

Not Human Subjects Research

All proposed projects must be submitted to the IRB prior to beginning research activities. Do not attempt to determine for yourself if your project is not research involving human subjects. Completion of the IRBNet Prisma Health IRB Application will determine whether the project constitutes research involving human participants. *Final determination about whether IRB review will be required rests with the Prisma Health IRB using criteria under federal regulations 45CFR46.102. The Prisma Health IRB does not issue retrospective NHR determinations to facilitate publication requirements. NHR determinations must be made prior to beginning research activities.*

Federal Regulations found in Code of Federal Regulations Title 45CFR46, provides the following definitions:

Human Subject:

A living individual about whom an investigator is conducting research obtains:

- (1) Information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
- 45CFR46.102(e) (2) Uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Research:

A *systematic investigation*, including research development, testing, and evaluation designed to develop or contribute to *generalizable knowledge*.

- *Systematic Investigation* - An activity that involves a prospective plan that incorporates data collection, either quantitative or qualitative, and data analysis to answer a question. Often include surveys, interviews, data analyses, cognitive experiences, or medical chart reviews.
- *Generalizable Knowledge* - Knowledge from which conclusions will be drawn that can be applied to populations outside of the specific study population. This usually includes one or more of the following concepts: Knowledge that contributes to a theoretical framework of an established body of knowledge; the primary beneficiaries of the research are other researchers, scholars, and practitioners in the field of study; dissemination of the results is intended to inform the field of study (though this alone does not make an activity constitute research "designed to contribute to generalizable knowledge"); the results are expected to be generalized to a larger population beyond the site of data collection; the results are intended to be replicated in other settings.

The following items are not considered research:

- Scholarly and journalistic activities (oral history, journalism, biography, literary criticism, legal research, and historical scholarship)
- Public Health surveillance activities including collection and testing of information or bio-specimen, conducted, supported, requested, ordered, or required by a public health authority. Collection and analysis of information, bio-specimens, or records by or for a criminal justice agency for activity authorized by law or court solely for criminal justice or criminal investigative purposes.
- Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.