



Self-Certification Form for Determining Whether a Proposed Activity is Research Involving Human Subjects

Use this form if you are unsure if your project is research and whether or not you need to submit your project to the MSDH IRB.

This form is not an approval by the MSDH IRB of research as Exempt or any other level of review. If your project meets the definition of human subjects research you must submit the project to the MSDH IRB for review.

Name _____

Mailing Address _____

Email _____

Phone _____

Project Title _____

1) Is your project “research”?

“Research” is defined under 45 CFR 16.102(d) as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes.

<p>Is your project a “systematic investigation”?</p>	<p><input type="checkbox"/> No <input type="checkbox"/> Yes</p> <p>“Systematic investigation” is an activity that involves a prospective research plan that incorporates data collection, either quantitative or qualitative, and data analysis to answer a research question.</p> <p>Systematic investigation involves a predetermined method for studying a specific topic, answering a specific question, testing a specific hypothesis, or developing theory.</p> <p>Examples of systematic investigations include, but are not limited to, observational studies, interview (including those that are open-ended) or survey studies, group comparison studies, test development, and interventional research.</p>
<p>Is the primary intent of the project for the purpose of contributing to generalizable knowledge?</p>	<p><input type="checkbox"/> No <input type="checkbox"/> Yes</p> <p>Investigations designed to develop or contribute to generalizable knowledge are those designed to draw general conclusions (i.e., knowledge gained from a study which may be applied to populations outside of the specific study population).</p> <p>To develop or contribute to generalizable knowledge requires that the results (or conclusions) of the activity are intended to be extended beyond a single individual or an internal program. Intent to publish results/conclusions in a peer-reviewed journal or to present at a regional or national meeting does not determine this response. Thesis or dissertation projects conducted to meet the requirements of a graduate degree are usually considered generalizable.</p>

If you answered No to both questions, you may stop here. You are not conducting research that needs to be reviewed by the MSDH IRB. A copy of this completed form should be maintained in your project file. Do not submit a copy of this form to the MSDH IRB.

2) Does your project involve “Human Subjects”?

Human Subject is defined under 45 CFR 46.102(f) 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.

Does the project involve “intervention” or interaction with a human subject?	<input type="checkbox"/> No <input type="checkbox"/> Yes “Intervention” includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject.				
Does the project involve collection or access to identifiable “private information” by you or your staff?	<input type="checkbox"/> No <input type="checkbox"/> Yes “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, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.				
Does the project involve receipt of data/specimens that were collected by another source with identifiable private information?	<input type="checkbox"/> No <input type="checkbox"/> Yes (please answer the two below questions) <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="border-bottom: 1px solid black;">Are the data/specimens coded such that they could not be re-identified without access to a link?</td> <td style="border-bottom: 1px solid black; text-align: right;"><input type="checkbox"/> No</td> </tr> <tr> <td style="border-bottom: 1px solid black;">Is there a written agreement that prohibits you and your staff access to the link?</td> <td style="border-bottom: 1px solid black; text-align: right;"><input type="checkbox"/> Yes</td> </tr> </table>	Are the data/specimens coded such that they could not be re-identified without access to a link?	<input type="checkbox"/> No	Is there a written agreement that prohibits you and your staff access to the link?	<input type="checkbox"/> Yes
Are the data/specimens coded such that they could not be re-identified without access to a link?	<input type="checkbox"/> No				
Is there a written agreement that prohibits you and your staff access to the link?	<input type="checkbox"/> Yes				

If you answered No to all 3 questions in section 2, or No to the first two questions and Yes to the third questions and both sub-parts, you are not conducting research that needs to be reviewed by the MSDH IRB. A copy of this completed form should be maintained in your project file. Do not submit a copy of this form to the MSDH IRB.

Any other combination of answers means that the proposed activity may be research that involves human subjects. You must submit an application to the MSDH IRB before starting your project. Visit the MSDH website, www.healthymms.gov, under the Institutional Review link for information and resources for submitting your project to the MSDH IRB.

Your signature

Date _____
 Print Name _____
 Signature _____

I certify that the information above is true and accurate.