

A few specific sub-categories of human subjects research are defined as “Exempt” from the federal regulations governing IRB operations. In addition, University of Michigan policy permits “flexibility initiative” Exemptions for some studies that are not federally funded or FDA-regulated. U-of-M applies Exemptions only to minimal-risk research. Exempt studies do not require ongoing IRB oversight through “continuing reviews,” and do not require specific approval of processes or documents for obtaining consent. Importantly, University of Michigan policy requires that IRB staff or UMOR confirm eligibility for Exemption before the research starts by evaluating a streamlined application in eResearch.

[SCREENSHOT OF PAGE 01-1 WITH “Exempt human subjects research” POINTER.] Exempt determinations do not require full board review or expedited review by a single member on behalf of the Board.

Research on education methods, and studies based on survey and interview methodologies, may be eligible for federal Exemption category 1 or 2, or for U-of-M “flexibility initiative” Exemption 2a.

Exemption #1 covers research conducted in established or commonly accepted educational settings, involving normal educational practices. [DISPLAY THE WHOLE TEXT OF THE EXEMPTION, BUT HIGHLIGHT THE PART I READ.] “Educational settings” most often means a school, but also applies more broadly to any place where instruction takes place. “Normal educational practices” are defined as activities that typically occur in a classroom or other educational setting. Examples include test development, experimentation with instructional methods, evaluation of classroom or school activities, and assessment of attitudes about learning or curriculum. For instance, research on new teaching and training methods used in the University of Michigan Health System Clinical Simulation Center [SHOW PICTURE?] is often eligible for Exemption #1.

Exemption #2 covers research where the data collection methods are limited to educational tests, survey or interview procedures -- including focus groups -- or observation of public behavior. [DISPLAY THE WHOLE TEXT OF THE EXEMPTION, &c.] If the responses of subjects are particularly sensitive, meaning a subject **could** be at **risk** of criminal or civil liability, or damage to financial standing, employability, or reputation, the data must be recorded anonymously to be eligible for the exemption.

Survey and interview studies where the subjects are minor children are **not** Exempt. [GRAY OUT OR OTHERWISE DE-EMPHASIZE “survey procedures, interview procedures”]

For instance, web-based or in-person surveys are often eligible for Exemption when the subjects are adults, and a study drawing upon Twitter posts may be Eligible as “observation of public behavior.”

Exemption #2 is **not** available for studies that involve **any** physical or behavioral intervention with subjects.

U-of-M Exemption 2a extends Exemption eligibility to minimal risk research with adults that involves a **non-invasive intervention** followed by data collection via survey, interview (including focus groups),

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test, observation, and/or recording of physiological measurements. Non-invasive interventions may include viewing a video, reading a story, playing an economic game, using a computer program, using an experimental tool like a robot arm or mechanical object, or exposure to stimuli such as sound, color, or light.

To qualify for Exemption 2a, a study must pose **no more than minimal risk** to subjects, must **not** involve federal funding, and must **not** involve other regulatory or contractual restrictions such as FDA-regulated components or an NIH-issued Certificate of Confidentiality.

Contact the IRB with questions about Exempt human subjects research, including Exemptions 1, 2, and 2a.

List of references:

<http://www.irb.umich.edu/application/exempt.html>

<http://medicine.umich.edu/medschool/research/office-research/institutional-review-boards/guidance/exempt-research>

<http://www.hhs.gov/ohrp/policy/faq/exempt-research-determination/index.html>

http://www.irb.umich.edu/education/downloads/IRB-HSBS_Newsletter_Spring_2013.pdf

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