

Research with Human Subjects

Flow Chart for Guidance on Whether a Class Project Requires IRB Review

Is the project a senior capstone project, honors thesis, master's thesis, or doctoral dissertation?



IRB Review Required



Is the project solely for a class assignment where data will not be used outside of the classroom context and data are destroyed at the end of the project with no further use?



IRB Review Required



Marketing Study?



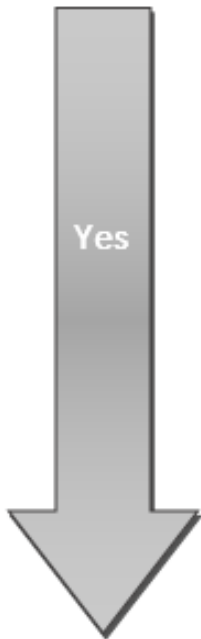
Marketing Study (students collecting data for a business):
 (1) Students are simply giving the collected data to the business, and the data are for the business's internal use only (e.g., the data will not be presented in a public forum).
 (2) Students have no plans to use the data for an honors thesis, research presentation at conferences, master's thesis, or dissertation.
 (3) The project does NOT involve protected populations or sensitive information (as defined at the end of this document).



All 3 conditions met, IRB review NOT required



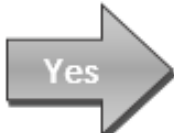
Any of the 3 conditions not met, IRB review required



Does the project involve protected populations, collection of sensitive information, or entities covered by another IRB, e.g., EMMC, Penobscot Nation? (See examples on next page.)



IRB Review NOT Required



IRB Review Required

Examples of Protected Populations/Sensitive Areas/Other Exceptions

Protected Populations – Examples include, but are not limited to:

- Children/Minors (under the age of 18) (**Exception** – projects conducted in established or commonly accepted educational settings involving normal educational practices. Contact IRB office for guidance.)
- Prisoners (now includes non-publicly available secondary data)
- Pregnant women
- Fetuses and products of labor and delivery
- People with diminished capacity to give consent
- Mentally or physically challenged individuals

Sensitive Information – Examples include, but are not limited to:

- Information relating to an individual's psychological well-being or mental health
- Information relating to sexual attitudes, preferences, or practices
- Information relating to the use of alcohol or drugs
- Information relating to illegal behavior
- Information that if released could reasonably place the individual at risk of criminal or civil liability or be damaging to the individual's financial standing, employability, or reputation
- Information that would normally be recorded in a patient's medical record and the disclosure could reasonably lead to discrimination, stigmatization, etc.

Other –

- Be aware that there could be instances where a class project could fall under the authority of another IRB such that these guidelines would not apply – e.g., studies proposed to involve Eastern Maine Medical Center (EMMC) staff or patients, members/citizens of the Penobscot Nation (specifically targeted).

Instructors/students who are unsure of whether a proposed project meets the guidelines for class projects should contact the IRB Office at 1-2657, email: umric@maine.edu. Remember, the IRB will not conduct retroactive reviews, so ask questions early and plan early! Conducting research with human subjects without IRB approval is a violation of the University's Policy on the Protection of Human Subjects.