

MEMO TO: IRC FWA CLIENTS

A number of small companies are receiving federal funding to do research with human subjects. Before federal money is released, the company must submit a Federal Wide Assurance. Within this document the company or institution promises that it will adhere to the "Terms of Assurance" in which an institutional policy is the core. IRC has received a number of questions about the content of such a policy. No one policy will accommodate all situations. Below we have the skeleton of an outline. Put it in your own institutional format and make it appropriate for your institutional mission, culture and document format.

NOTE: This is a *very sketchy* idea. Your institution - small as it might be - should have the super-structure to support research. It may be small but it should be well thought out and should fit within your other policies.

XYZ INSTITUTIONAL POLICY PROTECTION OF HUMAN SUBJECTS

Version Number:

Version Date:

I XYZ INSTITUTIONAL COMMITMENT

This institution is committed to what?

to protection of the subjects in all of our studies?

Anything else?

This institution has created an institutional HRPP – Human Research Protection Program. The major HRPP functions include:

Ideas:

- Compliance requirements
- Education requirements
- IRB review
- organizational structure
- legal?
- contract??

The major institutional units affected by the HRPP include:

- clinical lab?
- legal, etc.

This policy is adopted and disseminated from the very highest level of this organization. Protection of subjects is an important part of our culture....

This institution will use the federal requirements found in 45 CFR 46 Subpart A (“The Common Rule”) for (either *all research* or *only federally funded*) research (CAUTION this is a critical decision.)

This institution will use the federal requirements found in 45 CFR 46 Subpart s B, C, and D (vulnerable subjects) for (either *all research* or *only federally funded*) research (CAUTION this is a critical decision.)

II. ADMINISTRATIVE HIERARCHY

The Institutional official:

Name, Title

Duties: Set policy and
establish culture of conscience/compliance
more?

The Human Subject Protection Administrator:

Name, Title

Duties: tracking company studies and IRB reviews
Subject complaint handling
Others

ORG Chart attached illustrating responsibility for the HRPP.

III. COMMITMENTS TO SUBJECTS

- A. Financial: It is the policy of this company that ...
 - ... no subject should be financially harmed as a result of participation in one of our studies.
 - ... we may argue with investigators and insurers over payment but that subjects with a righteous claim will not be burdened with knowledge of these disagreements.
 - ...we will carry insurance sufficient to cover direct and liability costs for related to injuries to subjects.
 - Etc. policy on
 - compensation for direct expenses (e.g. additional office visits)
 - compensation for indirect expenses (e.g. childcare, transportation)
- B. Timely Results
- C. Adverse Events
- D. Information – Rights – Compliance
- E. Other???

IV COMMITMENT TO INVESTIGATORS

- A. Support
- B. Freedom from Conflicts of Interest?
- C. Training
- D. Publication rights?

V. COMPLIANCE

- A. Monitoring of institutional records
- B. Monitoring of investigator site
- C. Monitoring of IRB

VI. EDUCATION

- A. Education of institutional Officials
 - Baseline: Completion of OHRP modules
 - Additional: GCP courses? Web courses?
- B. Education of Investigator and staff
 - Baseline: Completion of course (you decide on best site for your company needs and ideals. (consider citiprogram.org)
 - Additional: GCP courses? Web courses?

VII. IRB REVIEW AND RELATIONSHIPS

- A. Business relationships
 - FWA – Initial review
 - A copy of this policy will be sent to the company providing the IRB service.
 - FWA – IRC Continuing Review
 - Insurance
 - Communication
- B. Review relationship
 - The IRB and the Investigator have the primary relationship; this institution will assist the investigator in the preparation of materials and provision of whatever else is needed.
- C. Use of external IRBs
 - IRC may be your “internal” IRB of record but some of your studies may be conducted at institutions with their own IRB. Will the institution agree to accept the determination of that IRB (and thus list it on the FWA) or will duplicative review be needed?

THINK about the kinds of relationships your company has with other companies.
How will they be handled?

VIII SIGNATURES

This document has been accepted as an official policy of this (named) institution.

Highest person: (signature)(printed name)(date)

