
University of Michigan
IRB Health Sciences and Behavioral Sciences
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### Table of Contents

Introduction to Human Subjects Research Protection for Student Investigators 4

Chapter 1 – Before You Begin 5
  - Why does research with human subjects require review? 5
  - What is an Institutional Review Board? 5
  - What is the IRB Health Sciences and Behavioral Sciences (IRB-HSBS)? 6
    - The Board 6
    - The IRB-HSBS Office 6

Chapter 2 - Student/Faculty Responsibilities in Human Subjects Research 8
  - Students as PIs 8
  - What are the responsibilities of the faculty advisor? 8
  - What are the responsibilities of the student investigator? 8

Chapter 3 – How do I know if I am conducting human subjects research? 10
  - Is it research? 10
  - Does my project involve human subjects? 10
  - What if I’m not sure if my project involves research with human subjects? 11
  - Do I need to submit an application? 11

Chapter 4 – The eResearch Application 12
  - What is eResearch? 12
  - Getting Started 12
    - PEERRS Training Requirement 12
    - Logging Into eResearch 12
  - Your Workspace 12
  - General Guidance 13
  - Application Help 13
  - Application Tips by Key Section 13
  - Communication via eResearch 14

Chapter 5 – IRB Review of Research with Human Subjects 15
  - What type of review is required for my project? 15
  - What is minimal risk? 15
  - Exempt Review 15
    - What is exempt research? 15
    - How is exempt research reviewed? 15
    - How long will the review take? 15
  - Expedited Review 16
    - What is expedited review? 16
    - How is expedited research reviewed? 16
    - How long will the expedited review take? 17
  - Full Board Review 17
    - What projects require review by the full (convened) board? 17
    - How is research reviewed by the full board? 17
How long will the review take? 18

Chapter 6 - What is Informed Consent? 19
  Elements of Informed Consent 19
  The Informed Consent Process 20
  Waiver of Documentation of Informed Consent 20
  Waiver of Informed Consent 20

Chapter 7 - Investigator Responsibilities After IRB Approval 21
  Amendments 21
  Scheduled Continuing Review 21
  Reporting Adverse Events/Other Reportable Information or Occurrences (AE/ORIOs) 21
  What do I do when I have completed my study? 22

Chapter 8 - Special Considerations 23
  Collaboration with Researchers outside UM 23
  Data Security 23
  International Studies 23
  Research in Schools 24
  Secondary Data Analysis Projects 24
  Deception and Concealment Studies 25
  Use of Subject Pools 25

Appendix I - Core Ethical Principles and Regulatory Framework 26
Appendix II - Categories of Exempt Research 28
Appendix III - Regulatory Elements of IRB Review 29
Appendix IV - Expedited Review Categories 33
Appendix V - IRB Determinations 35
Appendix VI - Useful Resources 36
Introduction to Human Subjects Research Protection for Student Investigators

It is a privilege and not a right to conduct research with human subjects. Responsible conduct of research with human volunteers in social, behavioral or biomedical research requires commitment to the rights and welfare of participants and to the professional standards of the investigator’s academic discipline. This guide is designed to help student investigators at the University of Michigan understand their ethical obligations as a researcher, the federal regulations governing human subjects research and the University’s policies and procedures associated with the conduct of such research. This guide has been prepared for student researchers conducting research under the oversight of the UM Institutional Review Board Health Sciences and Behavioral Sciences (IRB-HSBS) with a focus on research in the social and behavioral sciences.

Key Resources

The following key resources may be helpful to the student investigator:

University of Michigan

- Institutional Review Board Health Sciences and Behavioral Sciences (IRB-HSBS)
  540 E. Liberty St. #202
  Ann Arbor, MI 48104-2210
  Phone: 734-936-0933
  Email: irbhbs@umich.edu
  Website: [http://www.irb.umich.edu](http://www.irb.umich.edu)
  The IRB website includes contact information for IRB staff and IRB chair; guidance materials, including informed consent templates; a schedule of formal training sessions as well as departmental “IRB-on-the-Road” hours; application submission due dates and the schedule of meetings of the full IRB.

- eResearch Regulatory Management System (RM)
  Website: [http://eresearch.umich.edu](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/](http://my.research.umich.edu/peerrs/).
  PEERRS is a series of training modules for UM researchers. Successful completion of either of the human subjects research modules in the PEERRS curriculum is required prior to IRB approval of research.

Federal

- US Department of Health and Human Services (HHS), Office of Human Research Protections (OHRP)
  Website: [http://www.hhs.gov/ohrp/about](http://www.hhs.gov/ohrp/about)
  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.
Chapter 1 – Before You Begin

Why does research with human subjects require review?
The University of Michigan is responsible for ensuring that the rights and welfare of research participants, or human subjects, are adequately protected in research conducted by its faculty, staff and students. Federal laws 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 is found in the US Department of Health and Human Services Policy for the Protection of Human Subjects (45 CFR 46), also known as the “Common Rule.” See http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm. These regulations codify the key ethical principles found in the Belmont Report. See http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm. These principles are:

- Respect for persons
- Beneficence
- Justice

In essence, the Belmont Report tells us that for research to be ethical, subjects must choose to participate voluntarily after being fully informed about the research study (respect for persons), that the benefits of the research out-weigh the risks associated with the research (beneficence), and that the selection of subjects is equitable (justice).

Other federal regulations may also apply to the conduct of human subjects research at UM. These are:


See Appendix I for more information on the ethical and regulatory framework governing the conduct of human subjects research.

What is an Institutional Review Board?
Institutional Review Boards (IRBs) were established by the federal government to protect the rights and welfare of human subjects participating in research. IRBs review human research activities to ensure that the University, affiliated institutions, and investigators are compliant with ethical standards, state and federal laws, and institutional policies governing human subjects research.

An IRB is an independent committee made up of at least five members from the academic disciplines for which it has oversight and at least one member who is not affiliated with the university. The membership comes primarily from the faculty, but also includes staff, students, and members of the local community. The membership must have the experience and expertise necessary to evaluate proposed research projects and must be diverse in terms of race, gender, and cultural backgrounds.
At the University of Michigan in Ann Arbor, human subjects research is reviewed by the IRB Health Sciences and Behavioral Sciences (IRB-HSBS) or one of the Institutional Review Boards of the University of Michigan Medical School (IRBMED).

All activities conducted by UM faculty, staff or students that involve research with human subjects as defined by the federal regulations, including those conducted for undergraduate honors thesis, master’s thesis, or doctoral dissertation, are subject to IRB review or exemption (See Chapter 3). Student investigators and their faculty advisors must be aware of their responsibility to seek IRB review. There are, however, some types of scholarly or scientific inquiry that involve interactions with people that do not require IRB review. See the Part IV of the Human Research Protection Program Operations Manual (http://www.hrpp.umich.edu/om/) for more information. The IRB staff can assist investigators with making project-specific determinations concerning the need for IRB approval.

What is the IRB Health Sciences and Behavioral Sciences (IRB-HSBS)?

The Board
The IRB-HSBS serves as the IRB for research conducted by investigators from the Ann Arbor campus, other than research that is subject to the oversight of the IRBMED (such as FDA-regulated projects). Major units or schools under the jurisdiction of IRB-HSBS include:

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<td>Anthropology</td>
<td>Institute for Social Research</td>
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<td>Architecture/Urban Planning</td>
<td>Kinesiology</td>
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<td>Business</td>
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<td>Communication Studies</td>
<td>Music, Theatre &amp; Dance</td>
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<td>Dentistry (non-FDA regulated)</td>
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The IRB-HSBS is lead by at least one Chair appointed by the Vice President for Research. The IRB-HSBS meets twice each month. Designated members of the board also conduct expedited review of applications on a rolling basis.

The IRB-HSBS Office
The IRB-HSBS is supported by the IRB-HSBS administrative staff. IRB staff members assist faculty, staff, and students seeking IRB approval; provide educational programming in support of the responsible conduct of research; and support the operations of the board. Most researcher interaction with the IRB is with the IRB-HSBS administrative staff. The IRB staff manages the application workflow and communications between the investigator and the reviewers. In addition, qualified IRB staff members have authority to make specified application determinations, such as issuing exempt and not regulated decisions and approving certain amendments and continuing review applications.

In addition, the IRB staff provides the following services for faculty, staff, and students involved in human subjects research:
- assistance with general questions about human research review procedures;
- assistance with study-specific questions;
- coordination and delivery of educational programs;
• in-person consultation at IRB-on-the-Road sessions, an IRB program offering office hours within academic units; and
• responses to researcher, community, and research participant questions and concerns.
Chapter 2 - Student/Faculty Responsibilities in Human Subjects Research

Students as PIs
At the University of Michigan, students may serve as principal investigators for their own research projects and are responsible for submitting the IRB application. The IRB reviews and holds student research projects to the same standards as human subjects research conducted by faculty or staff. IRB approval or exemption must be obtained prior to initiating any research activity under IRB oversight. Research for undergraduate honors’ theses, master’s theses, and doctoral dissertations involving human subjects requires IRB review. “Retroactive” IRB approval or exemption is not permitted under federal regulations and University policy. Failure to obtain IRB approval for research with human subjects may preclude the use of the previously collected data and could result in other institutional sanctions.

What are the responsibilities of the 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 the IRB application and for ensuring that the study adheres to relevant policies and regulations (institutional, state, federal and international – where applicable). Under the mentorship of the faculty advisor, the student investigator must:

• be familiar with the ethical and regulatory requirements for human subjects research and must complete the PEERRS human subjects research training module found at: http://my.research.umich.edu/peerrs/;
• submit an accurate and complete application to the IRB, allowing adequate time for review;
• obtain IRB approval prior to the initiation of research (including subject recruitment);
• conduct the research in accordance with the approved protocol;
• inform the IRB of all changes or additions to the previously approved study protocol;
• submit scheduled continuing review applications to the IRB, if required;
• manage research data carefully to ensure subject confidentiality;
• consult with the faculty advisor when problems are encountered; and
• report all unanticipated problems or serious adverse events involving risk to human subjects to the IRB as soon as possible.

What are the responsibilities of the faculty advisor?
The faculty advisor is an active mentor to the student researcher and shares the responsibility for the ethical conduct of the research with the student. The advisor is expected to discuss the general principles of research ethics prior to the initiation of any project involving human subjects, help students determine whether their project requires IRB review, and guide students through the IRB application process. The advisor must also support the student in the conduct of the research after the project has attained IRB approval. All research proposals from undergraduates, graduate students and post-doctoral fellows must include a faculty advisor as member of the study team.

Faculty advisors must:
• be familiar with the ethical and regulatory requirements for human subjects research and must complete the PEERRS human subjects research training module, found at: http://my.research.umich.edu/peerrs/;
• discuss research ethics with students, including the professional ethics of the discipline;
• assess whether projects require IRB review and assist students with the IRB application process, including timely submission of the application;
• assist students with designing a human subjects research project appropriate to the student’s training and experience (Note: Under UM policy, research conducted by undergraduate investigators must be limited to projects that pose no more than minimal risk to human subjects);
• instruct students on the use of good data security practices;
• counsel students conducting research in international settings on the importance of understanding local customs and regulations for subject and student safety and assist the student with establishing local relationships or local sponsorship for their research;
• monitor student projects, paying special attention to maintaining confidentiality, privacy, level of risk, informed consent process and voluntary participation and withdrawal of subjects;
• assure that the student reports unanticipated problems or serious adverse events the IRB; and
• assist students with issues regarding data ownership, publication authorship and other research conduct problems.
Chapter 3 – How do I know if I am conducting human subjects research?

Research projects meeting the regulatory definition of research with human subjects require either review and approval by an IRB, or a determination that the research is exempt. Not all activities that involve people, their data, or specimens are covered by the regulations governing human subjects research and may not require review by an IRB.

The first question that must be considered is whether a project fits the regulatory definition of research, and if so, whether it also involves human subjects.

Is it research?
The federal regulations define research as “a systematic investigation, including development, testing, and evaluation, designed to develop or contribute to generalizable knowledge” (45 CFR 46.102(d)).

- A systematic investigation is an activity designed to test a hypothesis and to permit conclusions to be drawn. The research is described in a formal protocol that sets forth an objective and a set of 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 meeting generally, but not always, indicates an intention to contribute to generalizable knowledge.

Research generally does not include activities such as the practice of public health, medicine, counseling, or social work. 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. See: http://www.research.umich.edu/hrpp/om/Part4.html for more information.

**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. For more information on this topic, see the UM Policy on Class Activities at http://www.hrpp.umich.edu/classroomresearch.html. 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.

**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. See also: http://www.research.umich.edu/hrpp/om/Part4.html for more information.

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” (45 CFR 46.102(f)(1)(2)).
• “Living individual” refers to data (information or specimens) collected from living subjects. For example, research using data from the 1880 Census would not be human subjects research.
• “About whom” refers to the fact that the information collected must be personal information about an individual. For example, a survey that collects data about the activities of an organization is not human subjects research.
• “Intervention” includes physical procedures, manipulations of the subject or the subject’s environment for research purposes. For example, taking a saliva or blood sample from a subject or having a subject view a video would be considered a research intervention.
• “Interaction” refers 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. Research with a de-identified data set is not research with human subjects because the data are not individually identifiable.
• “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 if your project involves research with human subjects. UM has identified a number of project types that are “not regulated” and therefore, do not require review by the IRB as human subjects research:

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

More information on these project types can be found in the UM Human Research Protection Program Operations Manual, Part IV (http://www.research.umich.edu/hrpp/om/Part4.html).

Do I need to submit an application if my project does not involve research with human subjects?
An IRB application is not required for most types of “not regulated” research. If you would like a formal “not regulated” determination from the IRB, or if you are not sure if your project requires review, you can submit a brief application via eResearch, the web-based IRB application system (see Chapter 4 for more about eResearch). 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.
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 UM 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.

Getting Started
Once the student investigator and faculty advisor have agreed on the research methodology for the student research project, the student investigator should prepare the eResearch IRB application. Before beginning the application, gather together all of the materials that will be needed in the process (exempt applications need not submit the elements marked with an *), including:

- research protocol;
- the ePAF identifier and related documentation, if there is financial support;
- performance site information, including site approval letters or IRB approval;*
- informed consent documents (including text for studies using an oral consent process);*
- recruitment materials (flyers, posters, letters, text of emails or oral recruitment scripts);*
- survey/interview/focus group questions; and
- audio/visual materials to be used in the research (e.g. film or audio clips).*

(*materials not required for exempt applications)

PEERRS Training Requirement
All key members of the study team (principal investigator, co-investigators, faculty advisors, and project manager/study coordinators) must complete a PEERRS human subjects research training module (http://my.research.umich.edu/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.

Logging Into eResearch
Prior to starting the application, all UM 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 UM 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, when you save and exit, it will be available from your home workspace.
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.

Application Help
The eResearch application provides Help information along the right column of the application. Read it!

Application Tips by Key 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 UM 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. A sample letter is available on the IRB-HSBS website (http://www.irb.umich.edu/Consent/consent.html).
- **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** – See the IRB website (http://www.irb.umich.edu/Consent/consent.html) 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. Remember to include the IRB merge fields (used by the IRB to apply an approval date to the document), in the footer of the consent document.
- **Survey Research** – You must provide a copy of your proposed survey/interview/focus group questions.
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. **Tip:** 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. **Tip:** 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. **Tip:** 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.

If you need help with the application content...
Please call the IRB office or send us an email if you have any questions about the application or the application process. 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. You can also meet with a staff member in person at our office or at an IRB-on-the-Road session. IRB-on-the-Road provides an opportunity to meet with the IRB staff one-on-one sessions scheduled at many schools and colleges. See our website (http://www.irb.umich.edu/) for the schedule and for other helpful information, including informed consent templates and sample documents and other guidance materials.

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, contact the ITS (formerly MAIS) help desk at 734-936-7000 or maishelpdesk@umich.edu. The eResearch Regulatory Management website (http://www.umich.edu/~eresinfo/rm.html) also provides “How Tos” and other materials that you may find to be helpful.
Chapter 5 – IRB Review of Research with Human Subjects

What type of review is required for my project?
Projects that meet the definition of research with human subjects require documented IRB approval or a determination of exemption before starting any research activities, including pilot activities, advertising or recruiting. All applications are submitted to the IRB for review via eResearch (http://eresearch.umich.edu). Once submitted, applications undergo one of the following types of review:

- exempt
- expedited
- full board

Studies meeting one of six specific exemption categories and an additional UM category are reviewed via the exempt review process. Studies involving no more than minimal risk are generally reviewed via expedited review. Studies that involve greater than minimal risk are reviewed by the full board. Studies with complicated research elements or involving vulnerable populations 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 the regulatory definition. To be exempt, a project must fall under one of six exempt categories listed in the federal regulations (45 CFR 46.101(b)) or one exemption category that has been added by the University of Michigan. Exemptions are not granted for research involving prisoners as well as 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 (see Appendix I, Ethical and Regulatory Framework) 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 the review take?
Most exempt projects are reviewed in less than a 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 regardless of whether they are reviewed via an expedited or a full board review process (see Appendix III, Regulatory Elements of IRB). The same standard eResearch application and supporting materials (protocols, informed consent documents, recruitment materials, 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 (See Appendix IV, Expedited Review Categories). 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 may 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 the designated IRB reviewer. The expedited reviewer completes 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. (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 IRB approval is received via eResearch.
How long will the 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 UM policy, undergraduate researchers may not conduct research that poses greater than minimal risk to the subjects.

How is research reviewed by the full board?
A designated IRB staff member conducts the initial administrative review of each application identified as requiring full board review. The staff reviewer may 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 asked 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 IRB approval is received via eResearch.
How long will the 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://www.irb.umich.edu/). 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 7 – 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.
- Don’t 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.

Elements of Informed Consent
Regulations identify the following required elements of informed consent. See 45 CFR 46.116 (http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.116):

- 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;
- 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 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).

See the IRB website at: http://www.irb.umich.edu/ 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. See 45 CFR 46.117 (http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.117).

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 (see Chapter 9 – Special Considerations for more information).
Chapter 8 - Investigator Responsibilities after IRB Approval

Approval of a research project by the IRB does not end an investigator’s 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 (consent, survey instruments, and recruitment materials) 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, investigators 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 investigators 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. Investigators 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 the investigator is 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 will 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; see IRBMED guidance at http://med.umich.edu/irbmed/ae_orio/index.htm#retro.
What do I do when I have completed my study?

By submitting a Termination Report (via the eResearch SCR application), the researcher confirms 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 the investigator wishes to enroll new subjects for the study, or otherwise engage human subjects in research after the study is terminated, a new eResearch application must be submitted. Therefore, an investigator should only terminate a study when he/she is no longer enrolling new subjects, using research interventions on existing subjects, collecting data (including follow-up data), or performing analysis of identified data as part of the approved study.
Chapter 9 - 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. See http://www.hhs.gov/ohrp/humansubjects/guidance/engage08.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. See the UM Information Technology Security Services website at http://www.safecomputing.umich.edu/MDS/ 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 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 will 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. See the IRB-HSBS website (http://www.irb.umich.edu/) 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)
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)
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 were collected anonymously, or
• the data set has been de-identified, meaning that any data elements that could be used to identify an individual have been stripped. See UM 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 (See 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/humansubjects/guidance/cdebiol.pdf.

**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 (http://www.lsa.umich.edu/psych/undergrad/research/pool/). 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.
Appendix I - Core Ethical Principals and Regulatory Framework

Ethical Framework

Nuremberg Code
The history of the ethical regulations in human subjects’ research began in the 1940s with the Nuremberg Code. The Nuremberg Code was developed following the Nuremberg Military Tribunal which judged human experimentation conducted by the Nazis. The Code encompasses many of the basic principles governing the ethical conduct of human subjects’ research today. The Nuremberg Code states that “the voluntary consent of the human subject is absolutely essential” and it further explains the details implied by this requirement: capacity of participants to consent, participants’ rights to participate or not, freedom from coercion, no penalty for withdrawal, and comprehension of the risks and benefits involved. More information can be found at: http://www.nihtraining.com/ohsrsite/guidelines/nuremberg.html.

Declaration of Helsinki
In 1964, the World Medical Association established recommendations to guide medical doctors in biomedical research involving human subjects. The Declaration governs international research ethics and defines rules for "research combined with clinical care" and "non-therapeutic research." The Declaration of Helsinki was revised in 1975, 1983, 1989, and 1996 and is the basis for Good Clinical Practices used today. More information can be found at: http://ohsr.od.nih.gov/guidelines/helsinki.html.

Issues addressed in the Declaration of Helsinki include:
- research involving medical interventions with humans should be based on the results from laboratory and animal experimentation;
- research protocols should be reviewed by an independent committee prior to initiation;
- informed consent from research participants is necessary;
- research should be conducted by medically/scientifically qualified individuals; and
- risks should not exceed benefits.

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.

<table>
<thead>
<tr>
<th>Principle</th>
<th>Application</th>
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<tr>
<td>Respect for Persons</td>
<td>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.</td>
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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 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/humansubjects/guidance/belmont.htm](http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm).

**Regulatory Framework Governing Human Subjects Research**

**Federal Regulations**
Since the release of the Belmont Report, the federal government has codified the protection of the rights and welfare of human subjects by establishing regulatory codes and regulations.

- **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 basic 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/humansubjects/guidance/45cfr46.htm](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm).

- **U.S. Food and Drug Administration Regulations**
The U.S. Food and Drug Administration, under the Department of Health and Human Services, also provide guidance for Institutional Review Boards. FDA regulations differ from the Common Rule in some ways. See: [http://irb.jhmi.edu/Guidelines/FDAvsOHRP.html](http://irb.jhmi.edu/Guidelines/FDAvsOHRP.html). More information can be found at [http://www.fda.gov/oc/ohrt/irbs/](http://www.fda.gov/oc/ohrt/irbs/).

- **Health Insurance Portability and Accountability Act (HIPAA)/Privacy Rule**
The Health Insurance Portability and Accountability Act “Privacy Rule (HIPAA) is a federal law that generally prohibits health care providers (such as physicians or other health care practitioners, hospitals, nursing facilities and clinics) from using or disclosing "protected health information" (PHI) without written authorization from the patient. The full text of the Privacy Rule can be found at the HIPAA privacy website of the Office for Civil Rights (OCR): [http://www.hhs.gov/ocr/hipaa](http://www.hhs.gov/ocr/hipaa).
Appendix II – Categories of Exempt Research

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 #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 - Regulatory Elements of IRB Review

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.

Regulatory Elements of IRB Review

1. **Risks to subjects are minimized**
   Minimal risk means that the probability and magnitude of harm and discomfort anticipated in the proposed 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 harm include economic, legal, physical, psychological, and social. Each type of harm may occur in social research either to participants or to people not directly involved in the research, such as family members.

2. **Risks to subjects are reasonable in relation to anticipated benefits, if any**
   **Risks**
   In social and behavioral projects, primary risks to subjects tend to be related to psychological distress or harms resulting from a breach of confidentiality. Subjects may feel stress caused by the research questions or procedures. Questions raise painful memories or unresolved issues. Questions about at-risk behaviors may cause embarrassment, feelings of guilt, or result in legal liability when that behavior is generally illegal or socially unacceptable. Most psychological risks are minimal and transitory, but investigators must be aware of the potential for serious psychological harm.

   A breach of confidentiality may be a significant risk to participants in social and behavioral research. If confidentiality of research data is not maintained, a participant might experience risks to reputation, employment, financial standing or insurance coverage. Information about subjects' activities may place them at risk of legal action. For example, if subjects divulge information about their participation in illegal or stigmatizing activities, any disclosure of that information could place the subjects at risk of significant harm.

   The kind and level of risk is determined by context. For example, research regarding political activism in some countries may put subjects in serious jeopardy, while it would not in other countries.

   In many cases, risk to privacy/confidentiality can be eliminated or reduced by careful procedures for ensuring confidentiality. Psychological support and referrals can be built into studies when emotional distress may be an outcome. The referrals can be made via an information card or debriefing sheet provided to the subject by the study team. Consent forms that describe the kinds of questions the researcher will ask allow participants to choose whether they wish to divulge certain types of information or participate in the study at all.

   **Benefits**
   Direct benefits for individual subjects may be present in studies offering interventions for behavioral, psychological, or physical problems. However, most social and behavioral research provides no direct benefit to subjects. Where the benefit is indirect, the potential risks and harms must be carefully evaluated. When there is no direct benefit to subjects, they must be told what the researcher is trying to learn and why. Compensation to subjects is not considered a benefit in the risk/benefit analysis, nor
is the fact that participants may find volunteering for research to be interesting, educational or rewarding.

3. **Selection of subjects is equitable**
   When evaluating the criteria used to select participants, the IRB focuses on whether a specific population is unfairly targeted or avoided. Fulfilling the goal of equitable selection does not preclude using demographic and other characteristics to justify differential selection of participants for legitimate research purposes.

   The IRB applies special care in protecting individuals who may not be able to exercise their decision making capacity due to personal circumstances or environmental constraints. Examples of populations that might be considered vulnerable include prisoners, children, non-English speaking individuals, and people who are socially or economically disadvantaged. The IRB also applies special care when reviewing research that involves student-teacher and employee-employer relationships.

   As part of evaluating the equitable selection of subjects, the IRB carefully reviews plans for participant recruitment and compensation.

4. **Informed consent will be sought**
   Informed consent is the process of telling potential subjects about the key elements of a research study and what their participation will involve. The human 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. (See the Code of Federal Regulations: [http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm)). See Chapter 5 for a discussion of the informed consent document and the required elements of informed consent.

   In addition to the consent document, the IRB reviews the consenting process to ensure that a potential subject’s decision to participate is voluntary and not subject to coercion or undue influence. For example, a consent process may be judged coercive when participants are subject to the formal or informal authority of others (e.g., prisoners, students, employees, or patients), when there are communication issues (e.g., non-English speaking individuals or low literacy rates among subjects), when there are capacity issues (individuals with mental illnesses), and when it is reasonable to believe that the incentives offered reduce the individual’s capacity to make a reasoned, voluntary participation decision.

5. **Informed consent will appropriately documented, or, if requested, that the research meets the requirements for any waivers or alterations**
   Federal regulations require that informed consent be documented by the use of a written consent form approved by the IRB and signed by the participant. The IRB can waive this requirement in certain circumstances.

   • **Waiver of Documentation of Informed Consent**
     The IRB can waive the requirement for signed consent, referred to as documentation of informed consent, under two circumstances: 1) when the only link between a participant and the research is the consent form and the principal risk is potential harm resulting from a breach of confidentiality; or 2) the research presents not more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context.
The first waiver is often recommended by the IRB for sensitive projects where simply linking a participant to a research study might place a participant at risk (e.g., a study of domestic violence). The second waiver is routinely given for telephone or Internet surveys. The investigator is still obligated to offer the elements of informed consent to participants when a waiver of documentation is granted for either reason. This can be accomplished via an oral script or a written consent document.

• **Waiver of Informed Consent**
  The IRB can also grant a waiver of elements of informed consent, or the entire informed consent process, in certain situations where the consent process might be culturally inappropriate, not possible given the nature of the research (impracticable), or where a full consent process might have an negative impact on the outcome of the research (deception studies). Where a waiver of informed consent is granted, the IRB must find that: 1) the research involves no more than minimal risk to the subjects; 2) the waiver or alteration will not adversely affect the rights and welfare of the subjects; 3) the research could not be practically be carried out without the waiver or alteration; 4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation (such as debriefing document).

6. **The research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects**
   The evaluation of this criterion is common in biomedical research, but rarely applies in social research except when direct interactions with subjects may produce harm.

7. **Protection of subject privacy and data confidentiality**
   The protection of privacy and confidentiality are important issues in the protection of human research subjects. Protection of subject privacy and confidentiality are extensions of the principles of autonomy (respect for persons) and beneficence from the Belmont Report. Privacy and confidentiality are different concepts.
   • **Privacy** is personal and can be defined in terms of having control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others.
   • **Confidentiality** relates to data and pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others in ways that are inconsistent with the understanding of the original disclosure without permission.

The investigator must describe plans to protect the subject's identity as well as the confidentiality of the research records and should include this information in the informed consent document. Care should be taken to explain the mechanisms that have been devised to protect the privacy of the subjects, for example, the use of numbers or codes as opposed to their name to protect their identity as well as the encryption of electronic data. Furthermore, the investigator should describe who has access to the data and under what circumstances a code may be broken in order to reidentify a subject. Subjects should be informed of whether the data collected will be retained, and if so, for what purpose, what period of time, or whether and when data will be de-identified and destroyed. Special care must be taken with video or audio taped data and photographs since these media may provide additional potential means for subject identification.

For projects that involve the collection of sensitive data, the IRB may recommend that the investigator obtain a Certificate of Confidentiality (CoC) from the National Institutes of Health. A CoC protects the
investigator from being compelled to disclose data that could be used to identify a participant with a research project. Data are considered to be sensitive if disclosing the information could have adverse consequences for participants, such as posing civil or criminal liability or be damaging to their financial standing, employability, insurability or reputation. Examples of studies that might be considered sensitive include those collecting genetic information, information on illegal behaviors (such as substance abuse), or information on sexual behaviors or sexually transmitted diseases. The NIH may grant a CoC for any sensitive project, regardless of whether the project receives NIH funding. For more information, see the NIH Certificate of Confidentiality Kiosk http://grants.nih.gov/grants/policy/coc/. See also the UM Human Research Protection Program procedures for submitting a CoC application (http://www.hrpp.umich.edu/Documents/certificates.html).

It should be noted that CoC protects only against compelled disclosure. Appropriate data security measures should be implemented to protect against accidental or intentional breaches of confidentiality.

8. **Protection of Vulnerable Subjects.**
In human subjects research, certain research populations are considered to be vulnerable. People who cannot competently understand the information regarding a study and cannot give true consent, such as individuals with psychiatric, cognitive or developmental disorders, and substance abusers, are considered vulnerable. A vulnerable population may include any group that is subject to undue influence or coercion. For example, an individual may feel compelled to participate in research because it is being conducted or supported by a teacher or employer. Research that specifically targets a vulnerable population will receive a higher level of scrutiny than projects that do not involve vulnerable populations.

While any individual who fits the above category can be considered vulnerable, federal regulations offer additional protections to three groups of people:

- **Pregnant women, fetuses, and neonates** are considered vulnerable because they may be at a greater risk than others due to their physical status. Special regulatory protections, however, are geared toward medical research rather than social/behavioral research. (http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#subpartb)
- **Prisoners** are considered to be vulnerable in that their incarceration which could affect their ability to make a truly voluntary and uncoerced decision on whether or not to participate as subjects in research (http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#subpartc). Research projects involving prisoners as research subjects typically require review by the full IRB. The IRB-HSBS will not approve undergraduate research projects that involve research with prisoners.
- **Children** are considered vulnerable because they may not be able to completely understand the information presented about a study. (http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#subpartd)
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) uncanulated 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). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b) [4]. This listing refers only to research that is not exempt.)

(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. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b) (2) and (b) (3). This listing refers only to research that is not exempt.)

(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 VII – Useful Resources

University of Michigan

IRB Health Science and Behavioral Sciences (IRB-HSBS)  
http://www.irb.umich.edu

eResearch (Regulatory Management and Proposal Management)  
http://www.eresearch.umich.edu/

IRBMED  
http://www.med.umich.edu/irbmed/

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

Office of Human Research Compliance Review  
http://www.ohrcr.umich.edu/

PEERRS  
http://my.research.umich.edu/peerrs/

Information Technology Security Services (ITSS)  
http://www.safecomputing.umich.edu/

Division of Research Development and Administration  
http://www.drda.umich.edu/

UM International Center  
http://www.internationalcenter.umich.edu/

UM Office of General Counsel  
http://www.ogc.umich.edu/

Federal


Centers for Disease Control and Prevention (CDC)  http://www.cdc.gov

• Human Participant Protection in CDC Research  http://www.cdc.gov/od/science/regs/hrpp/


Office of Civil Rights (HIPAA policy)  http://www.hhs.gov/ocr/privacy/index.html

Office of Human Research Protection (OHRP)  http://www.hhs.gov/ohrp/

• Regulations  http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm

• Decision Charts  http://www.hhs.gov/ohrp/policy/index.html#decision

• Guidance and Policy  http://www.hhs.gov/ohrp/policy/

• FAQs  http://www.hhs.gov/ohrp/faq.html

• International Research Policies  http://www.hhs.gov/ohrp/international/index.html#NatlPol

U.S. Food and Drug Administration (FDA)  http://www.fda.gov/


• Human Subjects Research  http://www.ed.gov/about/offices/list/ocfo/humansub.html

• Family Policy and Compliance Office (FERPA and PPRA)  
National Science Foundation [http://www.nsf.gov]


**Discipline-Specific Resources**

- American Anthropological Association (AAA) [http://www.aaanet.org]
- American Educational Research Association (AERA) [http://www.aera.org]
- American Psychological Association (APA) [http://www.apa.org]
- American Public Health Association (APHA) [http://www.apha.org]
- American Sociologic Association (ASA) [http://www.asanet.org]
- National Association of Social Workers [http://www.naswd.org/code.htm]