

# POLICIES AND STANDARD OPERATING PROCEDURES FOR THE INSTITUTIONAL REVIEW BOARD

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**Please take a few minutes to read these important directions.**

## OVERVIEW OF THE TEMPLATE

According to the Food and Drug Administration and the Office for Human Research Protections, Institutional Review Boards (IRBs) are accountable for adhering to the regulations governing the oversight of research in human subjects and for **following their own standard operating procedures (SOPs)**.

These SOPs are generic. You should take the time to customize them before putting this manual on the shelf. The directions for customizing the SOPs are clearly given and well-marked *in italics*. Suggestions for what might be appropriate customization are provided close to the text of the procedure.

Regulations require that IRBs have written policies and procedures and that activities at the institution are carried out as described in the written policies and procedures document. These SOPs are written to enable IRBs to maintain a system of compliance. The SOPs of an IRB reflect not only the laws and regulations, but also the underlying ethical principles that are the basis of the IRB's mandate. Finally, these policies also reflect our overarching commitment to provide protection for all the human subjects involved in research at this facility.

The forms, checklists, and other documents that are part of the SOPs are included in order to assure that the procedures are integrated into the daily activities of not only IRB members and staff, but into the activities of the investigative site as well. The forms are flexible and take into account numerous details of the day-to-day activities required of the IRB to fulfill its mandate.

Oversight of biomedical and behavioral research require specialized knowledge, which includes regulatory requirements, Good Clinical Practice (GCP), and medical ethics.

Institutions are obliged to establish an institutional culture where studies are conducted in an ethical and scientifically rigorous manner and where safeguards to subjects who participate in clinical studies are of paramount importance. Ensuring an institutional culture of research excellence begins with the establishment of operational policies and standard operating procedures that address the regulatory requirements, ethical conduct and sound implementation of all research conducted on human subjects.

### **The Organization of the SOP Manual**

- The organization of this SOP Manual is intended to group together related activities and/or concepts. There are 9 general sections that include the SOPs for specific activities of the IRB. These general sections are:
- **GA 100: General Administration** includes sections on the IRB's responsibilities and authority. It includes sections that address the activities that require IRB review, maintenance of SOPs, training, personnel management, and conflicts of interest. These activities form the infrastructure of a human subject protection program.
- **OR 200: IRB Organization** addresses the make-up and management of the IRB.
- **FO 300: Functions and Operations** details the procedures to ensure that the IRB meets its regulatory mandate to oversee research. It includes SOPs for submission requirements, determining and documenting research that is exempt from IRB review, meeting administration, and documentation.
- **RR 400: Review of Research** contains the policies and procedures for initial review and continuing review of research. The SOPs in this section describe the criteria for approval, the methods employed to assure adequate continuing review and the actions the IRB may take as a result of such review.
- **SC 500: Reviews Requiring Special Consideration** includes SOPs for research that involves vulnerable populations and for types of research that require additional considerations by the IRB, such as clinical trials involving investigational medical devices and prospective research in emergency settings, among others.
- **CO 600: IRB Communication and Notification** contains the SOPs to ensure timely and adequate notification of IRB decisions regarding research projects to Investigators and other entities that may have an interest in the outcome of IRB review.
- **IC 700: Informed Consent** focuses on the general requirements for informed consent and documentation of the informed consent process, exemptions to informed consent process or documentation, and the assent of minors. This section also includes template consent forms and checklists of required and optional elements of consent.

- **RI 800: Responsibilities of Investigators and Sponsors** provides instructions to Investigators and Sponsors regarding the IRB's requirements for Investigators, from initial submission through continuing review and study completion.
- **QA 900: Quality Assurance** In order to ensure that the IRB meets a high standard of performance, and to prepare the IRB for audits by regulatory agencies, this section includes checklists and procedures to ensure adequate and consistent procedures by IRB staff and key members.
- **WA 1000: Waiver of Authorization** Regulations at 45 CFR 164.512(i) give IRBs the authority to Waive Authorization for certain research activities. Although institutions might confer additional responsibility and authority for overseeing compliance with the Privacy Rule, any additional responsibility should be addressed in the covered entity's SOPs for Privacy Rule compliance.

Each individual SOP consists of the following parts --

- 1. Policy - Elucidates the **INSTITUTION/FACILITY'S** guiding principle for an area of IRB activity.
- 2. Scope – Defines the extent of the SOP.
- 3. Responsibility – Lists the positions responsible for ensuring that the SOP is carried out.
- 4. Applicable Regulations and Guidelines – Cites the federal regulations and guidance that impact the specific policy and procedures. From a customization perspective, it should also include any state and local codes that need to be addressed in the procedures (for example, California's requirements for consent, or Massachusetts's requirement for IRB registration.)
- 5. References to Other Applicable SOPs – Lists other related SOPs.
- 6. Attachments – Lists the forms, templates, checklists and/or documents available to integrate the policies and procedures into the daily operations of the IRB and ensure compliance.
- 7. Process Overview: Summarizes the SOP.
- 8. Procedures Employed to Implement the Policy: Details the individuals and daily activities of IRB staff and members to carry out the requirements of the SOP.
- Finally, this SOP Manual contains an extensive library of attachments, which include narrative guidelines, checklists, logs and other forms. These tools are not required (with just a few exceptions), but are available as a resource. The attachments may be used as is, modified or adapted as needed, or simply replaced with forms that have been developed previously and are already being used. The forms are either *controlled* or

*non-controlled* – controlled forms contain information that becomes part of the record of the IRB's review and determinations. Non-controlled forms are management tools that are designed to facilitate day-to-day operations. These forms are not considered part of the permanent record.

## **DIRECTIONS FOR USING THE TEMPLATE**

The basic procedures are described step-by-step for a given topic. These represent a typical listing of what operations are ordinarily carried out in conjunction with that particular topic. **Here is the first place for customization.**

- *Delete the procedures your site does not carry out.*
- *Add text to describe procedures that your site does carry out.*

Following the SOPs are the attachments. These are the IRB-specific forms and checklists that describe the details for carrying out the procedures. **This is the second place for customization.**

- *Where you have checklists and forms that you use, label them with the appropriate attachment letter and insert them.*
- *Where you do not have attachments, samples are provided that may be useful to you.*

Attachments can be changed without changing the text of the SOP.

## **CAVEATS**

**You must customize these SOPs** so they reflect the actual practices of your IRB. You may decide to follow the practice described in the SOP – but remember, **if you do not carry out the activities and practices described in your SOPs, you will be in violation of federal regulations.**

In order to customize these SOPs, you will need to replace certain sections, phrases and titles with those that are appropriate to your research program. To include the name of your institution or facility, search for "INSTITUTION NAME" and replace it with the name of your institution or facility.

To include the titles that pertain to your facility, search for "CHAIRPERSON" "ADMINISTRATOR" or "INSTITUTIONAL OFFICIAL". If a title does not fit in any of these categories, it has been labeled "CUSTOM TITLE".

These Policies and Procedures are written based on an IRB that uses a Primary Reviewer system. If your IRB does not employ such a system, you must be sure to change the pertinent procedures.

If you have multiple boards, each board must have its own SOPs. These SOPs may be exactly the same, but must reference each IRB (i.e. "institution IRB 1").

If you have an MPA or FWA, this document should be added to the Appendices. You will also need to add a list of all entities affiliated with your institution or group to which these SOPs apply, and include the list of committees that may impact the SOPs of the IRB.

Please see GA-101, Policies and Procedures Maintenance for further information on using the SOPs and revising them. These SOPs should be reviewed periodically to ensure that they are up-to-date, that new legislation or regulations are reflected in the policies and that daily activities are being performed as described in the SOPs.

In conclusion, this SOP Manual is the starting line in establishing the institutional culture of research excellence -- not the finish line. These SOP must be read, understood and used by all staff for an appropriate period of time. After this "shake-out" period, the SOP Manual should be assessed, adapted and improved as experience dictates. Thereafter, periodic review and updating will ensure this SOP Manual remains a living, useful document, and not a placeholder on a shelf.

## **NOTICE**

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