers to communication between the investigator and the subject. This includes face-to face, mail, internet and phone interactions, as well as other modes of communication.
- **"Individually identifiable"** means the identity of the subject is or may be readily ascertained by the investigator or others.
- **"Private information"** includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, or information that has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public. Examples of private information include medical or academic records or personal journals.

**What if I'm not sure if my project involves research with human subjects?**
The IRB staff can help you determine whether your project involves research with human subjects and requires an IRB application. Some scholarly activities that involve interactions with people (or their data or specimens) do *not* require IRB approval. For example, research using data from the 1880 Census would not be human subjects research. A survey that collects data about the activities of an organization is not human subjects research. Taking a saliva or blood sample from a subject or having a subject view a video would be considered a research intervention. Research with a de-identified data set is not research with human subjects because the data are not individually identifiable. Studies for internal management purposes such as program evaluation, quality assurance, or quality improvement are not research because the intent is not to draw conclusions beyond the activity or program being studied.

Projects that do not meet the regulatory definition of human subjects research are referred to as "Not Regulated" at U-M. U-M has identified a number of project types that are "not regulated" and therefore, do not require an IRB application:

- case studies
- class activities/research methods classes
- quality assurance/quality improvement/program evaluation activities
- journalism/documentary activities
- oral history
- research on organizations
- secondary analysis of publicly available data sets or other de-identified data sets that have been stripped of all identifiable information
- standard public health surveillance or prevention activities

If you are not sure whether your project requires review, or you would like a formal "not regulated" determination from the IRB, you can submit a brief application via eResearch, the web-based IRB application system (see Chapter 4). For some categories of research, eResearch allows investigators to use this process to self-generate a determination letter. You may also send this application to the IRB staff for review and determination. The IRB staff will issue a "not regulated" determination or will advise the investigator that the project does involve human subjects research and will recommend the submission of an exempt or standard application type via eResearch. For more information on this topic, please see http://research-compliance.umich.edu/operations-manual-part-4.

**A note about class activities –** Class projects and research methods classes may involve data collection activities for training purposes that do not require IRB review and oversight because the intent is to teach methods, not to contribute to generalizable knowledge. When class activities are designed to collect data to be used by students beyond the classroom, for example for scholarly publication or use for future research, it is the responsibility of faculty advisor to assist students in obtaining IRB approval or exemption prior to the initiation of a human subjects research project. For more information, please see the U-M Policy on Class Activities at http://research-compliance.umich.edu/human-subjects/human-research-protection-program-hrpp/hrpp-policies/class-assignments-irb-approval.

**A note about student internships –**Students within many units of the university are involved in internships or practica. Some student practica/internships may include research activities that are designed to contribute to generalizable knowledge and, thus, involve research that requires IRB review. Contact the IRB for assistance with determining whether your internship activities require IRB oversight.

## Chapter 3 - Student/Faculty Responsibilities in Human Subjects Research

### What are my responsibilities as a student investigator?

The student investigator, under the guidance of the faculty advisor, serves as the principal investigator for their research project and has primary responsibility for ethical conduct of the research. The student investigator is responsible for preparing and submitting the IRB application and for ensuring that the study adheres to relevant policies and regulations.

Under the mentorship of your faculty advisor, you must:

- Complete the PEERRS "Human Subjects" training module at: http://my.research.umich.edu/peerrs/
    - All key members of the study team (principal investigator, co-investigators, faculty advisors, and project manager/study coordinators) must complete PEERRS. The IRB recommends that you complete this training before beginning the eResearch IRB application, as it will help prepare you for the questions asked in the application.
- Submit an accurate and complete application to the IRB, allowing adequate time for review
- Obtain IRB approval or an exemption *prior to the initiation of research* including subject screening and recruitment
- Conduct the research in accordance with the approved protocol
- Submit amendments to inform the IRB of any proposed changes or additions to the previously approved study protocol before implementing those changes.
- Submit scheduled continuing review applications to the IRB if required
- Manage research data carefully to ensure subject confidentiality. Please see http://research-compliance.umich.edu/data-security-guidelines
- Consult with your faculty advisor when problems are encountered
- Report all unanticipated problems or serious adverse events involving risk to human subjects to the IRB as soon as possible. Please see http://research-compliance.umich.edu/incident-reporing-aeorio

### What are my faculty advisor's responsibilities?

Faculty advisors are active mentors for student researchers and share responsibility for the ethical conduct of research conducted by students. All research proposals from undergraduates, graduate students, and post-doctoral fellows must include a faculty advisor as member of the study team. Faculty advisors are expected to:

- Discuss general principles of research ethics with students prior to the initiation of any project involving human subjects
- Help students determine whether their project requires IRB review
- Guide students through the IRB application process
- Support students in the conduct of research after a project has attained IRB approval.

## Chapter 4 - The eResearch Application

### What is eResearch?

UM uses the eResearch Regulatory Management system (http://eresearch.umich.edu) for all IRB applications. The eResearch application is designed to gather all of the information and materials necessary for the IRB-HSBS to evaluate and approve research in accordance with federal regulations and U-M policy. This includes research protocols, informed consent documents, recruitment materials, grant applications, survey instruments, and audio/visual materials. IRB staff, IRB reviewers and board members, and study team members all have access to the same application materials, as well as correspondence associated with the study, via the eResearch system. In addition, IRB staff and reviewers use regulatory checklists embedded in the eResearch system to guide their review of application materials

### General Guidance

As you prepare your application, remember that the IRB is primarily interested in the details of how you will be interacting with your research participants at each step of the research process. Your theoretical framework helps the IRB understand your project, but it is the interaction(s) with the human subjects and the risks and benefits of the research that are being assessed. Be sure that the information in your application is written clearly and concisely. Information entered should be consistent throughout the application and with the study documentation, including the protocol, informed consent, and recruitment materials. Missing or inconsistent information will delay the review of your application.

### Getting Started

Once you and your faculty advisor have agreed on the methodology for your research project, you should prepare the eResearch IRB application. Before beginning the application, gather together all materials that will be needed in the process including:

- ePAF identifier and related documentation, if there is financial support
- Performance site information, including site approval letters or external IRB approvals*
- Research protocol
- Recruitment materials (flyers, posters, letters, text of emails or oral recruitment scripts)*
- Informed consent documents or scripts for studies using an oral consent process*
- Survey/interview/focus group questions
- Any audio/visual materials to be used in the research (e.g., film or audio clips)*
  (*Materials *not* required for exempt applications)

### Logging Into eResearch

Prior to starting the application, all U-M study team members (including the faculty advisor) who have not used the eResearch system previously should log into the eResearch system using their uniqnames and Kerberos passwords. This will ensure that the study team member is registered in the system and can then be added to an application. If you will have any non-UM collaborators, they will need to obtain a Friends account via the U-M system. All key study team members will be required to upload a CV or resume the first time they are added to an eResearch application.

### Your Workspace

When you log into eResearch, you are taken to your home workspace. This is your personal eResearch homepage that gives you access to all applications with which you are associated.

To begin a new application, click NEW APPLICATION in the left column of the screen. After working on the application, it will be available from your home workspace when you save and exit.

**Application Tips by Section**

- **Study Team Members** – All student researchers (including PhD candidates and post-doctoral fellows) must include a Faculty Advisor as a member of the study team.
- **Application Type** – Most projects follow the standard application path, but check the descriptions and help for the other application types to see if your research might qualify for a shorter application type.
- **Sponsor Information** – If your research project is funded (sponsored project), be sure to enter your ePAF number.
- **UM Study Functions** – You "are" the University of Michigan for the purpose of this application. Select all of the activities you or your U-M collaborators will do as part of the research.
- **Performance Sites** – If you will conduct research at a location outside of UM, list that location as a performance site. If you will collaborate with researchers at another institution, that institution should be listed as a performance site. You may be asked to provide documentation of IRB approval or letter of support from the research site.
- **Research Design** – Remember, the IRB must understand how you will interact with human subjects in your research. Provide details.
- **Benefits and Risks –** Many social and behavioral research projects do not provide a direct benefit to research participants; explain instead how your project may benefit society. Compensation for participating is NOT a benefit of the research. Most research poses some risk to participants, even if it is quite minor; provide subjects with an accurate description of risks, as known.
- **Subject Recruitment** – Provide specific details about how you will recruit participants into your study. Upload recruitment materials, including text of oral scripts or email messages you may use.
- **Informed Consent –** Please see http://research-compliance.umich.edu/informed-consent-guidelines for informed consent templates and sample consent documents. Using these documents that contain required informed consent language will speed the review of your application. Use the extensive help provided in the eResearch application.
- **Survey Research** – You must provide a copy of your proposed survey/interview/focus group questions.

**Application Help**

The eResearch application provides Help information along the right column of the application. Please read it. Please also see http://www.umich.edu/~eresinfo/errm/training/training.html

If you need *technical assistance with the eResearch system***,** if you experience technical difficulties with the eResearch application, such as system timeouts, problems with uploading documents, or navigating through the application, please contact the ITS Service Center:
Phone: (734) 764-HELP (4-4357) between 7 AM and 7 PM Monday through Thursday, 7 AM and 6 PM Friday, and 2 PM - 7 PM Sunday
E-mail: 4Help@umich.edu
Website: http://its.umich.edu/help/

If you need help with the *application content*, please call the IRB-HSBS office (734) 936-0933, or send us an email irbhsbs@umich.edu. We are happy to assist you. Once your application is submitted to the IRB, an IRB staff member is assigned to your project and will be your point of contact throughout the review process.

**Communication via eResearch**

All communication associated with your IRB application is conducted within the eResearch system. Be sure to monitor your email once you have submitted your eResearch application to the IRB, since the system will send notices to your email account when an action on your part is required.

- **Posted Correspondence** – Posted correspondence is used for general communication purposes. This tool can be used by the IRB staff and reviewers to communicate with the study team and by the study team to communicate with the IRB staff and with one another. Be aware that anything entered in posted correspondence is visible to everyone who has access to the application – study team members, IRB staff and reviewers – and cannot be deleted once posted. Be sure to select a recipient when posting a correspondence, otherwise the note will appear in the application, but no notice will be sent to alert the recipient.
- **Changes Required By Core Staff** – When you receive this notice, it means that the application has been returned to you for some required action. This communication will include a list of changes that are needed before the IRB can continue its review. After you make the changes requested, you must remember to return the application to the IRB for review by clicking SUBMIT CHANGES TO CORE STAFF.
- **Contingencies Pending** – When you receive this notice, it means that your application has been reviewed and approved in principle but requires some additional changes before final approval can be issued. After you respond to the contingencies, you must remember to click SUBMIT CONTINGENCIES to return the application to the IRB. All contingencies must be met and cleared by the IRB before you may begin to conduct your research.
- **Approval, Exemption or Not Regulated Notices** – You will receive the final outcome or approval notice for your study via the eResearch system. You will also find a copy of this notice in the study workspace.

## Chapter 5 – What type of review is required for my project?

Once submitted, IRB applications undergo one of the following types of review:

- exempt
- expedited
- full board

Studies meeting one of six specific exemption categories and two additional U-M categories are reviewed via the exempt review process. Studies involving no more than minimal risk that do not qualify for exemption are generally reviewed via expedited review. Studies that involve greater than minimal risk must be reviewed by the full board. Studies with complicated research elements or involving vulnerable populations or sensitive identifiable data may also be reviewed by the full board.

**What is minimal risk?**

As defined by the regulations, "minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests." Types of risk include the potential for economic, legal, physical, psychological, or social harms. For social and behavioral research, the primary risks considered by the IRB include reputational, legal or financial harms that might result from a breach of confidentiality or emotional/psychological distress or discomfort experienced by the subject in responding to research interactions or interventions.

**Exempt Review**

**What is exempt research?**

Exempt research is research with human subjects; however, it is "exempt" from the IRB regulations only after initial review to determine if it meets specific criteria for exemption. To be exempt, a project must fall under one of six exempt categories listed in the federal regulations or two exemption categories that have been added by the University of Michigan (Appendix II). Exemptions are not granted for research involving prisoners of for some types of research activities involving children.

**How is exempt research reviewed?**

Exempt research requires submission of an eResearch Exempt application. A designated IRB staff member reviews the completed application and associated materials to confirm that the research fits one of the exemption categories. If exempt, the IRB will issue an exemption determination letter via the eResearch system. Applications that do not meet the criteria for exemption are returned to the investigator with instructions regarding the correct application type to be submitted.

Exempt research projects are not subject to continuing IRB oversight, but investigators are expected to conduct exempt research in accordance with the ethical principles of the Belmont Report and the ethical codes of their professional discipline. IRB approval for exempt projects does not expire. However, if you plan a significant change to the exempt protocol that would exceed the scope of the exemption category, an *amendment* must be submitted for IRB review and determination.

**How long will an exempt review take?**

Most exempt projects are reviewed in less than one week. If your application is unclear or incomplete and must be returned for changes, the review process may take longer.

**Expedited Review**

**What is expedited review?**
Federal regulations specify conditions under which research may be reviewed by the IRB using expedited review procedures. Expedited review is carried out by designated IRB members. Expedited review is conducted on a rolling basis and is not subject to submission deadlines. The IRB-HSBS uses the expedited review procedure for most of the research subject to its oversight.

All human subjects research projects are subject to the same review criteria (Appendix III) regardless of whether they are reviewed via an expedited or a full board review process. The same standard eResearch application and supporting materials (protocols, recruitment materials, informed consent documents, surveys, etc.) are submitted for either type of review.

Only research proposals that present *no more than minimal risk* to participants qualify for review using expedited procedures. In addition, the research must fall within one of the nine categories of activities that qualify for expedited review (Appendix IV). The IRB will determine the appropriate expedited review category for your research.

The expedited review procedure may *not* be used for:

- research where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal;
- classified research involving human subjects; and
- most research involving prisoners.

**How is expedited research reviewed?**
A designated IRB staff member conducts the initial administrative review of each application and makes a preliminary determination about whether it meets the criteria for expedited review or will require review by the full board. The staff reviewer will return the application to the investigator for changes if the application and supporting materials are incomplete or unclear.

If the research qualifies for expedited review, the IRB staff forward the completed application to an IRB reviewer. The reviewer conducts the review based upon the criteria described in Appendix III and issues a determination. The IRB staff communicates the outcome of the review via the eResearch system. The reviewer may approve the research, require modifications in the research before approval, or refer the submission to the full board for further review. Please see Appendix V for a description of the types of determinations that the reviewer may issue for a proposal.

Investigators may not begin research activities until documentation of final IRB approval is received via eResearch.

**How long will an expedited review take?**
The expedited review process typically takes 2-4 weeks, depending on the quality and completeness of the application as well as the volume of other applications under review by the IRB during the same period. If this is your first application, allow for longer processing time, since you may need to make changes or corrections to your application. If you are traveling out of the country to conduct your research, be sure to submit your application to the IRB at least 8 weeks in advance of your planned travel date.

**Full Board Review**

**What projects require review by the full (convened) board?**
Projects that involve *more than minimal risk* or that do not fit into one of the specified expedited review categories must be reviewed by the full board at a convened meeting. Examples of other projects that may require review by the full board include:

- projects posing no more than minimal risk to participants but that involve vulnerable populations, sensitive topics, or complex research designs that would benefit from a review by the breadth of expertise represented at the full board. This includes studies that collect sensitive data that will require an NIH Certificate of Confidentiality (CoC) to protect subject data from compelled disclosure.
- projects referred to the full board by an expediting reviewer. For example, a reviewer may seek guidance from the full board in determining whether a study meets the regulatory definition of minimal risk or when the scientific question posed by the PI exceeds the expertise of the available expediting reviewers.
- research involving prisoners.

According to U-M policy, undergraduate researchers are not permitted to serve as PI for projects that pose greater than minimal risk to subjects.

**How is research reviewed by the full board?**
A designated IRB staff member conducts the initial regulatory review of the application. The staff reviewer will return the application to the investigator for changes if the application and supporting materials are incomplete or unclear.

Once complete, the application is added to the agenda for the next available meeting of the IRB-HSBS. A primary IRB reviewer and a secondary reviewer (for new applications) are assigned to present the proposed research to the board at the convened meeting. All members receive a copy of the submission materials via eResearch. Consultants may also be invited to assist in the review of research where additional expertise is necessary. In some circumstances, the investigator may be invited to attend the board meeting to respond to the board's questions.

After the meeting, the board's decision will be communicated to investigators via eResearch. The board may vote to approve the research, approve with minor modifications, or defer action on the application if significant revisions are required. See Appendix V for a description of the types of determinations the IRB may issue for a study.

Investigators may not begin research activities until documentation of final IRB approval is received via eResearch.

**How long will a full board review take?**
Projects that require review by the full board may take a minimum of 4-8 weeks for review. The schedule of IRB meetings, including application submission deadlines, is posted on the IRB-HSBS website (http://research-compliance.umich.edu/irb-health-sciences-and-behavioral-sciences-hsbs). If you are traveling out of the country to conduct your research and you think it may require review by the full IRB-HSBS, be sure to submit your application to the IRB at least 12 weeks in advance of your planned travel date.

## Chapter 6 – What is informed consent?

Informed consent is the process of telling potential subjects about the key elements of a research study and what their participation will involve. The subjects in the study must participate willingly, after having been adequately informed about the research. If the subjects are from a vulnerable population, such as prisoners or children, additional protections are required.

Consent documents must be clearly written and understandable to subjects. The informed consent document is an information tool, rather than a legal contract.

- Use non-technical language (comparable to the language in a newspaper or general circulation magazine), free from scientific, legal or academic jargon.
- Be aware of the reading level of your subject population. In general, aim for an 8th grade reading level.
- Do not use the "first person" in the body of the consent (I understand, I agree, etc.), before you have actually explained the research. Use the "second person" to tell the subject about your project.
- Regulations preclude the use of exculpatory language that implies that the subject is waiving any legal rights by agreeing to participate.
- Check reading level using an available tool (e.g., Flesch Kincaid)

For more information, please see http://www.hhs.gov/ohrp/sachrp-committee/recommendations/2011-october-13-letter-attachment-a/index.html

**Elements of Informed Consent**

Regulations identify the following required elements of informed consent:

- A statement that the **activity is research** and describing **its purpose**;
- A description of **procedures** involved in the research, including a statement of the length of **time** the subject is expected to participate (for example, a one hour survey, three one hour interviews over the course of three months);
- A description of all reasonably **foreseeable risks** and discomforts to the subject (includes possible psychological, social, or economic harm, discomfort, or inconvenience, in addition to physical risks);
- A description of **benefits** of the research to the individual subject or to society in general;
- A description of plans to protect the **confidentiality** of records identifying the subject (if appropriate);
- A disclosure of **alternative** procedures or treatment available should a subject decide not to participate in the research (rarely applies to social and behavioral research);
- For projects involving more than minimal risk to participants, an explanation regarding whether compensation or medical treatment is available if injury occurs (rarely applies to social and behavioral research);
- Persons **(PI and Faculty Advisor**) to contact for answers to questions or in the event of a research-related injury or emergency;
- Contact information for the **IRB** for answers to questions about the subject's rights as a research participant;
- Statement that participation is **voluntary** and that refusal to participate or discontinuing participation will not result in any consequences or any loss of benefits that the person is otherwise entitled to receive.

Other optional elements as appropriate to the research project include:

- **Payment** for participation (include information regarding payment if the subjects ends participation before completing the research);

- For surveys and interviews, a statement that the subject may **skip** any question they don't wish to answer.

For projects involving *research with children*, investigators *must* in most cases obtain both the consent (permission) of one or both of the parent(s) as well as assent of the minor child depending on the design of the study. Projects involving participants who are cognitively impaired may require consent from a legally authorized representative (LAR).

For more information, please see http://www.hhs.gov/ohrp/regulations-and-policy/guidance/checklists/ and http://research-compliance.umich.edu/informed-consent-guidelines for informed consent templates, sample consent documents, and detailed guidance materials.

**The Informed Consent Process**
Informed consent is documented by the use of a written consent form that is signed by the subject or legally authorized representative. A copy of the consent document should be provided to the person signing it.

Regulations allow for some exceptions to the requirement for documented (signed) informed consent and may allow for waiving informed consent.

**Waiver of Documentation of Informed Consent**
According to 45 CFR 46.117, an IRB may waive the requirement for the investigator to obtain a signed consent document if it finds either:

- That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality, OR
- That the research presents *no more than minimal risk* of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

For projects on sensitive topics, use of a waiver of documentation may minimize the risk to participants by making it impossible to link them to the research project. Subjects are still provided with all of the information required for informed consent, either in written or oral form, but no signed consent document is obtained.

More commonly, the IRB waives the requirement for documented informed consent for minimal risk projects such as those involving web-based or telephone surveys where obtaining a signed consent document might be impractical. Again, subjects are still provided with the elements of informed consent through written material or an oral description.

**Waiver of Informed Consent**
In some circumstances, the IRB may approve a consent procedure that does not include or waives some or all of the elements of informed consent. In order to waive informed consent, the regulations (45 CFR 46.116) require that:

- The research involves no more than minimal risk to the subjects;
- The waiver or alteration will not adversely affect the rights and welfare of the subjects;
- The research could not practicably (feasibly) be carried out without the waiver or alteration; AND
- Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

The waiver of informed consent is primarily utilized in research involving the secondary analysis of existing datasets or with research involving deception.

## Chapter 7 – What are my responsibilities *after* IRB approval?

Approval of a research project by the IRB does not end your responsibilities with respect to reporting to the IRB. IRB review and approval must be obtained before any change to a research protocol or associated materials (recruitment materials, consent, survey instruments) can be implemented, unless the project is exempt. All non-exempt human subjects research projects continuing to interact with subjects or analyzing data must be re-reviewed by the IRB prior to the expiration of the approval period, as determined by the IRB. For projects that involve more than minimal risk or for some other special consideration, the IRB may require a more frequent review. Finally, you have an obligation to report adverse events, unanticipated problems, or protocol deviations to the IRB as soon as they are aware of the problem.

**Amendments**

An amendment is a modification to an approved research project. IRB review and approval is required before you may implement a modification to a research protocol, except when necessary to eliminate immediate hazards to the subjects, which rarely applies to social and behavioral research. Any proposed change to a previously approved project must be submitted to the IRB as an amendment via the eResearch system. For exempt projects, an amendment is required ONLY if the study is modified in such a way that the exemption criteria no longer applies. Contact the IRB staff if you have questions.

**Scheduled Continuing Review**

The IRB conducts continuing review of research studies continuing to involve human subjects according the approval period issued. The scheduled continuing review (SCR) application must be submitted at least 30 days before the end of the approval period to allow for timely IRB review. You will receive eResearch reminders at 90, 60 and 30 day intervals prior to the expiration of the study approval. Also, IRB approval must be renewed as long as you are actively analyzing the data collected as part of the project, unless the data set has been completely de-identified (including destruction of the key to coded identifiers).

*Expiration of Approval Period* - If the approval period for an active study has expired (or lapsed), all research-related procedures must stop, except where doing so would jeopardize the welfare of the human subjects. This means that no subjects may be enrolled in the research, no data may be collected, and data analysis must stop. The IRB may require the submission of an ORIO report (see below) describing the circumstances of the lapse before the expired study will be renewed.

**Reporting Adverse Events (AEs) and Other Reportable Information or Occurrences (ORIOs)**

Adverse events are events that involve physical, social, economic or psychological harm to subjects or others. Such adverse events may also indicate risks of harm to other subjects or to others. ORIOs are unplanned or unexpected occurrences associated with the research, such as a lapse in IRB approval, a significant subject complaint, a deviation from the approved research protocol, or a data security breach such as the theft of a laptop. An Adverse Event or ORIO is reported to the IRB via the AE/ORIO report in the eResearch system.

Please contact the IRB for guidance if one of these events occurs during your research. IRB-HSBS has adopted the IRBMED reporting guidelines for AE/ORIOs, as well as UaPs. Please see IRBMED guidance at: http://med.umich.edu/irbmed/ae_orio/index.htm#retro and https://research.medicine.umich.edu/office-research/institutional-review-boards-irbmed/guidance/adverse-events-aes-other-reportable-information-and-occurrences-orios-and-other-required-reporting/unanticipated-problems-involving-risks-subjects-or-others

**What do I do when I have completed my study?**

By submitting a Termination Report (via the eResearch SCR application), you confirm that the study is finished and that there will be no further interaction with subjects or their data. Once the IRB receives and acknowledges the Termination Report, the study is terminated in the eResearch system. Note: If you wish to enroll new subjects for your study, or otherwise engage human subjects in research after the study is terminated, a new eResearch application must be submitted. Therefore, you should only terminate a study when you are no longer enrolling new subjects, conducting research interventions with existing subjects, collecting data (including follow-up data), or performing analysis of identified data as part of the approved study.

## Chapter 8 - Special Considerations

### Collaboration with Researchers outside UM

Projects that involve collaboration with non-UM researchers or non-UM research sites that are "engaged" in the research may require additional external IRB approvals or inter-institutional agreements before a research project can receive final approval. An institution is engaged in research when its employees or agents intervene or interact with research subjects, including obtaining informed consent, or obtain individually identifiable private information for research purposes. Please see http://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html.

### Data Security

In social and behavioral research, breach of confidentiality is a serious risk posed to participants. Rigorous data security is a key element of protecting subject data from an accidental or malicious breach. Data security includes a plan to manage the physical documentation associated with the project, such as paper surveys, signed consent forms or documents that contain contact information for subjects, to insure that those materials are not lost or accessed inadvertently by an unauthorized person. Increasingly important is the management of electronic data on desktops or servers as well as on mobile devices such as laptops and flash drives. Please see the U-M Information Technology Security Services website at https://www.safecomputing.umich.edu/ and http://research-compliance.umich.edu/data-security-guidelines for detailed guidance on how to protect your data.

### International Studies

Research conducted outside the United States may create additional challenges for the student researcher and the IRB. Cultural, economic, or political conditions of the host country may alter the risk for participants compared to the same research conducted within the U.S. Other countries and institutions within those countries may have Institutional Review Boards, Ethics Committees or other research oversight bodies which require review of the research before it can be conducted in that country. Conversely, some may have no mechanism for ethics review of social and behavioral research. Except for research which is federally funded and the international site is engaged, the regulatory authority of the Common Rule (see Appendix I) does not cover research outside the U.S.; therefore, the IRB must ensure that equivalent protections for human subjects participating in research are in place.

In its review of your application, the IRB may consider the following information:

- description of where the research will be conducted (including geographic location and specific performance sites, where applicable). Note: In some areas, government–issue research visas are required;
- information about the local research context, including the current economic, cultural, political, or religious conditions of the area that may affect the conduct of the research, and a description of the investigator's personal experience conducting research (or studying or residing) in the region;
- the language(s) in which consent will be sought from participants and the research will be conducted, as well as whether the investigator is fluent in this language or whether an interpreter will be required. If an interpreter will be used, it should be clear what limitations or risks, if any, this might present for participants, as well as how these potential problems will be overcome or minimized;
- a description of the informed consent process as appropriate for the culture;
- copies of translated study documents (recruitment materials, informed consent, study instruments);
- any benefits to the local community that will remain in the community once the research is complete;
- if compensation is being offered, a description of its appropriateness for the setting;

- procedures for data security and storage in the local setting and for transfer of data and/or specimens to UM; and
- a copy of local IRB or equivalent ethics committee approval, where applicable. Depending on the location, this may take the form of a letter of approval from an IRB or research ethics committee, local university department sponsoring the research, institutional oversight committee, or an indigenous council. If the research is federally funded, check with the IRB for other regulatory requirements.

If you are traveling to an international setting for your research, submit your IRB application well in advance of your planned travel date. This is particularly crucial for projects that involve more than minimal risk to participants that will require full board review. Please see the IRB-HSBS website (http://research-compliance.umich.edu/irb-health-sciences-and-behavioral-sciences-hsbs) for meeting submission dates.

**Research in Schools**
Research conducted in primary and secondary schools, as well as in colleges and universities, receiving U.S. Department of Education funds may be subject to additional federal regulation. Schools that grant access to researchers may also impose requirements, such as district approvals or informed consent processes that would not be required by the IRB.

- **The Family Educational Rights and Privacy Act (FERPA) (34 CFR Part 99)**
  http://www.ed.gov/policy/gen/guid/fpco/ferpa/index.html
  FERPA applies to research involving student education records for any institution receiving U.S. Department of Education funding, meaning that it applies to most public and private K-12 schools as well as most public and private colleges and universities. Access to identifiable student records requires written permission from the parent (for minors) or from the adult student unless the research is being conducted by the researcher on behalf of the school.

- **The Protection of Pupil Rights Amendment (PPRA) (34 CFR Part 98)**
  http://www.ed.gov/policy/gen/guid/fpco/ppra/index.html
  The PPRA, created by the No Child Left Behind Act, applies to survey research conducted in elementary and secondary schools receiving funds under U.S. Department of Education programs. The provisions of the PPRA apply to surveys that involve specific sensitive survey topics. The PPRA includes requirements for parental permission as well as for making survey questions available for parental review prior to administration.

**Secondary Data Analysis Projects**
Projects that involve only the secondary analysis of data collected as part of a different research project do not require IRB review and approval if:

- the data set is publicly available;
- The data set has been de-identified, meaning that any data elements that could be used to identify an individual have been stripped. Please see U-M Guidance on De-Identified or Limited Data Sets: http://www.med.umich.edu/irbmed/PB/data-sets-info.rtf.

*Projects using Coded Private Information or Biological Specimens* - If you will be using a data set provided by another investigator that has been coded for your use, your project may not require IRB oversight. *Coded* means that identifying information that would enable the investigator to readily ascertain the identity of the individual to whom the private information or specimens pertain has been replaced with a number, letter, symbol, or combination thereof (i.e., the code); and a key (or cross-walk) to decipher the code exists, enabling linkage of

the identifying information to the private information or specimens. Research using such a coded data set is not regulated by the IRB if the data were not collected for the proposed study and the investigator does not have access to the code linking to the identifiable information (Appendix VI,UM Guidance of De-Identified or Limited Data Sets for a list of data elements considered to be personal identifiers.) An application must be submitted to the IRB for this determination to be made. More information regarding coded private information or biological specimens can be found at: http://www.hhs.gov/ohrp/regulations-and-policy/guidance/research-involving-coded-private-information/index.html.

**Deception and Concealment Studies**

Deception is the intentional *misleading* of a subject about the nature of the study. *Withholding* of full information is known as concealment. Misleading or omitted information might include the purpose of the research, the role of the researcher, or what procedures in the study are actually experimental. Deception increases ethical concerns and should be used with discretion, because it interferes with the ability of the subject to give informed consent. The IRB recognizes that deception or concealment may be necessary for certain types of behavioral research. Because people act differently depending on circumstances, full knowledge by the subject might bias the results in some cases.

Special requirements for deception or concealment projects:

- **Waiver of Informed Consent**
  Because participants are not provided with all of the details of the proposed research at the time consent is obtained, deception projects must meet the criteria for waiver of informed consent including that the project poses no more than minimal risk to the subjects.
- **Debriefing**
  Subjects have the right to full disclosure as soon as possible after participation in deception or concealment research; a post-participation debriefing is usually required. The debriefing should disclose the full or true purpose of the research and allow the subject to indicate that their data not be used in the study. In exceptional circumstances, the full or true purpose of the research may not be revealed to the subjects until the data collection is complete. In such cases, subjects should not be exposed to undue stress or embarrassment and must have the right to full disclosure of the purpose of the study as soon as possible after the data have been collected.

**Use of Subject Pools**

Some academic units at the University operate student subject pools that grant academic credit for participation in research. While the IRB has oversight for the research conducted in these pools, the administration of the pools is governed by the academic units. The largest pool is the Introductory Psychology Subject Pool (https://lsa.umich.edu/psych/undergraduates/subject-pool.html). Use of this pool is typically limited to researchers who have an affiliation with the Department of Psychology. The Psych Subject Pool requires that student research participants be provided with an educational debriefing that elaborates on the purpose of the study and provides at least two citations to literature related to the study.

**Genetic Analyses**

Please contact the IRB-HSBS directly if your research study involves genetic analyses of *any* kind.

**Mobile Technology**

If your research involves mobile technology (including mobile applications), please contact the IRB-HSBS directly for information on institutional policies, regulatory issues, licensing requirements, and commercialization processes that might apply.

**Appendix I - Ethical Principals and Regulatory Framework and Governing Human Subjects Research**

**The Belmont Report**

In 1978, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research created "The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research." The Belmont Report sets forth the basic principles governing the ethical conduct of research involving human subjects. The Belmont Report encompasses three key principles: respect for persons (autonomy), beneficence, and justice.

| Principle | Application |
|---|---|
| Respect for Persons | Respect for persons requires that protocols (including the informed consent process) be designed to promote personal capacity to consider alternatives, make choices, and act without undue influence or interference of others. The principle is reflected in requirements that legally effective informed consent be obtained, unless specific requirements for waiver of informed consent are met and appropriately documented; and that subjects with diminished capacity and others who are vulnerable to coercion or undue influence receive special protection or consideration. |
| Beneficence | Beneficence entails an obligation to protect individuals from harm. The principle can be expressed in two general rules: (1) do no harm; and (2) protect from harm by maximizing possible benefits and minimizing possible risks of harm. It is reflected in a requirement that principal investigators design and IRBs approve protocols only under circumstances where the benefits to the subjects and/or the importance of the knowledge to be gained justify the risks to the subjects sufficiently to warrant a decision to allow the subjects to accept those risks. |
| Justice | Justice requires fairness in distribution of burdens and benefits. The principle often is expressed in terms of treating persons of similar circumstances or characteristics similarly. It is reflected in the requirement that selection of subjects is equitable and is representative of the group that is intended to benefit from the research. |

More information can be found at: http://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/

**Federal Policy for the Protection of Human Subjects (Common Rule) (45 C.F.R. 46)**

In 1981, the Department of Health and Human Services codified the Policy for the Protection of Human Subject (45 C.F.R. 45). These regulations, called the "Common Rule," provide for the foundation of the Institutional Review Boards. This federal policy has been adopted by the 18 federal agencies that conduct, support, or otherwise regulate human subjects research, hence the title "Common Rule." The Policy also provides specific protections to vulnerable populations such as pregnant women, fetuses, and neonates (Subpart B), prisoners (Subpart C), and children (Subpart D) involved in human subjects research. More information can be found at: http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/

## Appendix II – Exemption Categories

**EXEMPTION #1 (45 CFR 46.101(b)(1)):** Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

**EXEMPTION #2 (45 CFR 46.101(b)(2)):** Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research that could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. Note: The use of Exemption #2 for research with children is limited to use of educational tests or public observation where the researcher does not interact with the children in any way.]

**EXEMPTION #2A (UM IRB-HSBS only):**
Minimal risk research that involves a non-invasive intervention followed by data collection via survey, interview (including focus groups), or observation unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. The research is not federally sponsored or intended to collect pilot data to support proposals for federal funding. This exemption applies only to projects that are not federally-funded, regulated by the FDA, or conducted under a Certificate of Confidentiality. If you receive federal funding for the project, please notify the IRB immediately. U-M Exemption #2a cannot be applied to federally-funded projects.

**EXEMPTION #3 (45 CFR 46.10(b)(3)):** Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

**EXEMPTION #4 (45 CFR 46.101(b)(4)):** Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

**EXEMPTION #5 (45 CFR 46.101(b)(5)):** Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

**EXEMPTION #6 (45 CFR 46.101(b)(6)):** Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or

below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

**EXEMPTION #7 (UM IRB-HSBS only):** Research in which study activity is limited to analysis of identifiable data. For the purposes of this research study, all research subject interactions and interventions have been completed and the data continues to contain subject identifiers or links. The research is not federally-funded, regulated by the FDA or conducted under a Certificate of Confidentiality.

## Appendix III - Criteria for IRB Approval

When the IRB reviews a research protocol, it must make eight specific regulatory determinations in order to grant approval. These determinations find their basis in the ethical principles of the Belmont Report and codified in the Common Rule: respect for persons, beneficence, and justice.

(a) In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

(1) Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §46.116.

(5) Informed consent will be appropriately documented, in accordance with, and to the extent required by §46.117.

(6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

(7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(b) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

## Appendix IV – Expedited Review Categories

**(1) Clinical studies of drugs and medical devices** only when condition (a) or (b) is met. (a) 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.)(b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 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 samples by finger stick, heel stick, ear stick, or venipuncture** as follows: (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or (b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

**(3) Prospective collection of biological specimens for research purposes by noninvasive means.** Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

**(4) Collection of data through noninvasive procedures** (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving 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.) Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject=s privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

**(5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes** (such as medical treatment or diagnosis).

**(6) Collection of data from voice, video, digital, or image recordings made for research purposes.**

**(7) Research on individual or group characteristics or behavior** (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social

behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

**(8) Continuing review of research previously approved by the convened IRB** as follows: (a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or (b) where no subjects have been enrolled and no additional risks have been identified; or (c) where the remaining research activities are limited to data analysis.

**(9) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption** where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

## Appendix V – IRB Determinations

After completing its review of an application, the IRB will notify investigators of one of the following actions:

**Approved** – The IRB approves a research proposal when the application is complete and the IRB has determined that the study has met the regulatory criteria for approval. Once the approval determination is issued via eResearch, the research may be conducted according to approved procedures and parameters.

**Approval with Contingencies** – The IRB approves an application with contingencies when the proposal meets the regulatory criteria for approval but needs specified changes to the protocol, informed consent document(s), or other supporting materials prior to final approval. Such changes must require no more than the simple concurrence of the investigator. The investigator is notified of the study outcome via an eResearch

**Contingencies Pending** notice and is provided with detailed instructions regarding required changes to the application or study materials that must be completed before the application can receive final approval. For projects reviewed by the full board, the IRB, in its vote, must indicate whether the response to contingencies can be reviewed and approved by the chair or another board member or returned for review and approval by the convened board. For projects reviewed by expedited review, the contingency review may be completed by IRB staff or by an expediting reviewer. Once all contingencies are met, the IRB will issue an approval notice via eResearch. No research may be conducted until final approval is released by the IRB.

**Action Deferred –** The IRB-HSBS full board may vote to defer action on an application when a significant action on the part of the investigator is required before the IRB can consider approval or disapproval of the research. Action is deferred on applications that are found to have major deficiencies, such as incomplete procedures and documentation, or major ethical issues, including unreasonable risk to subjects that make it impossible for the IRB to approve the research, as proposed. The application is returned to the investigator via a **Changes Required by Core Staff** notice within eResearch that details the issues that must be addressed in the application/materials before it can be reconsidered by the IRB. Upon revision of the application and resubmission to the IRB, the study will be rescheduled for review by the full IRB.

For projects considered via expedited review and returned by the reviewer without a determination, the IRB staff will return the application to the investigator using a **Changes Required by Core Staff** notice within eResearch that details the required changes. Upon revision of the application and resubmission to the IRB, the application will be returned to the expediting reviewer who requested the changes for review. The reviewer will then issue approval or return the application to the investigator for additional changes until all issues are satisfactorily addressed.

**Disapproval** - The IRB-HSBS full board may vote to disapprove an application to conduct human subjects research when it determines that the study design does not provide, and is unlikely to be modified to provide, adequate protection to subjects. Disapproval of an application usually follows several attempts by the investigator, in conjunction with the efforts of the IRB, to modify the study design to afford protection to the subjects. This action can only be taken by the full board at a convened meeting. The investigator will be sent a rationale for the disapproval and may ask that the IRB reconsider the disapproval.

## Appendix VI - Resources

The following key resources may be helpful for you as a student investigators:

**Federal**

- US Department of Health and Human Services (HHS), Office of Human Research Protection (OHRP)
  Website: http://www.hhs.gov/ohrp/
  *OHRP is the federal agency that has regulatory oversight for research with human subjects. The OHRP website contains many useful resources related to the ethical conduct of research with human subjects and the regulations governing such research.*

- NIH Certificate of Confidentiality Kiosk
  Website: http://grants.nih.gov/grants/policy/coc/

**University of Michigan**

- Human Research Protection Program
  Website: http://www.hrpp.umich.edu/

- Institutional Review Board Health Sciences and Behavioral Sciences (IRB-HSBS)
  Address: North Campus Research Complex, 2800 Plymouth Road, Building 520, Ann Arbor, MI 48109-2800
  Phone: 734-936-0933
  Email: irbhsbs@umich.edu
  Website: http://research-compliance.umich.edu/irb-health-sciences-and-behavioral-sciences-hsbs

- eResearch Regulatory Management System (RM)
  Website: http://eresearch.umich.edu
  *eResearch is the IRB application tool for all human subjects research at the University of Michigan. eResearch is managed by Information and Technology Services (ITS). The eResearch RM website also provides useful training information and links to other research resources at UM.*

- Program for Education and Evaluation in Responsible Research and Scholarship (PEERRS)
  Website: http://my.research.umich.edu/peerrs/.
  *PEERRS is a series of training modules for U-M researchers. Successful completion of either of the human subjects research modules in the PEERRS curriculum is required prior to IRB approval of research.*