

1.11 STANDARDS OF RESEARCH ACTIVITIES

Policy: Research conducted within Title X clinics may be subject to Department of Health and Human Services (DHHS) regulations regarding the protection of human subjects (*Title X Program Requirements 13.4 and 45 CFR 46*). <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>

Research projects and activities that are considered under this policy are those carried out by Title X clinic staff or a non-Title X staff researcher at the agency or by an outside researcher conducting a project to which clients are formally referred to the agency.

Definitions:

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains:

- (1) Data through intervention or interaction with the individual, or
- (2) Identifiable private information.

Categories of Research:

Category One

This category includes studies that entail only processing of information for betterment of client care, carried out within or between individual programs and in which there is no deviation from normal client care procedures. Additionally, the information gathered is for internal decision-making, results of the study will not be published, and only program personnel have access to client records. Gathering and analysis of clinic level data (such as the percent of clients in a certain age group, client satisfaction questionnaires) are included in this category.

Projects and activities in Category One do not need to be submitted to the WMHS for review and approval.

Category Two

This category includes projects or activities in which information is collected by Title X clinic personnel or by others outside the program agency for analysis and reporting verbally or in writing outside the agency. Additionally, there is no departure from normal procedures or from Title X Program Requirements and the QFP in client interviewing, counseling, or medical care, and the information collected is recorded by the investigator in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects.

Projects and activities in Category Two must be submitted to the WMHS and the Office of Population Affairs (OPA) Regional Office for review and approval. Signed informed consent and approval by an Institutional Review Board (IRB) may or may not be required, as determined by the WMHS.

Category Three

This category includes all projects or activities involving departure from normal agency procedures in interviewing, medical care or counseling procedures; departure from Title X Program Requirements and QFP; or investigation of experimental alternative forms of social, psychological, or medical care. This category also includes all collecting and analysis of information for reporting verbally or in writing outside the agency in which the information is recorded in such a way that subjects could be identified directly or through identifiers linked to the subjects, or so the subjects' sexual behavior or use of fertility control services could be ascertained by those who would not otherwise be aware of this information.

Projects in Category Three must be submitted to the WMHS and the OPA Regional Office for review and approval. Signed informed consent and approval by an Institutional Review Board (IRB) may or may not be required, as determined by the WMHS.

Procedure:

1. Title X clinics developing research projects using Title X clients as subjects must notify WMHS in writing prior to the research as appropriate.
2. Title X clinics considering research in Categories Two or Three must submit a summary of the proposed research to WMHS for approval. The summary must include:
 - a. specific aim of the project
 - b. method of selecting study participants
 - c. any inducement offered to clients to participate
 - d. description of information to be collected
 - e. description of data gathering process
 - f. proposed number of participants and estimated loss to follow up
 - g. analysis plan
 - h. discussion of problems which may arise in carrying out the project
 - i. presentation of expected or potential risks and benefits to project participants
 - j. documentation of Institutional Review Board (IRB) or brief explanation of why IRB approval is not necessary
 - k. copy of informed consent form (if used) based on Federal regulations, *45, CFR 46*
 - l. A statement of assurance that the research project is in compliance with Federal regulations *45, CFR 46*.
3. WMHS will advise the OPA Regional Office in writing of research projects involving Title X clients as subjects to determine if the project meets the requirements outlined in *45 CFR 46 (HHS Grants Policy Statement 2007, II-9)*.
4. The WMHS will submit all research projects to the DPHHS Office of Epidemiology and Scientific Support for approval as appropriate.
5. Proposed research summaries will be reviewed by the Montana Title X Family Planning Medical Standards Committee for appropriateness, completeness, and compliance with basic ethical principles. The committee, through a review and approval process, will assure that local research activities protect client's rights.
6. Research activities required for the Montana Title X Family Planning Medical Standards Committee review include activities that:
 - a. Are analyzed and published by personnel outside the local agencies or Title X network.
 - b. Depart from normal program procedures.
7. The Montana Title X Family Planning Medical Standards Committee will utilize the "Belmont Report: Ethical Principles and Guidelines for Protection of Human Subjects" as a reference for the review process (<http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html>). Topics include informed consent and doing no harm.
8. The WMHS will notify the sub-recipient whether the research project is approved.