University and federal policies and procedures require that all research involving human subjects receive prior approval from the appropriate board. Application material is available at: http://www.humanresearch.msu.edu/

HUMAN SUBJECTS

Does the thesis or dissertation you are submitting include research involving human subjects?

No _____________ Yes _____________

If yes, indicate IRB number for the approved protocol and attach the IRB Approval Letter for that protocol to this form.

IRB Number: ______________________________

_________________________  __________________________
Signature of Student        Date                  Signature of Adviser  Date

_________________________
Print Name of Student     Print Name of Adviser
CONTACT INFORMATION
University Committee on Research Involving Human Subjects (IRB)
Michigan State University,
207 Olds Hall
East Lansing, MI 48824
Phone: (517) 355-2180; Fax: (517) 432-4503; E-mail: irb@msu.edu
Website: http://www.humanresearch.msu.edu/ or http://www.humanresearch.msu.edu/sirb.html
Hours: Monday - Friday, 8 a.m. - 5 p.m.

Why IRB?
“IRB is an Institutional Review Board (IRB). Federal and University regulations require that all research projects involving human subjects and materials of human origin be reviewed and approved by an IRB before initiation. Under the regulations, research is defined as a formal investigation designed to develop or contribute to generalizable knowledge. A human subject of research is an individual from whom an investigator obtains data by interaction or intervention or about whom the researcher obtains confidential information.” (From the IRB Instructions, p.1)

Both Anthropology and the Graduate School at MSU require IRB compliance. Both require forms indicating whether human subjects approval was necessary, and if so, whether it was secured prior to the initiation of research.

Contracts and Grants will not release funds without IRB approval. Neither will some funding agencies (that information will be in their literature. IRB does not keep a list.)

Please note the exemption for student research in courses (more information at the web site).

IRB does not review the scientific merit of a project. IRB does review the human subjects protocols, including protection provisions, risks/benefits to the subject population, and methodology as it applies to the subject population.

HOW IT WORKS
There are three categories of review, “exempt from full review,” “expedited review,” and “full review.” Applications in the first two categories are sent to a sub-committee, and once the sub-committee approves, the application is approved. Full review proposals are also initially sent to a sub-committee. After the sub-committee approves, it is brought to the attention of the entire committee at the monthly meeting for full IRB approval.

At any time during the review process, reviewers are allowed to raise questions, which must be answered in writing by the project investigators.

Approval is for one calendar year, and data collection beyond that date must receive renewed approval.

All revisions to the human subjects portion of a project must be approved prior to implementation.

TIPS
Think through your research in terms of human subjects guidelines before you finish your research proposal. Keep questions 12, 14, and 15 from the application in mind. Use the human subjects review process as an aid, not an obstacle.

Think through your informed consent language and informed consent form (question 16). Use the guidelines in the IRB application instructions and “tips” handout. Additional information on informed consent can be found at: http://ohrp.osophs.dhhs.gov/humansubjects/guidance/ictips.htm.

Fill out the application completely and provide appropriate supporting documentation (e.g. consent form). Keep your answers limited to the space guidelines. Appropriate contact information is vital, and include multiple ways of contacting you, if possible. (Indicate if co-investigators should receive comments, letters, etc.)

Turn in your application in person and introduce yourself to the committee staff.
Allow yourself adequate time for the review process.
Do not begin until you have your approval letter!
Always feel free to contact the IRB office.
Required Informed Consent Elements
By recommendation of the Office for Protection from Research Risk

This list is NOT exhaustive of required elements of consent, but highlights elements of the consent process that have been recently reinterpreted by the federal government or are of special concern to IRB reviewers.

1. Informed consent is a process, not just a form. Information must be presented to enable persons to decide voluntarily whether or not to participate as a research subject. It is a fundamental mechanism to ensure respect for persons who may be willing to offer their bodies and experiences to assist investigators in research without promise of benefit. The procedures used in obtaining informed consent should be designed to educate the subject population in terms that they can understand. Therefore, informed consent language and its documentation must be written in “lay language”, (i.e. understandable to the people being asked to participate). Think of the document primarily as a teaching tool not as a legal instrument.

   Simple declarative sentences are most appropriate for explaining the study’s purpose, duration, experimental procedures, alternative treatments (if applicable), risks, and benefits. Use of the first person (e.g., “I understand that...”) or statements starting with “You understand that” are not recommended because they could be interpreted as suggestive and can constitute coercive influence over a subject. Use of scientific jargon and legalese is not appropriate. The only “I” statement necessary is one above the signature line declaring that participants understand the procedures and voluntarily participate.

2. Statements concerning confidentiality should include language equivalent to the following: “Your privacy will be protected to the maximum extent allowable by law.” Since there are situations in which a researcher may be compelled to break the confidentiality of subjects (e.g. in response to a subpoena), absolute guarantees are not possible.

3. All consent forms should have the researcher’s contact information, in the event that participants want to discuss any questions about the research or research related injuries. IN ADDITION, the form should contain contact information for the IRB separate from the Principle Investigator for participants with questions about their role as a subject of research. Please include David Wright as that contact:

   If you have questions or concerns about your role and rights as a research participant, would like to obtain information or offer input, or would like to register a complaint about this study, you may contact, anonymously if you wish, the Michigan State University's Human Research Protection Program at 517-355-2180, Fax 517-432-4503, or e-mail irb@msu.edu or regular mail at 207 Olds Hall, MSU, East Lansing, MI 48824.

   The IRB Interim Director is Kristen Burt 517-884-6020
   The Chair of the SIRB (Social Sciences IRB) is Harry McGee, MPH (Chair), mcgeeh@msu.edu

   Office Of: Regulatory Affairs

   The Chair of the BIRB (Biomedical IRB) is Ashir Kumar, MD Kumar, Ashir B 140E LIFE SCIENCE EAST LANSING MI 48824-1317 US, 517-353-3529 kumara@msu.edu

   Office: Regulatory Affairs, Office Of

   For further information regarding consent language and necessary elements of consent, check out the NIH website: http://www.nih.gov/