Michigan Technological University

Office of Compliance,
Integrity, and Safety

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Human Subject Research Forms Checklist

For related links and information pages, visit us online at:
http://www.mtu.edu/research/administration/integrity-compliance/review-boards/

Friendly REMINDER: Submit your application package to allow for ample review time with a minimum of two weeks prior to your start date; see our web site for posted internal submission deadlines when your study requires full board review.

The following list will inform you of what document(s), [template(s) from the above web site], or [form(s) from the IRBNet library] you need to prepare to complete your package. To avoid a delay in the review process, please submit all required forms at the time of initial submission or your package may be returned, not reviewed.

Which form(s) should you submit for research involving human subjects?

Exemption Request Form
You must submit the Request for Exemption Form through IRBNet
*If your study involves survey or evaluation procedures, you may submit a "Request for Exemption Form". This form is located on our web site (listed above) in the resources box on the right side of the page **or** also found in the IRBNet library.*

Exemption does not mean that you do not need to submit a study for review; our office requests information about your study to have on file for informational purposes.

New Project Application Coversheet (required IRBNet wizard document for each submission)
After registering with IRBNet, you are required to complete this IRBNet document wizard when assembling a NEW study package. It is found in Designer in IRBNet by clicking on "Add New Document". This will automatically upload to your package when you have completed the form.

This form must be completed and attached to your package with the initial request for review of your study or your request will be returned, unprocessed.

Required Elements Guide (guidance for preparing documents for your package)
This guide helps you to prepare the required elements to be submitted for a smooth IRB review. This form is found in the IRBNet library or on our web site and will aid you in providing more complete information to the committee for approval determination.

Request for Waiver of Written Consent Form (template and guidance found on web site listed above and also in the IRBNet library)
You may request a waiver of written consent. There is no template for this document. You need to include a document with your submission package to explain the reason for the request. If an oral consent is planned, you must include a copy of what will be said to the participant prior to engaging in the study. According to regulations:

DHHS – 45 CFR 116: "An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents 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 practicably be carried out without the waiver or alteration; and
4. whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Consent and Assent Forms (these are required document(s), unless you submit a Request for Waiver of Written Consent Form)

Submit applicable consent and assent forms with the initial application. Our web site has templates to use for various situations (e.g., parent/guardian consent, child assent, adult consent, anonymous surveys, etc.)

The types of consent forms and assent forms required depend on your participants. Use the following information to determine what to submit to the IRB:

1. Adult volunteers (ages 18+), not identified, use the consent template for "anonymous survey"
   a. Anonymously returned paper survey
   b. Oral / informal interview
   c. Web based survey or questionnaire
2. Adult volunteers (ages 18+), identified or coded to block identity, use the "informed consent template"
3. Minors (up to age 18)
   a. Use **BOTH** the "child assent form" and "parental consent letter"

Recruitment Materials, Permission Letters, and Data Collection Instruments

Submit all applicable materials such as samples of recruitment flyers, ads, letters, emails, etc. and questionnaires or survey instruments with the initial application. There are no templates for these types of documents, however you can always call our office for assistance with the type of information that they should contain.

1. If you are conducting research elsewhere (other than on the Michigan Tech campus such as another school or place of employment), attach permission letters from that institution indicating acknowledgement of your study.
2. If another IRB has reviewed and approved a study which you are collaborating with, you need to provide copies of the approval from the other institution.
3. Instruments which cannot be attached, such as Survey Monkey questionnaires must be explained in detail and you must provide examples of questions being asked.

Request for Renewal to continue a project for another year

*Submit the **"Update / Modification / Completion Form"** prior to the project expiration date.*

If changes are required to continue, you must be sure to provide more detailed information.

Request for Protocol Change during approval period

*Submit the **"Update / Modification / Completion Form"** any time you need to modify your protocol during the approval period.*

This form must be submitted any time protocol changes are needed; this must be submitted for review and approved **PRIOR** to implementing any changes.

Request for Personnel Change at any time

*Submit the **"Update / Modification / Completion Form"** any time you need to modify your personnel during the approval period.*

This form must be submitted any time personnel changes are needed during the study. This request must be submitted for review and approval in addition to the required CITI online training completion for each new investigator prior to them engaging with human subjects in the study.

End of Project

*Submit the **"Update / Modification / Completion Form"**.*

Be sure to answer all questions.

Unanticipated Problem or Serious Adverse Event (UP/SAE)

*Submit the **"Unanticipated Problem or Serious Adverse Event (UP/SAE) Form"**.*

You must report all unanticipated problems or adverse events which occur during the course of the approved study.