



6.2 HUMAN SUBJECTS CLEARANCE (RESEARCH)

POLICY:

Research conducted within Title X projects may be subject to Department of Health and Human Services regulations regarding protecting human subjects (45 CFR Part 46). The grantee/sub-recipient must inform their project officer of any research projects involving Title X clients.

PROCEDURE:

Recipient submits 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, refer to the HHS Office of Human Research Protections.

Subrecipients must inform the state office of any research projects involving Title X clients. The state office will then notify the project officer and submit a request in Grant Solutions.

If selected, the grantee is expected to participate in OPA research and evaluation activities and must agree to follow all evaluation protocols established by OPA or its designee.

RESOURCES:

[Mini-Tutorials | HHS.gov](https://www.hhs.gov/ohrt/mini-tutorials)

[Institutional Review Board \(IRB\) | Health and Human Services North Dakota](#)