



Stratton VA Medical Center IRB Standard Operating Procedure: Control & Distribution of IRB Standard Operating Procedures

POLICY

It is Stratton VA Medical Center's policy to comply with all applicable federal, state, and local regulations, and ICH guidelines in the conduct of human subject studies. Written procedures are used to guide personnel through various procedural steps and standardize practices to ensure subject protection and promote responsible research.

REFERENCE DOCUMENTS

N/A

PROCEDURE

The Research Office is responsible for the preparation and revision of IRB SOPs. The IRB and Research and Development Committees (R&D) review and approve the SOPs or any revisions to the SOPs. The Medical Center Director approves the SOPs or any revisions to the SOPs through her/his membership on the R&D Committee.

Each first page of an individual SOP procedure will contain a header with the following information:

TITLE: Title of SOP.

IRB: refers to the procedures related to operation and support of the IRB.

SOP Content

Each individual SOP will be written with the following section headings:

POLICY: An associated institutional, legal, or safety policy that affects activities described in the SOP.

REFERENCE DOCUMENTS: Any written material referred to in the SOP such as operating manuals, publications, related SOPs, etc.

PROCEDURE: Step-by-step description of all activities to be performed in following SOP directions. A short narrative may be included in this section to further explain, provide background, or clarify procedures.

Creation of new SOPs

The Research Office assigns a number and title to the new SOP.

The Research Office drafts the SOP and distributes the draft to IRB and R&D members to review and approve a final SOP.

The Research Office records the approval of the SOP and enters the document onto the research website.

SOP Revision

Revisions to an SOP are warranted whenever procedures are changed.

The Research Program staff revises the SOP and distributes the revision to the IRB & R&D to review and approve a final SOP revision.

SOP Periodic Review

The entire SOP is reviewed at least annually by the IRB.

Storage of IRB SOPs

The Research Office is responsible for distribution of the IRB SOP to the website and investigators, as necessary.

The Research Office maintains a copy of all SOP versions.