**Clinical Research-Experimental Therapies- Investigational Drugs**

**Section:** Operations

**Compliance:** URAC Specialty Pharmacy 2.1

**URAC Standards:** PHARM Core 37

**Policy ID:** 5.1

**Approved by:**

**POLICY**

This policy specifies how <insert practice name>, its employees and patients will participate in the provision of drug therapies that are experimental, not-yet FDA approved or investigational.

**PROCEDURE [PHARM Core 37]**

For provision of each specific therapeutic agent, the Director of Research, of <insert practice name>, shall directly develop or supervise development of procedural protocols that address the following:

1. Rights and responsibilities of each patient
2. Documentation of informed consent from each patient including right to decline treatment
3. Documentation that patients will not experience discrimination for participation in research or study or as a result of declining to participate in same
4. Which personnel may participate in provision of medications and related services and how those personnel have been trained for participation
5. Definitions, procedures or policies specific to each regimen

The pharmacy department at <insert practice name> does not dispense investigational medications. The policies and procedures for this activity are kept in the Research dept.

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