

Many academics are familiar with grant requirements. However, working outside the academic arena can alter the complexity and perception of the federal demands. Non-academics will need familiarity with some basics. For everyone, some basic facts are critical.

1. Institutions get grants – people don’t.

Large academic medical center or 2-person corporation, funding is still directed to the company. An institution is “any public or private entity or agency (including Federal, State or other agencies).

2. Institutions give assurances to agencies – IRBs and investigators don’t.

45 CFR 46. is the DHHS policy on protection of human subjects (It’s FDA counterpart is 21 CFR 56.) Section .103 describes the assurance process and requirements. The opening sentence says,

“Each institution engaged in research which is covered by this policy and which is conducted or supported by a federal department or agency shall provide written assurance satisfactory to the department or agency head that it will comply with the requirements set forth in this policy.”

Assurances were known as MPAs and SPAs until December, 2000.

An FWA is granted for 3 years. Re-application is NOT required for each study.

3. IRBs are registered – Institutions are not.

An FWA lists those registered IRBs associated with the institution. An institution may designate one or multiple IRBs. Registered IRBs are listed on the OHRP website. IRC’s number is IRB00000762.

4. Institutional officials signing the assurance are making promises.

The “Terms of Assurance” describe the promises made. The central promises include development of and adherence to an institutional policy regarding protection of human subjects, a monitoring plan and a training plan.

5. FWA applications and IRB applications are totally separate.

An FWA is a high-level administrative agreement. IRB approval is between an investigator and the IRB. Each application may be initiated at any time.

6. This simple system can be highly complex.

At this site we have only discussed the basics of the FWA. The nuances and information about more complicated relationships are on the OHRP web site. As the system matures there will be changes. Many will be made to ease the reporting of complicated relationships.

**There are many documents on the OHRP website.
SEE PAGE 2.4.3. for OHRP SITES**

