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| Title: Human Subjects Research      | Policy Number: 1.8            |
| Approved By: Belinda Pettiford, MPH | Program Area: Family Planning |
| Effective Date: 1970                | Revised Date: 7/18/12         |

**Purpose Statement of Policy:**

To assure adherence to legal requirements governing human subjects research involving men and women of child-bearing age who are using Title X family planning services.

**Definition:**

Defined within the Human Subjects Research policy the following areas must be addressed:

- Any clinical or sociological research using Title X Family Planning clients must adhere to the legal requirements governing human subject research at 45 CFR Part 46, as applicable.
- Written notification must be sent to the Women’s Health Branch of any research projects involving Title X Family Planning clients.

**Responsibilities:**

It is the responsibility of the local health department and its designated personnel to develop, implement, and ensure compliance among all staff on the administration of the Human Subjects Research policy in the Title X Family Planning Clinic.

**Policy:**

The local health department will ensure that written policies are in place that address the above required areas in the definition section for the provision of human subjects research involving clients in the Title X Family Planning Clinic.

**Legal Authority:**

This policy is based on Title X regulations (January, 2001) Section 5.5 concerning human subjects research among clients in the Title X Family Planning Clinic; and 45 CFR Part 46, as applicable.

Title X Guidelines can be accessed at:

[https://www.grantsolutions.gov/gs/servlet/document.DownloadPdfPublicServlet?document\\_id=7157](https://www.grantsolutions.gov/gs/servlet/document.DownloadPdfPublicServlet?document_id=7157)

45 CFR Part 46 can be accessed at:

<http://www.hhs.gov/ohrp/documents/OHRPRegulations.pdf>

**For examples of policies from the local level, please contact your Regional Women's Health Nurse Consultant.**