

The University of Vermont Committees on Human Research

Protocol Exemption Review and Determination Checklist

A. Will the activity involve research? Yes No

45 CFR 46.102(d) defines 'research' as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Examples of projects that may not be research include quality improvement programs or required program evaluations that will not be published or disseminated formally.

If YES - continue to Section B.

If NO, - **STOP!** 45 CFR part 46 does not apply to the activity and IRB review is not required.

B. Does the activity meet the definition of "human subjects research"? Yes No

45 CFR Part 46 defines human subject as a living individual about whom and investigator conducting research obtains: (1) data through intervention or interaction with the individual or (2) identifiable private information.

If YES - continue to section C.

If NO – **STOP!** Complete "Research Not Involving Human Subjects Review and Determination" form and submit for IRB review.

C. Will the project involve any of the following populations? Yes No

1. Pregnant Women;
2. Fetuses; or
3. Prisoners.

If YES – **STOP!** Project does not qualify for exempt status. Proceed to Section H for guidance.

If NO – Continue to section D.

D. Will your research involve children? Yes No

If NO – Continue to Section E.

If YES – **STOP!** Exempt research is only allowed with children when, (a) the research involves normal educational practices, or (b) the project involves use of educational tests, or observation of public behavior when the investigator(s) do not participate in the activities being observed, or (c) collection or study of existing data or specimens, when the data are recorded in such as manner that subjects cannot be identified.

Does the project involve only the research as noted above? Yes No

If YES – Continue to Section G.

If NO – **STOP!** Project does not qualify for exempt status. Proceed to Section H for guidance.

E. Will the project utilize educational tests, survey procedures, interview procedures, observations of public behavior? Yes No

If NO, continue with question F.

If YES, answer the following question.

Is the information obtained recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; **AND** Yes No

Would any disclosure of the human subjects' responses outside the research reasonably place the subjects at risk of criminal or civil liability, or be damaging to the subjects' financial standing, employability, or reputation, or deals with sensitive aspects of the subject's own behavior, such as illegal conduct, drug abuse, sexual behavior or the use of alcohol.

If you respond **YES** to the above question – **STOP!** Project does not qualify for exempt status. Proceed to Section H for guidance.

If **NO**, continue with question F.

F. Will your research use existing or archived data, documents, records, or specimens only?** Yes No

If **NO**, proceed to Section G.

If **YES**, complete the following questions:

1. Will any data, documents, records or specimens be collected that is not existing at the time of the submission of this application? Yes No
2. Will any data, documents, records or specimens be labeled in such a manner that subjects can be identified? Yes No

If you respond **YES** to 1 or 2 above – **STOP!** Project does not qualify for exempt status. Proceed to Section H for guidance.

G. Your project initially appears to be exempt from committee review. The Committee, however, needs to make the final determination. Submit a completed “Protocol Exemption Review and Determination” form. Once it has been determined that it is exempt from review you will receive a statement to that effect. You are not to begin research activities until you have received this statement from the Committee.

H. Your project is not exempt from Committee review. Refer to our Research Manual for further instructions on the different types of review.

***Harm to subjects** means that any disclosure of the human subjects’ responses outside the research could reasonably place the subjects at risk of criminal or civil liability or can be damaging to the subjects’ financial standing, employability or reputation.

****Existing data** is defined as materials that are on the shelf either 1) at the time the research is submitted to the IRB or 2) if externally funded, at the time the grant is written (whichever occurs first).