



**FAMILY PLANNING PROGRAM  
POLICY AND PROCEDURE MANUAL**

**SECTION:** Program Administration  
**SUBJECT:** Human Subjects Clearance  
(Research)

**POLICY:** Delegate agencies considering clinical or sociological research must adhere to the legal requirements governing human subjects research. Prior to initiation of any research involving individuals, through invasive or noninvasive means, the risks, benefits and protection of human subjects must be assessed by a properly constituted institutional review board.

**GUIDELINES:**

1. Prior to initiation of any research involving individuals, through invasive or noninvasive means, the risks, benefits and protection of human subjects must be assessed by a properly constituted institutional review board (IRB).
2. Review of research projects by an IRB may fall into one of three categories: exempt, expedited or full review. Guidelines for review may differ slightly by institution, however, the regulations are applied consistently. (See Appendix of this section for “Human Subjects Review Flow Chart’ and “Institutional Review Categories”)
3. Basic requirements for human subjects protection:
  - Review of all federally-funded research involving human subjects.
  - Assessment of risks/benefits.
  - Insure adequate informed consent.
  - Special protections for vulnerable populations (i.e., fetuses, pregnant women, In Vitro fertilization, prisoners, children, handicapped or mentally disabled, economically or educationally disadvantaged).
  - Equitable subject selection.
  - Protection of confidential information.
4. It is important to distinguish between biomedical and behavioral research and the practice of accepted therapy in order to know what activities ought to undergo review for the protection of human subjects of research.

For the most part, the term “practice” refers to interventions that are designed solely to enhance the well-being of an individual patient or client and that have a reasonable expectation of success. The purpose of medical or behavioral practice is to provide diagnosis, preventive treatment or therapy to particular individuals.

By contrast, the term “research” designates an activity designed to test an hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge



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(expressed, for example, in theories, principles, and statements of relationships). Research is usually described in a formal protocol that sets forth an objective and a set of procedures designed to reach that objective.

5. Criteria for IRB approval of research:

- Risks are minimized (minimal risk means “the probability and magnitude of harm or discomfort anticipated...are not greater...than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.”).
- Risks are reasonable in relation to anticipated benefits, if any, and to the knowledge that may result.
- Selection of subjects is equitable.
- Informed consent is sought.
- Informed consent is documented.
- Research plan is adequate for monitoring data collected to ensure participants’ safety.
- Adequate provisions exist to protect privacy of participants and confidentiality of data. (See Appendix for this section for “Guidelines for Clinical-Research Protocols” and “Regulations Pertaining to Informed Consent”)

6. Delegate agencies must advise the State Family Planning office in writing of research projects involving Title X clients or resources prior to initiation of the project. Included shall be the following:

- objectives of the study;
- scope of the study – exempt, expedited or full review;
- timeframes;
- forms used in the study, e.g., informed consent, etc.;
- protocols or algorithms developed for use in the study;
- documentation of review by an IRB.

References:

1. Program Guidelines for Project Grants For Family Planning Services, p.6, Section 5.5 Human Subjects Clearance (Research).
2. Title 45--Public Welfare Subtitle A--Department Of Health and Human Services Part 46--Protection Of Human Subjects ([http://www.access.gpo.gov/nara/cfr/waisidx\\_99/45cfr46\\_99.html](http://www.access.gpo.gov/nara/cfr/waisidx_99/45cfr46_99.html))

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