

The Franklin University Evidence-Based Project Review Team will review all DNP Scholarly Project proposals to ensure, among other things, that they do not meet the federal definition of human subjects research (per 45 CFR Part 46) and require IRB review:

\_\_\_\_\_ : "A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities." [45 CFR 46.102(l)]

\_\_\_\_\_ : "A living individual about whom an investigator (whether professional or student) conducting research: Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or Obtains uses studies, analyzes, or generates identifiable private information or identifiable biospecimens." [45 CFR 46.102(e)]

While DNP projects do not fall under the purview of Franklin University's IRB, some will require review by the institutional IRBs where projects are undertaken. For example, many hospitals have IRBs with policies requiring that all projects must be submitted to their IRB for review, even if the proposed work does not meet the federal definition of research. Moreover, institutional policies may require you to undergo additional training that ranges from CITI courses to seminars. It is your responsibility to identify and adhere to those research policies.

Institutional policies are highly variable and may mandate involvement from the Franklin University IRB. Our IRB will review these projects on a case-by-case basis. You should contact the DNP program chair and Franklin's IRB if you anticipate this situation.

The following examples include possible scenarios that necessitate involvement from Franklin's IRB:

An institution requires evidence of Franklin IRB review before issuing a letter of support.