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FWA – BASIC FACTS

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- ✓ The Basics - below
- ✓ IRC Information about Federal Wide Assurances
- ✓ Application form for IRC Signature on an FWA

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. The changes were well-intentioned and excellent but were introduced before the details were well worked out. The system is maturing as we use it.

3. **IRBs are registered**.
   An FWA lists those registered IRBs to be associated with the institution. An institution may designate multiple IRBs. Each must sign the assurance statement. Registered IRBs are listed on the OHRP website. IRC's number is 00000762.

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. **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 to explain the Terms of Assurance and to provide other information. Other documents to be found there include several to establish relationships. The OHRP website also contains the training modules.

TOPIC	Websites
OHRP site	http://ohrp.osophs.dhhs.gov/
Assurance area	http://ohrp.osophs.dhhs.gov/humansubjects/assurance/fwas.htm
Educational materials 45 CFR 46	http://ohrp.osophs.dhhs.gov/educmat.htm These materials relate to duties of those on an FWA rather than investigator duties.