



A Human Research Protection Program (HRPP) is meant to join all facets of an institution engaged in Human Research together by outlining a system that will provide the best protection for its Human Subjects. An institution with a comprehensive HRPP will take into consideration the interactions between all of its internal and vendor component parts as they apply to Human Subject Protection. For example; legal department, contracting department, pharmacy, nursing, risk management, the IRB, device supply room, medical records, survey assistance and interviews, relationships with subcontractors, etc. It is important to note that institutions differ in size and complexity; the recommendations given below are the absolute minimum that any institution should have.

A Basic HRPP will address at least these four specific areas in a single document (should be a minimum of a page in length):

1. **Ethical Principles** - Many institutions choose to adopt the principles of the Belmont Report. Simply stating this is sufficient. However, it behooves you to keep a current copy of the Belmont Report on file for reference, and also to be familiar with its contents. A current copy of the Belmont Report can be found on OHRP's website:

<http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm>.

2. **Continuing Education** – State that everyone under your authority who participates in Human Research will be properly educated in what is commonly referred to as the Responsible Conduct of Research (RCR), and Good Clinical Practices (GCP). Also, state how, and how often this education is to be accomplished. Most education of this sort is accomplished through online courses, and revisited no less than every three years. In larger institutions it is sometimes beneficial to separate education regarding RCR as it applies to investigators and as it applies to management. Note: In order to obtain a Federal Wide Assurance (FWA) OHRP requires that all Principal Investigators and Research Assistants complete the “Human Subject Assurance Training” offered on their website (<http://ohrp-ed.od.nih.gov/CBTs/Assurance/login.asp>). IRC also requires proof of completion of this course.

3. **Use of an IRB** - State that you will use an IRB to review your human research.

4. **Monitoring** – Basically, this is a simple statement that says all actions and allegations of research misconduct will be reported through the proper lines so that appropriate action can be taken. Being specific on how, when, and whom you report to is highly recommended and will help you in the long run. Also, take a look at the Terms of Assurance section 4 (<http://www.hhs.gov/ohrp/humansubjects/assurance/filasurt.htm>) and make sure that those issues are addressed as well.