A5.9 – HUMAN SUBJECTS CLEARANCE (RESEARCH)

Purpose

The purpose of this policy is to describe the Iowa HHS process for ensuring compliance (including SRs, and service sites) with the legal requirements governing human subjects research.

Policy

Clinical or sociological research on Title X clients must adhere to the legal requirements governing human subjects research at 45 CFR Part 46, as applicable. Iowa HHS will contact their assigned OASH Title X Project Officer in writing for approval of research projects that involve Title X clients.

Procedure

If a SR would like to engage in human subjects research, the SR shall submit their request to Iowa HHS Title X Program Director. The Iowa HHS Title X Program Director will forward a copy of the request to the Human Research Committee for approval. When a request for human subject clearance is received, the following will take place:

- Institutional Review Board (IRB): Iowa HHS will submit Institutional Review Board (IRB) approvals, when required, via Grant Solutions Grant Notes within 5 business days of receipt from the IRB. No activities that require IRB approval may take place prior to receipt of the IRB approval. For more information on 45 CFR Part 46 Protection of Human Subjects, recipients should refer to the HHS Office of Human Research Protections.

Iowa HHS will monitor this as part of the site visits with each SR as well as part of the manual review process.

Date Revised	September 2023
References	Title X Program Handbook (https://opa.hhs.gov/sites/default/files/2022-08/title-x-program-handbook-july-2022-508-updated.pdf#)
Additional Resources	