



Although the purpose of an IRB is to protect human research subjects, an IRB cannot do this alone. The IRB should be an integrated part of a larger program. Generically such programs are called HRPPs or Human Research Protection Programs.

HRPPs were spoken of only casually prior to about 2000, at which point the OHRP, under Dr. Greg Koski, encouraged their development. HRPPs are a key concept in OHRP assurance policies and the AAHRPP accreditation concepts.

Although development of an HRPP is conceptually simple within a single institution, it is infinitely more difficult in a virtual environment. An HRPP should encompass several functions:

- Establish a culture
- IRB Review
- Accountability
- Compliance
- Conflict of Interest
- Privacy
- Safety measures
- Education

An HRPP should include several functional units

- Institution
- IRB
- Funding agent/sponsor
- Units (pharmacy, library, clinical lab..)
- Investigator (and staff)
- Subject
- Contracts & Grants
- Legal Affairs

IRC's HRPP

IRC can contribute our IRBs' review to a client's HRPP. The client is responsible for conduct of the study and providing the remaining functions. No two HRPPs will be the same. Each will reflect IRC plus all of the other functions many of which may be sub-contracted.

INSTITUTION

IRC, as a business corporation, is a "public or private entity" as defined in 21 CFR 56 and in the Common Rule. The president of IRC, Erica Heath, has established an organizational culture in which protection of subjects is paramount. The IRB is kept as free from business concerns as possible.

IRC provides adequate resources, education and staff for the IRB and the IRB staff.

RELATIONSHIPS

All subject interactions are at sites remote from IRC and outside its institutional jurisdiction. Therefore, all HRPP functions must be handled through relationships, education and assurances. Our expectations are laid out within this website in the relationship, contracts, and other sections.

