DOES MY PROJECT REQUIRE APPROVAL?

There are 2 conditions that must both be met for a project to require IRB approval:

1) It is conducted using human subjects/participants and
2) It constitutes research

CONDITION 1 – HUMAN SUBJECTS/PARTICIPANTS:

A human subject/participant is a living individual who is the subject of the study about whom an investigator (faculty, staff, or student) conducting a project obtains:
- information through intervention or interaction with the individual and/or
- identifiable private information and/or
- observations in a setting/context where the subjects/participants would reasonably expect privacy

For example, if one wanted to visit a mother/baby health clinic in an economically disadvantaged urban area to interview/survey health care providers about the clinic, its services, the general characteristics and demographics of the population served, funding sources, then the clinic is the subject of the project, and the project does not meet Condition 1. If one wanted to interview the health care providers about their personal feelings about the work they do and the population they serve, why they chose to practice medicine in that particular setting, seek information about their personal values, attitudes, beliefs, experiences, and/or behaviors associated with their work and/or their patients, the health care providers are the subject of the project, and the project meets Condition 1.

CONDITION 2 – RESEARCH

Research is defined as a systematic (not necessarily “scientific”) investigation, where there is a plan/strategy/procedure/methodology to:
- select and recruit participants
- develop/use an instrument/procedure for collecting information from the participants (e.g., interview questions or guides, focus groups, surveys, experiments, etc.)
- make use of that information and that this will contribute to generalizable knowledge. The definition of generalizable knowledge includes one or more of the following:
  - the results, information, findings, data are intended for scholars, practitioners, and/or researchers within a field of study
  - the results, information, findings, data will be publicly disseminated or presented (or may, at some point in the future, be publically accessible) in any form
  - results/findings can be applied to some population in addition to the immediate subjects/participants (sample) of the study
  - the study can be replicated by others
Examples of projects not considered to be research because they do not have the purpose of contributing to generalizable knowledge and are non-systematic investigations may include:

- Instructor/student evaluations used solely by the institution
- Class-related data/information collection projects using human subjects/participants conducted solely for pedagogical purposes where the results are not disseminated beyond the classroom
- Activities conducted for quality improvement/assurance/assessment intended solely for internal institutional use

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