

## INTRODUCTION

Regulations require that Institutional Review Boards (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 Standard Operating Policies and Procedures (SOP) 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 IRB's mandate. Finally, these policies also reflect the overarching commitment of the Institution/Organization to provide protection for all human subjects involved in research conducted under the direction of it's students, staff and faculty.

The ethically responsible researcher is expected to carry the dual burden to advance knowledge that can improve the human condition or generate new knowledge and, at the same time, to recognize the absolute imperative to treat human research subjects with the utmost care and respect.

It is not unreasonable to ask others to share this burden, indeed, the institutions and society as a whole who expect to benefit from this research should be expected to share in the responsibility of conducting ethical clinical research.

This burden also falls, then, to the men and women who sit on Institutional Review Boards. They are, certainly, expected to act as a gatekeeper, to slow down the drive of the research enterprise to find the newest therapy and to advance knowledge of the basics of biological and behavioral mechanisms, and they are expected to share the responsibility of protecting the subjects of this research.

These SOPs apply to all the day-to-day operations of IRB. The SOPs apply to all persons employed by IRB, all members who serve on it as part of their overall institutional responsibilities, and all others who must subscribe to its decisions and its requirements (for example, the clinical Investigators, research managers/coordinators, research nurses, support staff, etc.). FDA inspection of an IRB always includes an assessment of IRB's SOP.

The forms, checklists, and other documents that are part of the SOP 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 IRB to fulfill its mandate.

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

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.

These policies are based on current regulations, ethical principles, and guidelines for the protection of the human subjects of biomedical and behavioral research. The policies state what this institution requires for the ethical conduct of clinical research. The procedures detail how these policies are carried out.

The policies and procedures are not an end unto themselves. They are the framework upon which research activities in these facilities are conducted. Therefore, all members of the research enterprise who are working within this institution are expected to read, understand, and comply with them. This way, the burden of conducting sound, effective and ethical research can be shared.