

DNP projects need a determination by the IRB and or IRB approval

The IRB is only required to review studies that are governed by the federal regulations (meeting the federal definitions of engagement, research, and human subject).

An institution becomes "**engaged**" in human subjects research when its employees or agents interact with living individuals for research purposes, or obtain identifiable private information for research purposes (OHRP Guidance 2008).

Federal regulations define **research** as "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge" (Protection of Human Subjects 2017). As described in the *Belmont Report* "the term 'research' designates an activity designed to test a hypothesis [and] permit conclusions to be drawn... Research is usually described in a formal protocol that sets forth an objective and a set of procedures to reach that objective" (Citi program, 2109). Research methods used in social science include surveys, interviews, focus groups, participant observation, observations of public behavior, and the analysis of existing data. Topics include research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior.

In contrast, research does not include operational activities such as practice activities in medicine or studies for internal management purposes such as quality improvement. However, some of these activities may include or constitute research in circumstances where there is a clear intent to contribute to **generalizable knowledge** (Citi program, 2109). Hence, all DNP projects will undergo review by CUHSR. Additionally, because there is intent to contribute to **generalizable knowledge**, DNP projects that are determined to be exempt, must still assure that they comply with organizational requires to assure that HIPAA rules. Many projects are

indirectly affected by HIPAA rules. Specifically, if a covered entity is the source of their data and those data meet the definition of PHI. If the student's project takes place at a covered entity the student should contact the Privacy Officer / Security Officer to assure that the organization's requirements are met.

Many DNP projects, by their nature involve **human subjects**. Specifically, a subject for whom the DNP student obtains, uses, studies, or analyzes identifiable private information. This means if the DNP student has access to identifiers, it is research. Identifiable is further defined to include any data that could be combined to determine who the individual is (e.g. date and time of admission, or date of birth and institution). Think like Sherlock Holmes, could he figure out who this person was? If yes, then this info included identifiers. Data collection using non-identifiable information may belong to the exempt category. Projects that fall in the exempt IRB review category do not require an IRB approval but do require a determination by the IRB.

If there are identifiable data, or PHI, the DNP project is more likely to fall in the expedient category. To avoid this DNP students must use only fully de-identified data, or a "limited data set" is used, under an approved "data use agreement." Studies with PHI in the expedient category will require written informed consent forms. See other form for info on informed consents.

Citi Program (2019). Defining Research with Human Subjects & Research and HIPAA Privacy

Protections. *Social and Behavioral Research*. <https://about.citiprogram.org/en/homepage/>

OHRP (2008). Engagement of Institutions in Human Subjects Research.

<https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html>