

Instructions for Completing the APPLICATION FOR INITIAL REVIEW Of a Project Involving Human Subjects

Michigan State University's Institutional Review Boards (IRBs)

IRB Contact Information

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Although the primary obligation of the MSU IRBs is to protect the rights and welfare of human subjects of research, it is also concerned with the timely review of research projects. To facilitate the review of a project, the investigator should adhere to the following guidelines:

- **Completely answer all questions.**
- **Submit all necessary attachments to irb@msu.edu.** At the time you submit your IRB application through the online system, please provide all necessary attachments (any instruments/measures, consent forms, advertisements, the "Methods" section of your research proposal, an investigators' brochure for drug or device studies, etc.) See *Table 3*.
- **Consent templates** for biomedical or social science research are available to assist researchers in developing the consent document. The templates are available at http://www.humanresearch.msu.edu/form_instructions.html
- **Make sure that all investigators listed on the application have up to date training.** All individuals involved in a human subject research project who have contact with human subjects or their identifiable data must have current human research protection training. *MSU Human Research Protection Manual, Section 11-1-A, Education: Investigators and Research Staff*. This includes investigators, co-investigators, study coordinators and research staff, even if the individuals are not listed on the IRB application.
- **Review the "Human Research Protection Manual"** available at <http://www.humanresearch.msu.edu/> for additional information on the initial review process and what is required after approval.
- **Promptly submit the signed signature page.** After your application has been fully entered into the online application, a signature page will need to be printed, signed, and returned to the MSU IRB office. Faxed copies are acceptable.
- **Do not assume** reviewers are familiar with previously approved projects, other investigators' work or instruments you will be using.
- Please **refer to the IRB number** when making inquiries and on any correspondence. This number will be sent to you via email once your application is processed.
- **Contact the MSU IRB staff with any questions.**

Instructions by Question Number

The following instructions and definitions are provided to help you complete each item on the application.

1. **Project Investigator Information.** Complete **A**. Complete **B** and **C** if there are co-investigators for the project.

Identification Numbers. Certain types of identification numbers are requested for the differing academic ranks. Providing the appropriate identification number is necessary to be entered into the MSU IRB Online System. The following table lists the appropriate types of identification number that should be provided for a given academic rank:

Academic Rank	Identification number
Faculty, staff specialist, other MSU non-students	ZPID (Faculty/Staff Identification Number)
Students (including graduate students and residents)	APID (Student Identification Number)
Non-MSU affiliate	Contact the IRB for a G-PID

A. Responsible Project Investigator. Enter ID#

Responsible Investigator Requirements. “Only certain persons may be designated as the Responsible Project Investigator. These include MSU regular faculty, emeritus faculty and fixed term faculty employees with rank of assistant professor or higher. Students, staff and individuals holding other appointment titles, such as research associate, specialist, post-doctoral fellow, visiting, adjunct or clinical faculty, may be designated on the MSU IRB applications as an additional investigator, but not as the Responsible Project Investigator. In the case of graduate student research for theses or dissertations, the student’s major advisor should be designated on the MSU IRB applications as the Responsible Project Investigator and the graduate student as an additional investigator.” *Section 4-9, “Responsible Project Investigator”, MSU HRP Manual.*

B. Secondary Investigator. If there is a secondary investigator, enter ID#.

C. Additional Investigator(s). Additional investigator(s) should be listed in this section. If there are more investigators than the space provided, please attach a document that lists the additional investigator(s) names and appropriate identification numbers.

Correspondence

- Please note that unless otherwise requested, correspondence regarding the project is sent only to the Responsible Investigator, the secondary investigator and the study coordinator, if there is one. The addresses provided by the investigators will be the addresses to which the approval letter will be sent.
- For a more timely review, email is used to notify you of reviewer comments. Please provide the email address to which you would like the notification sent.

2. Study Coordinator. If there is a study coordinator (other than the responsible investigator or secondary investigator) that you would like correspondence such as notification of reviewer comment(s) or approval letter(s) sent to, enter ID#. This question may be left blank.

3. Title of Project. List your project title, even if you believe it may change later.

4. Preliminary Approval. If the project you are submitting has received preliminary approval, answer “yes” and complete **A.**

A. Preliminary IRB Number. List the IRB number assigned at the time of the preliminary approval. This will prevent your project from being assigned more than one IRB number.

5. Category of Review. After consulting Tables 1 and 2, select the appropriate review category and then specify the appropriate sub-category.

Levels of Review. There are three levels of review:

- Exempt review
- Expedited review
- Full review

Sub-Categories of Review. Within the Exempt review and Expedited review categories are sub-categories. Consult Tables 1 and 2 to select the appropriate sub-category for your project.

Reviewers. For initial review of your project, the reviewers assigned are based on the review category. In most cases, projects in the exempt review category are reviewed by the IRB staff or the IRB chair, as appropriate. Projects in the expedited review category are assigned two IRB member reviewers and projects in the full board review category are assigned four IRB member primary reviewers. Full board review requires review by the convened IRB.

Use of Prisoners. All research involving prisoners will be classified as full board review.

Change in review category. It is important for investigators to guide the IRB by categorizing their own research project. However, if a reviewer or the IRB chair determines that the project is not eligible for the category selected, the category will be changed, the investigator will be notified, and the application will be reviewed in the category designated by the reviewer.

6. **Education/Training Program Requirements.** Please select appropriate option.

7. **Resources.** If your project is externally funded, please attach the grant application.

A. *Funding Source(s).* Select appropriate option. If project is funded, complete 1.

1. List the funding agency (grants received or pending).

2. Complete 2 if project is externally funded.

B. *Resources.* This question must be answered. In answering the question, investigators should consider, when appropriate, the following types of resources:

- staffing and personnel, in terms of availability, number, expertise, and experience
- process to ensure that all persons assisting with the research are adequately informed about the protocol and their research related duties
- time to conduct and complete the research
- access to a population that will allow recruitment of necessary number of participants
- psychological, social or medical services, including counseling or social support services that may be required because of research participation
- psychological, social or medical monitoring
- ancillary care
- equipment needed to protect participants
- resources for participant communication, such as language translation services
- reliance on entities within MSU but not under control of investigator and where protection of participants requires those entities be prepared for involvement (e.g., student pool, counseling, educational or social services, nursing unit, pathology lab, pharmacy, billing unit, radiology clinic)

8. **Research Site.**

A. List all sites where the research project will be conducted. Please be as specific as possible. For example, if you know the name(s) of the hospital, elementary school, clinic, etc. that you will be conducting research at, please provide. If you are sending surveys, questionnaires, etc., please specify the area (i.e. campus, state, hospital, school, etc.) and list specific name (i.e. Ingham county, Michigan, etc.), if known. If you are collecting data via the Internet, list the location as Internet.

B. Indicate if any of the sites listed in 8A have their own IRB.

9. **Project History.** If there are related projects that have been previously submitted or approved by an MSU IRB, answer “yes” and complete A.

- A. Related Project(s) IRB Number(s).** List the IRB number(s) of those related projects. In some instances, this may facilitate the review. However, please do not assume that reviewers are familiar with your previous work.

Additional Phase(s). If this is an additional phase to an already approved project, please consult MSU IRB staff, as it may be possible to submit the additional phase as a revision rather than a new application.

10. **IRB Submission.** If this project has been or will be submitted to a non-MSU IRB(s) answer “yes” and complete **A-C**.

- A. Name of Institution.** List the name of the institution(s) to which this project has been submitted for IRB review.
- B. Category of Review.** List the review category (exempt, expedited, full review) of the project at the above listed institution(s).
- C. Status of Review.** Please indicate if the review at the other Institution(s) is pending, approved or not approved. If the project was approved at another institution(s), please submit a copy of the approval letter.

11. **IRB of Record.** The IRB of Record is the IRB that assumes the primary responsibility for review and approval of the project. If **another institution(s)** is relying on an MSU IRB as the IRB of record, answer “yes” and complete **A**.

- A. Name of Institution.** List the institution(s) that is relying on an MSU IRB review.

12. **FDA.** If a FDA approved drug/device/diagnostic test will be used, answer “yes” and enclose a copy of the package insert.

13. **FDA.** If you will be using a FDA approved drug/device/diagnostic test for a non-FDA approved indication, answer “yes”.

14. **FDA.** If the protocol has been submitted to the FDA or there are plans to submit the protocol to the FDA, answer “yes” and complete **A - D**.

- A. Investigation New Drug (IND) or Investigational Device Exemption (IDE) Number.** If there is an IND# or IDE#, answer “yes” and 1) indicate the name of the institution, organization or individual submitting the IND or IDE and 2) list the IND# or IDE#.
- B. Phase.** Is the project Phase I, II, III or IV? Select appropriate phase.
- C. Storage and Control of the Drug/Device.** Describe your procedures and plan for the storage and control of the drug/device. Be sure to describe how and where the drug/device will be stored. See Section 7-1, “Research Involving Investigational Drugs and Devices” and Section 12-2, “Storage and Handling of Investigational Drugs and Devices”, HRP Manual for guidance.

15. **Materials of Human Origin.** If this project will involve the use of materials of human origin (i.e. blood or tissue of human origin, etc.) answer “yes” and complete **A**.

- A. Specify.** Describe what you are collecting and why.

Federal regulation and University policy requirements

- Federal regulations and University policy require review of projects using not only live humans but also those using blood or tissue of human origin, whether or not the investigator has any contact with the donor(s).

- When Investigators are using human blood or tissue obtained from sources other than the donor, the project may fall into category 1-4 or 2-5 (see Tables 1 & 2).
- Any person that will be working with human blood or other human derived potentially infectious bodily fluid, unfixed tissue/organs, cell or tissue cultures, organ cultures, culture medium or other solutions that may contain blood borne pathogens must be included in MSU's Blood borne Pathogen Exposure Control Program. For more information contact the Biosafety Industrial Hygienist at ORCBS at 432-8044.

16. Research Category. Check **all** categories listed that apply to your research project.

Internet-based research. Internet based research can be defined as the use of the Internet with your project to collect data (e.g. online surveys, questionnaires, etc).

17. Project Description. Provide in lay terms a brief (200 words or less) description of the project including its purpose, hypotheses and general design. This can be identical or similar to the summary required when submitting a grant application to a funding source. Please limit your abstract to the space provided if possible.

18. Procedures. Briefly describe all project activities that involve human subjects, materials of human origin or existing data originally collected from human subjects. This includes methodologies and measures for collecting data and/or methods for analysis of pre-existing data originally collected from human subjects. For both prospective and retrospective research studies, it is important to describe the proposed analyses and include any appropriate descriptions and measure/indicators/variables. Investigators should attach instruments (e.g. surveys, interview questions, questionnaires, etc.) and measures. In your description, distinguish between any procedures already being done for non-research purposes (e.g., already done as part of curriculum, diagnostic purposes) and those being done strictly for research purposes (e.g., would not be done in absence of the research).

Pre-existing data

- If using pre-existing data, please describe your proposed analyses and use of this information.
- Use of pre-existing data may require permission from the data source/agency and/or subject especially if data is of a sensitive nature or if data was collected with subjects' expectation of privacy.
- Feel free to contact the MSU IRB staff if you have questions or need further clarification.

19. Incomplete Disclosure/Deception. Investigators may sometimes design a project in such a way that subjects do not initially know the actual intent of the research. In all cases of research involving incomplete disclosure and/or deception, the research is justified only if 1) incomplete disclosure/deception is truly necessary to accomplish the goals of research; 2) there are no undisclosed risks to subjects that are more than minimal, and 3) there is an adequate plan for debriefing subjects, when appropriate, and for dissemination of research results to them. Please note that Information about risks should never be withheld for the purpose of eliciting the cooperation of subjects, and truthful answers should always be given to direct questions about the research. Care should be taken to distinguish cases in which disclosure would destroy or invalidate the research from cases in which disclosure would simply inconvenience the investigator.

If there will be any incomplete disclosure/deception, answer "yes" and complete **A-C**.

- A. Necessity.** Explain why the incomplete disclosure/deception is truly necessary to accomplish the goals of the research.
- B. Undisclosed Risk(s).** If any of the undisclosed risks to subjects are more than minimal, answer "yes".

- C. *Debriefing Procedure.* Whenever possible, subjects must be debriefed when their participation is complete. These debriefing procedures, including any script or written statement that will be used, must be submitted and reviewed by the IRB before a project may be approved. Describe the debriefing procedure. Please attach a copy of the debriefing script that explains to the subjects 1) the incomplete disclosure/deception and 2) the true purpose of the research study.

20. **Subject Population.** Whenever possible, the choice of research subjects should be equitable and should come from various income and ethnic groups.

A. *Description.* Briefly describe the subject population.

B. *Age Range.* Indicate the estimated age range of subjects. It is important to consider and indicate whether children will be involved in your project. This may affect research procedures and consent forms and processes.

C. *Special Populations.*

1. Check all appropriate populations that will be either your target population or will be included incidentally.

Target Population can be defined as a particular group of subjects that a researcher is interested in or focusing on. Incidental Inclusion can be defined as subjects that may be included in your study by chance or without intention (i.e. subjects that may be included as a result of a random sample).

Special Categories of Human Subjects and Vulnerable Populations

- Certain categories of subjects whether part of a targeted population or included incidentally (e.g. as part of a random sample) may be provided special protections under the federal regulations.
- If the research can only be conducted using these vulnerable classes of subjects, MSU IRBs will review the project with particular attention to risks, benefits and consent procedures. Please refer to the Human Research Protection Manual (HRP) for more detailed information and/or contact the MSU IRB staff for further clarification.

2. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards must be included in the study to protect the rights and welfare of these subjects. If your research will likely involve subjects who are likely to be vulnerable to coercion or undue influence, answer “yes” and describe the additional safeguards included in the study to protect the rights and welfare of the subjects.

D. *Sample Size.* The sample size is the total number of human subjects to be included in your research, including controls. If using pre-existing data, indicate the number of cases. Approximations are acceptable.

E. *Sample Size.* Every discipline has established guidelines for the number of research subjects appropriate for the research design, whether it is an oral history, focus group, clinical trial or a survey involving thousands of subjects. In some cases, there are qualitative guidelines and in some cases sample size can be statistically determined (power analysis). How did you arrive at the sample size indicated in 20c? Justify the number given. For example, if you are doing one interview, is this an acceptable number based on your field of study?

F. Inclusion Criteria. Inclusion criteria are criteria that would make potential subjects eligible to participate or be included in your study (e.g., being over 18). Please list the criteria that will be used for the inclusion of subjects.

G. Exclusion Criteria. Exclusion criteria are criteria that will eliminate or exclude potential subjects from participating in your study (e.g., being under 18, contra indicators). Please list the criteria that will be used for the exclusion of subjects.

H. Recruitment of Subjects.

1. Description. Please describe how your subjects will be identified, recruited and enrolled. Who will make initial contact with the subjects?

2. Advertisement. If your project includes an advertisement and/or other information to recruit subjects (e.g. letters, phone scripts, flyers, newspaper ads, e-mails etc.) answer “yes” and complete **a.**

a. Description of Advertisement. Please specify what type of advertisement and/or other information will be used to recruit subjects (e.g., letter, phone script, flyer, etc) and attach. If the advertisement is multi-media (e.g., radio ad, television commercial), submit the multi-media advertisement.

“If investigators would like to use advertisements in their recruitment practices, the advertisements must meet certain requirements. The advertisement should be limited to the following but must contain (1) and (2):

1. The name and address (or phone number) of the investigator or research facility;
2. The study involves research, purpose of the research or condition under study and, in summary form, the eligibility criteria that will be used to admit subjects into the study;
3. Straightforward and truthful description of the benefits to the subject from participation in the study; and
4. The location of the research or research facility and the person to contact for further information.
5. Time or other commitment required of participants

Advertisements may not:

- Include IRB endorsement of research projects either in recruitment materials or consent forms.
- Include exculpatory language
- Emphasize the payment or amount to be paid, by such means as larger or bolder type
- State or imply a certainty of favorable outcome or other benefits beyond what is outlined in the consent document and the protocol
- Promise “free treatment” when intent only to say participants will not be charged for taking part in the investigation” *Section 6-5, “Selection of Subjects”, MSU HRP Manual.*

I. Association with Subjects. If you are associated with the subjects, answer “yes” and complete **1.**

1. Nature of Association. Describe the nature of the association. If there is any potential for coercion or undue influence with subjects (for example, in a teacher-student relationship), please discuss what measures you are taking (if any) to minimize that risk.

J. Recruitment Compensation. If anyone will receive payment and compensation for recruiting subjects, answer “yes” and complete **1.**

1. Recruitment Compensation Details. Provide the details including any conditions of awards/reimbursement/bonuses to the recruiter(s).

“The following types of payments by the sponsor to investigators, research staff, or those referring research participants are prohibited:

- Payments in exchange for referrals of potential participants (i.e. finder's fees)
- Payments designed to accelerate recruitment that are tied to the rate and timing of enrollment (i.e. bonus payments)” *Section 6-5, “Selection of Subjects”, MSU HRP Manual.*

K. Compensation Provided to Subjects. If subjects receive any compensation (e.g., *extra credit provided to student subjects, awards, reimbursement*), answer “yes” and complete **1**.

1. **Subject Compensation.** Provide the details concerning any payment or compensation arrangements to subjects including any conditions of awards/reimbursement. Be sure to address the consequences of withdrawing from a project prior to completion, including under what conditions subjects will receive partial or no compensation. Corresponding information **must** also be in the consent form.

Compensation Limits

- Prizes/awards given to subjects based on chance (e.g. entered into a drawing) should be limited to \$100.00 or less.
- There is no cash limit on awards/reimbursements that **all** participants receive. However, please note that compensation to volunteer subjects should never be so high as to constitute an undue inducement to participate in investigative work, and should generally be limited to nominal amounts, e.g. reimbursement for out-of-pocket expenses and time.

L. Additional Expenses for Subjects. If subjects will incur any additional expenses as a result of their study participation (including insurance co-payments on medical protocols), answer “yes” and complete **1**.

1. **Description of Additional Expenses.** Describe and include an explanation on the consent form.

M. Research in Foreign Countries. If research will be conducted with subjects in another country, answer “yes” and complete **1 and 2**.

1. **Specify Country.** Please indicate which country(s).
2. **Risk and/or Complications.** Discuss if the scope of the proposed research might potentially pose any real or perceived risk to subjects. If research with this group may pose complications, discuss how the proposed research involving this group may pose additional risks, including maintaining confidentiality and assuring informed consent, and what additional measures the investigator is taking to minimize these risks to research participants.

N. Subjects in U.S. Who Are From an Ethnic or Sub-Group or Other Non-Mainstream Minority. Certain populations may be marginalized or otherwise “disadvantaged” from a dominant “Western” society’s point of view. The investigator should decide if their subject population is somehow different from the “mainstream culture”. **If yes**, complete **1and 2**. Please note that as a general rule, research involving non-English speaking populations (both in and outside of the United States) would generally require a “yes” answer to 20n.

1. **Specify Country or Sub-Group.** Please indicate what country(s) or sub-group(s) the subjects will be from.
2. **Risk and/or Complications.** Discuss if the scope of the proposed research might potentially pose any real or perceived risk to subjects. If research with this group may pose complications, discuss how the proposed research involving this group may pose additional

risks, including maintaining confidentiality and assuring informed consent, and what additional measures the investigator is taking to minimize these risks to research participants.

21. **Subject Risks/Benefits.** *Risk* is defined in the HRP Manual as the probability of harm or injury (physical, psychological, social, legal or economic) occurring as a result of participation in a research study. *Benefit* is defined in the HRP Manual as a valued or desired outcome, an advantage.

- A. *Describe and Assess Risks.* Investigators should be aware that conducting research on human subjects might pose inherent risks. Risks to subjects posed by participation in research should be justified by the anticipated benefits to the subjects themselves, to other persons with similar conditions or with similar needs, or at least to society generally. Carefully analyze the risks. The ability to recognize and reduce potential risks to study participants, even “minor risks,” is a crucial concern of MSU IRB reviewers. Please take care to fully address any potential risk(s) and assess the likelihood and seriousness of such risk(s).
- B. *Procedure for Protecting Against or Minimizing Risks.* Describe your procedure for protecting against or minimizing risks. Include an assessment of the likely effectiveness.
- C. *Benefits.* Assess any potential benefit(s), if any to be gained by the subjects in the study and any benefits that may accrue society in general as a result of the planned work.

22. Subject Privacy.

- A. *Privacy.* Explain how the subjects' privacy will be protected. **Privacy** means having control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others. **Anonymity** means that no one, including the principal investigator, is able to associate responses or other data with individual subjects. Investigators may promise anonymity only under this condition. Face to face interviews are not considered anonymous.

Question 22B-D address confidentiality. **Confidentiality** means treatment of information that an individual has disclosed in a relationship of trust 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. In your answers, be sure to address both physical data (e.g., completed surveys, tapes of interviews) and the electronic data (e.g., data entered into statistical software).

- B. *Location and Length of Data Storage.* Specify where data will be stored and for how long. Will data be stored in a locked cabinet or on password-protected computers in a locked room?
- C. *Access to Data.* Specify who will have access to the data.
- D. *Integrity and Security of Data.* Explain how will the integrity and security of the stored data will be assured.
- E. *Data and Safety Monitoring.* This question asks whether it is appropriate for your research to have a monitoring plan to periodically assess the data to ensure the safety of subjects or to ensure negative outcomes do not occur (e.g., ongoing study of domestic abuse, clinical trial, full board projects). This question applies to all types of research. In determining whether your research needs a data safety monitoring plan, consider the following questions:
 - What is the risk level of the study (e.g., minimal risk vs. more than minimal risk)?
 - Is it possible that the intervention may have an adverse impact of the subjects? If yes, what is the adverse impact? Is it physical, psychological, social, economic, legal, emotional? What is the magnitude? How likely is it?
 - Does the study involve topics or areas that may cause distress to the subject? Is such distress foreseeable?

- Does the study involve topics that may place subjects at risk by participating in the research (e.g., domestic abuse)?
 - Does the study involve deception or incomplete disclosure? May such deception or incomplete disclosure cause distress to subjects?
 - Is this a longitudinal study? What is the length of the intervention?
 - Is it appropriate to review the data not only for current subjects' safety, but for the safety of future subjects?
 - Is this a clinical trial? If yes, a data and safety monitoring plan is required.
1. If it is appropriate to have a data monitoring plan, describe the plan. When answering, consider questions such as: how frequently should the data be reviewed? Is PI assessment sufficient? Are external boards needed?
 2. Answer "yes" if there will be a data and safety monitoring board or committee. Be sure to describe the composition, membership, and frequency of meetings. Attach a copy of the data safety monitoring plan. See 6-7, "Data and Safety Monitoring", HRP Manual, for a sample template for a plan.

Disposition of Research Data

- The researcher should discuss both on the MSU IRB application and in the consent form the disposition of the collected information.
- For more information see the University Research Council's guidelines on Research Data: Management, Control and Access on the MSU IRB web site (www.humanresearch.msu.edu).

Data Reporting

- In general, data gathered from subjects should be reported by investigators (e.g., articles, conferences etc.) only in the aggregate so that individual subjects may not be identified or associated with the data they provided.
- However, certain research projects by their nature may require reporting of data that is either directly identifiable or indirectly attributable, such as in oral histories. In these cases subjects should be explicitly informed in the consent document as to the limits of confidentiality being offered and how the data is to be reported.

23. HIPAA.

- A. Protected Health Information.** Answer "yes" if information about individuals that comes from a healthcare provider, health plan, or health care clearinghouse will be used for the project. This information (protected health information) is regulated under the HIPAA privacy rule. Answer "yes" if your research team or others will use this information for your project, e.g., staff at a clinic that reviews medical records for recruiting or data abstraction. If you answered "yes" to this question, please complete **B**.

Protected Health Information: Protected health information (PHI) is defined as individually identifiable health information that is transmitted or maintained in any form or medium.

Exclusions include education records covered by the Family Educational Rights and Privacy Act and employment records held by a covered entity in its role as employer. (45 CFR 164.501)

- B. HIPAA Authorization Form or Waiver.** If you answered **yes to B**, please complete items 1-7 below. If you answered **no to B**, please attach an authorization form for review. If you are requesting a waiver of authorization **and** will be using a HIPAA Authorization form, complete 1-7 below **and** attach the authorization form. This may occur if you are requesting a waiver of authorization to recruit potential subjects, but will be obtaining an authorization from subjects when conducting the research. For further information on HIPAA or developing your authorization form, please see the HIPAA information section at the MSU IRB website at www.humanresearch.msu.edu.

1-7. Waiver of Authorization Request. To request a waiver of authorization, you will be asked to provide:

- i) A description of the specific individual health information that is needed
- ii) An explanation why the individual health information is necessary for the research
- iii) An explanation why a waiver (or partial waiver) is needed
- iv) A description of the plan to protect any individual identifiers
- v) A description of the plan to destroy the individual identifiers at the earliest opportunity or reasons why they will be retained
- vi) Written assurance that the individual health information will not be reused or disclosed improperly.
- vii) Describe all planned uses and disclosures.

Waiver of Authorization Review

- Waiver of authorization requests that involve no more than minimal risk to the privacy of the subjects are reviewed under expedited procedures by one designated Research Privacy Board reviewer. Examples of research that may be included in this category are research on existing medical records, research requiring use of medical records for recruitment purposes when the researcher is not the health care provider.
- Waiver of authorization requests that involve more than minimal risk to the privacy of the subjects are reviewed under full Privacy Board procedures. The protocol is reviewed by three of the Research Privacy Board reviewers and presented for approval at a meeting of the full Research Privacy Board. Examples of research that may be included in this category are research on medical records that are active and being updated prospectively, research requiring psychotherapy notes (existing and active records), research on medical records that may include highly sensitive information such as HIV status or DNA analysis.

24. Consent.

- A. Consent Options.** Please check all that apply. A *Consent Form and Process* is the opportunity for subjects to make a fully informed decision whether or not to participate in the research. A *Waiver of Consent* is a request that research be done or data be collected without the knowledge or consent of the subjects.

Complete B if you are requesting an approval of a consent form and process only.

Complete C if you are requesting a waiver of consent only.

Complete B and C if you are requesting both an approval of a consent form and process and a waiver of consent. This may occur if there are multiple parts to your study. For example, an investigator may be examining existing records (waiver of consent requested), but will also be interviewing subjects (obtaining consent) as part of the same study.

- B. (1) Consent Form Description.** Informed consent is a process, not just a form and the consent procedure should be an opportunity for subjects to make a fully informed decision whether or not to participate in the research. Subjects should always have the opportunity to ask questions and express concerns to investigators about their participation in the research. Please describe the consent process, including who will be consenting subjects, who will be informing and educating the subject, as well as how and where informed consent will be obtained. If your research will involve children, please describe the parental permission process and the age appropriate assent process. See Section 6-4-C, "Parental Permission and Child Assent", HRP Manual, for guidance. If your research will involve individuals with diminished capacity, see Section 6-8-D, "Individuals with Diminished Capacity", MSU HRP Manual, for guidance on requirements and legally authorized representatives.

When developing an informed consent process, investigators should consider the following criteria as appropriate:

- the person who will conduct the consent interview
- the person who will provide consent or permission
- any waiting period between informing the prospective participant and obtaining consent
- steps taken to minimize the possibility of coercion or undue influence
- language used by those obtaining consent
- language understood by the prospective participant or legally authorized representative
- information to be communicated to the prospective participant or legally authorized representative

For consent templates for social science or biomedical research, visit

<http://www.humanresearch.msu.edu/forms.html> . Also, see Section 12-4, "Consent Form Guidelines", MSU HRP Manual, for guidance on developing a consent process and form. Please attach the consent document(s).

(2) Signature on the consent document. Will the subject or legally authorized representative sign the consent document? Federal regulations require a signature, unless the IRB determines certain criteria are met. If subjects **will not sign the consent document** (e.g., online survey, telephone interview), **complete a and b.**

(a) Explain why the subjects will not be signing a consent document (e.g., online survey, telephone interview, international research in a culture where it would be inappropriate to have the subjects sign)

(b) Select **either "i" or "ii"**. Read both statements, and select the statement that applies to your research project.

(i) Minimal risk. Explain why the research meets the criteria (i-1) and (i-2).

(ii) Only record linking; principal risk breach of confidentiality. Explain why the research meets the criteria (ii-1) and (ii-2).

C. Waiver of Consent Requirements. Under the following conditions (per 45 CFR 46.116 (d)), an IRB may waive the requirements for consent. Please note that the following conditions may apply, for example, to the use of existing data but all the conditions have to be met for the IRB to grant a waiver. The conditions are:

1. the research involves no more than minimal risk to the subjects; and
2. the waiver or alteration will not adversely affect the rights and welfare of the subjects; and
3. the research could not practicably be carried out without the waiver or alteration; and
4. whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Discuss and provide rationale for **each** condition (1-4).

25. Conflict of Interest:

The following information is from the MSU HRPP Manual, Section 10-1, Conflict of Interest.

Policy

All conflict of interest situations related to the design, review, conduct or reporting of human research protocols that could, or appear to, affect the rights and welfare of human participants must be reported appropriately as soon as they arise. Review of reported conflict situations must consider the associated risk to human participants. This includes conflict of interest situations for all protocols regardless of the funding source, including non-sponsored research, and all Institutional Review Board (IRB) members, IRB staff, investigators, research staff, or consultants serving in any capacity.

MSU faculty must report conflicts of interest according to MSU policies. See Section 14-15 (MSU Faculty Handbook, IV. Academic Human Resources Policies: Conflicts of Interest, Faculty).

Definitions

Conflict of Interest (COI)

Consistent with the MSU Faculty Conflict of Interest Policy, a conflict of interest exists when an individual's financial interests or other opportunities for tangible personal benefit may compromise or appear to compromise the independence of judgment with which the individual performs his/her responsibilities.

An individual's financial interests or other opportunities for tangible benefit must be judged not only by his/her personal holdings, but also on an aggregate basis with members of his/her immediate family (spouse, domestic partner, dependent children, and other dependents that reside with the faculty member) and any legal entity that one or more of them owns or controls.

Significant Financial Interest: Significant financial interests are defined in the Faculty Conflict of Interest Handbook for review under the Faculty Conflict of Interest Policy. The Handbook addresses review of reported financial conflicts involving clinical research in the narrative interpreting Paragraph 5 of the Faculty Conflict of Interest Policy.

A significant financial interest includes, but is not limited to, a financial interest in the sponsor, product, or service being tested, or in a competitor of the sponsor or product or service being tested.

"A financial interest is anything of monetary value, including, for example, payments for services such as consulting fees, salary, honoraria, or commissions; equity interests like stock and stock options; other ownership interests, like being a partner in a partnership or operating an unincorporated business; beneficial interests, *i.e.*, being the beneficiary of a trust or estate; indebtedness, like loans or mortgages; intellectual property rights, like owning a patent or a copyright, or the right to receive royalties or licensing fees from a patent or copyright; and gifts of goods, property, or services, like airline tickets, resort or hotel accommodations, or other recreational or personal amenities.

Service on a corporate board or as a corporate officer, or on the scientific advisory board of a company, is a financial interest in that entity, if the faculty member is paid for the service. But, even unpaid service as a corporate director or officer or as a corporate advisor can be an opportunity for tangible personal benefit that can form the basis for a conflict of interest.

A financial interest can arise from any kind of legal entity - - a corporation or limited liability company; a partnership, limited partnership, or joint venture; a trust or estate; a firm, franchise, "dba", sole proprietorship, unincorporated association, or other business; and so on. A faculty member's financial interests or other opportunities for tangible benefit must be judged not only by his/her personal holdings, but also on an aggregate basis with members of his/her immediate family (spouse, domestic partner, dependent children, and other dependents that reside with the faculty member) and any legal entity that one or more of them owns or controls.

With that as background, the following are deemed to create a "significant financial interest" and must be reported under the Policy:

1. salary, consulting fees, royalties or other payments of any kind from a single entity which exceeded \$10,000 over the last 12 months or which are expected to exceed \$10,000 over the next 12 months, or
2. ownership interests in a single entity which have a fair market value of more than \$10,000 or are more than one percent (1%) of its equity, or
3. intellectual property rights which have a fair market value of over \$10,000 or which generate, or are expected to generate, revenues of over \$10,000 per year, or
4. unvalued stock options or other options for ownership in a privately held company, or
5. paid or unpaid service on a governing or advisory board, or in a fiduciary or managerial role, for, or as a general partner of, an entity, or
6. serving as a trustee for a trust or estate, or having a beneficial interest in a trust or estate, whose value exceeds \$10,000, or
7. indebtedness to or from a single entity exceeding \$10,000, or

8. receipt of gifts of goods, property, or services, like airline tickets, resort or hotel accommodations, or other recreational or personal amenities whose value exceeds \$250 from a single entity.

The following financial interests are excluded from consideration and do not need to be reported under the Policy:

1. salary or other remuneration from the University or paid at the University's behest (including remuneration from a University-approved practice plan),
2. income from seminars, lectures, service on committees or review panels, or other educational activities sponsored by public or not-for-profit entities,
3. any financial interest arising solely by means of investment in a mutual, pension, or other institutional investment fund over whose management and investments neither the faculty member nor any immediate family member of the faculty member exercises control (e.g., TIAA-CREF), and
4. indebtedness from a bank, credit union, or other commercial lender."

In addition, the IRB requires the following situations be reported on the IRB initial application:

1. Ownership interest, stock options, or other ownership interest related to the research where there is an arrangement entered into where the value of the ownership interests would be affected by the outcome of the research
2. Compensation related to the research where there is an arrangement entered into where the amount of compensation would be affected by the outcome of the research

Investigator and Research Staff COI

Investigators are required to report Conflicts of Interest on the application for initial IRB review and approval. If the investigator is also an MSU faculty or academic staff, he/she is required to report the Conflict of Interest according to MSU Faculty Conflict of Interest Policy (see Faculty Handbook, Section IV). The investigator must disclose when investigators or research staff or an immediate family member of the investigators or research staff have a significant financial interest related to the research. The investigator must disclose whether any person responsible for the design, conduct or reporting of findings of the protocols receives has a significant financial interest or other opportunity for tangible personal benefit related to the conduct of the research that might compromise, or reasonably appear to compromise, the independence of judgment with which their responsibilities would be completed under this research protocol. If they answer "yes", the investigator must (1) describe the details of the conflict situation, (2) attach a report of the financial interest using the Model College Procedure (3) include a statement in the informed consent form that discloses the nature of the conflict of interest, or (4) state why such a statement in the informed consent is not necessary for the protection of human subjects. The investigator must disclose whether any financial arrangement, including compensation, ownership interest, stock options, or other ownership interest, has been established whereby the value of the compensation or ownership interests to investigators conducting the study is influenced by the outcome of the study. If they answer "yes" the investigator must (1) explain the details, (2) include a statement in the informed consent form that discloses the nature of the conflict of interest, or (3) state why such a statement in the informed consent is not necessary for the protection of human subjects. The investigator must disclose if this is a clinical study where the results may be used to support marketing applications for new human drugs and biological products and marketing applications and reclassification petitions for medical devices to the FDA as requirement by law.

If a COI develops after IRB approval, the investigator should promptly report the conflict of interest as required by the Faculty Conflict of Interest Policy and notify the IRB Administrator and/or IRB chair, submit the change as an amendment (revision) to the approved protocol and include a revised consent form including a statement addressing any potential conflict of interest. Additional requirements as specified in the MSU Faculty COI Policy and Faculty COI Handbook should be followed by MSU faculty and academic staff.

26. Timeline.

- A. *Scheduled to Begin.* Provide the estimated date in numerical form (MM/DD/YY) that data collection is scheduled to begin. Note that the actual date is dependent on IRB approval and

you may not begin data collection from human subjects or data analysis before obtaining MSU IRB approval.

- B.** *Estimated Duration of Project.* Provide the estimated date in numerical form (MM/DD/YY) that the project is to last.

Table 1 – Exempt Review Categories

A project is identified as **exempt review** if the project involves no more than minimal risk **and** only involves human subjects (or materials of human origin) in one or more of the following categories:

EXEMPT Review	
Category	Description of Human Subject Research Activities
1-1	Research conducted in established or commonly accepted educational settings, involving normal educational practices such as: 1) research on regular and special education instructional strategies or 2) research on the effectiveness of or the comparison among instructional techniques, curricula or classroom management methods.
1-2	Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior UNLESS: <ol style="list-style-type: none"> a. The information taken from these sources is recorded in such a manner that subjects can be identified, directly or through identifiers linked to the subjects; and b. Any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. <i>(Also see Expedited category 2-7.)</i>¹
1-3	Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior IF the human subjects are elected or appointed public officials or candidates for public office.
1-4	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. <i>(Also see Expedited Category 2-5)</i>
1-5	Research and demonstration projects which are conducted by or subject to the approval of the Department of Health and Human Services and which are designed to study, evaluate or otherwise examine: 1) public benefit or service programs; 2) procedures for obtaining benefits or services under those programs; 3) possible changes in or alternatives to those programs or procedures; or 4) possible changes in methods or levels of payment for benefits or services under those programs.
1-6	Taste and good quality evaluations and consumer acceptance studies , if wholesome foods without additives are consumed or 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 FDA or approved by the EPA/USDA.

¹ Category 1-2 **cannot** be used for research involving children, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

Children are defined in the HHS regulations as "persons who have not yet attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted."

Categories 1-1 through 1-6 **cannot** be used for classified research or research involving prisoners.

Categories 1-1 through 1-5 **cannot** be used for research to which FDA regulations and policies apply.

Table 2 - Expedited Review Categories

A project is eligible for **expedited review** if it involves:

1. no more than minimal risk (*Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests) **and**
2. only involves subjects (or materials of human origin) in one or more of the following categories:

Expedited Review	
Category	Description of Human Subject Research Activities
2-1	Clinical studies of drugs and medical devices only when (a) research on drugs for which an investigational new drug application is not required. Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review. Or (b) research on medical devices for which (i) an investigational device exemption application 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.
2-2	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 ¹ , 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.
2-3	Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.
2-4	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 indication.) 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 subjects privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging (MRI); (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

Expedited Review	
Category	Description of Human Subject Research Activities
	health of the individual.
2-5	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). <i>(Also see Exempt Review category 1-4)</i>
2-6	Collection of data from voice, video, digital, or image recordings made for research purposes.
2-7	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. <i>(Also see Exempt Review category 1-2)</i>
2-8	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.
2-9	Continuing review of research , not conducted under an investigational new drug application or investigational device exemption where categories 2-2 through 2-8 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.

¹ Children are defined in the HHS regulations as "persons who have not yet attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted."

Categories 2-1 through 2-9 cannot be used for classified research or research involving prisoners.

For research in Expedited category

- The expedited review procedure may not be used 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

Table 3 – Checklist for Attachments

Please take a moment and go through the following checklist. **Please note that not all items listed below will be applicable to your project.**

Required

- Completed application
- Signature page. **** Must** be sent to MSU IRB office**
- Instruments or measures (e.g. surveys, interview questions, questionnaires, etc)
- Consent form or script for verbal consent (unless requesting waiver of consent)

If Applicable

- HIPPA Authorization form
- Document entitled "Waiver of authorization"
- Assent form
- Debriefing form
- Translations of instruments and consents provided to non-English speaking subjects
- Recruitment materials (including advertisements)
- Investigator brochure
- Protocol
- Permission by school administration to allow researchers to conduct research in individual schools
- If submitted to other IRB(s), that institution(s) approval letter
- Contract or grant application for externally funded projects
- Package insert If using FDA approved drug/device/diagnostic test
- FDA form 3454 or 3455
- Methods chapter of research proposal (if available)
- DHHS-approved sample informed consent and complete DHHS approved protocol (for DHHS sponsored multi-center clinical trials)
- Any other pertinent documents related to the proposed study