When the Assurance comes a 'Knocking': Everything You Need to Know About OHRP's FWA and IRB Registration Processes

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March 28, 2013

Overview

- Why and When Assurances of Compliance are Required
- What Institutional Review Boards (IRBs) Must Register?
- IRB Registration Process
- FWA Process

Why and When Assurances of Compliance are Required

- 45 CFR part 46 require institutions to file with OHRP an assurance of compliance before engaging in non-exempt human subjects research (hsr) conducted or supported by HHS

Why and When Assurances of Compliance are Required, cont'd

- Institutions must also certify that an IRB has reviewed and approved the research.

Note: IRBs must be registered with OHRP before reviewing HHS-conducted or supported non-exempt human subjects research.

When is an Institution Engaged in Non-exempt Human Subjects Research

Generally, when the institution's employees or agents obtain:

- data about living individuals for research purposes, through intervention or interaction with them;
- individually identifiable private information for research purposes; or,
- informed consent of human subjects.

Federalwide Assurance (FWA)

- FWA is the only type of assurance OHRP accepts or approves.
- Institution pledges to conduct its HHS-funded or -conducted research in compliance with 45 CFR part 46.
- A U.S. institution also may voluntarily pledge to conduct all of its non-exempt human subjects research, regardless of funding source, in compliance with 45 CFR part 46 - often referred to as "check the box"

Federalwide Assurance (FWA), cont'd

- Two-thirds of U.S. institutions currently check the box, i.e. optionally elect to apply the:
  - Common Rule to all of its research, regardless of source of support; or,
  - Common Rule and Subparts, B, C, D, and E of 45 CFR part 46 to all of its research regardless of source of support

Federalwide Assurance (FWA), cont'd

- Other Federal Departments and agencies accept FWAs for human subjects research they support.

What IRBs Must Register?

- 45 CFR part 46, subpart E, require IRBs that review HHS-conducted or -supported human subjects research to register with OHRP.
- Food and Drug Administrations' (FDA) IRB regulations at 21 CFR part 56.106 require each U.S. IRB that:

(1) reviews clinical investigations regulated by FDA; or,

(2) reviews clinical investigations that are intended to support applications for research or marketing permits for FDA-regulated products, to register.

Registering IRBs and Obtaining an OHRP-approved FWA are two separate processes

Registered IRBs:

- As of March 5, 2013
- 5,834 total
  - 3,584 Domestic (61%)
  - 2,250 International (39%)

Approved FWAs:

- As of March 5, 2013
- 12,068
  - 9,163 – Domestic (76%)
  - 2,905 International (24%)
- Of the 9,163 Domestic:
  - 6,011 have optionally "checked the box" (66%)

IRB-Registration Process

IRB Registration

Poll 1

- Have you submitted your organization's registration?

Yes

No

IRB-Registration Process

Electronic Submission:

- Registration applications must be submitted electronically using OHRP's Electronic Submission System (ESS) http://ohrp.cit.nih.gov/efile/Default.aspx

unless

an institution lacks the ability to submit electronically.

IRB Registration Process Information Collected

- Name and mailing address of the organization operating the IRB(s)
- Organization Head Official's and Contact Person's: name, address, phone & fax #s
- IRB address, phone and fax #s, and e-mail
- IRB Chairperson name, phone # and e-mail

IRB Registration Process Information Collected, cont'd

Registration Information: for each IRB

- # of FTEs devoted to the IRB's administrative activities;
- Approximate # of active protocols being reviewed;
- Approximate # of active protocols conducted or supported by HHS (e.g, NIH, CDC, etc)

Active protocol – any protocol for which the IRB conducted an initial or continuing review at a convened meeting or under expedited review during the preceding 12 months

IRB Registration Process
Information Collected, cont'd

- Each IRB in the U.S. that reviews protocols regulated by FDA must provide:
  - Approximate # of active protocols involving FDA-regulated products and
  - Description of the types of FDA-regulated products in protocols
    - human drugs
    - medical devices
    - biological products
    - food additives
    - color additives
    - other, specify

IRB Registration Process
Information Collected, cont'd

- IRB Membership Roster, members:
  - names, gender
  - earned degrees
  - whether scientist or non-scientist
  - whether or not affiliated with the IRB organization

IRB Registration Process
OHRP Review & Acceptance Notification

How will an organization know its submitted IRB registration has been reviewed and accepted by OHRP?

- Once OHRP reviews and accepts the registration, the organization's contact person, head official, and IRB chairperson(s) all receive an automatically generated email informing them their organization's registration has been accepted.
- A copy of the reviewed and accepted registration will also be attached to the email.

IRB Registration Process
Update or Renew

When must an IRB registration be updated or renewed?

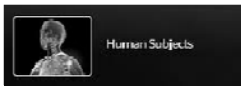
- IRB registration must be updated within 90 days after the Information Provider or the IRB chairperson changes.
- An organization must renew its registration every three years, even if no changes have occurred, in order to maintain an active registration.
- Any IRB update or renewal electronically submitted to, and accepted by, OHRP, begins a new 3-year effective period.

IRB Registration Process
Cessation of an IRB

Disbanding an IRB:

- An organization's decision to disband a registered IRB must be reported to OHRP in writing within 30 days after permanent cessation of the IRB's review of HHS-conducted or – supported research.

- FWA Process



Poll 2

- Have you submitted your institution's FWA?

Yes

No

FWA Process
ESS Requirement

Electronic Submission:

- Institutions must submit their FWA applications electronically using OHRP's Electronic Submission System (ESS) http://ohrp.cit.nih.gov/efile/Default.aspx

Unless

- An institution lacks the ability to submit its FWA application electronically.

FWA Process
Information Collected

- Identifying information for the:
  - Institution filing the FWA,
  - Human Protections Administrator (or a reliable point of contact) at the institution, and
  - Institution's signatory official signing the FWA.
- Name and location of components over which the institution has legal authority that operate under a different name which will be covered by the FWA

FWA Process
Information Collected, cont'd

- A statement of ethical principles to be followed in protecting human research subjects.
  - Belmont Report
  - Declaration of Helsinki
  - Other – must submit to OHRP for review & approval
- Commitment to apply FWA whenever its employees or agents are engaged to non-exempt human subjects research conducted or supported by any U.S. Common Rule department or agency,
- unless
  - a U.S. CR department or agency determines the research will be conducted under a separate assurance.

FWA Process
Information Collected, cont'd

- Optional for U.S. Institutions to "check the box"
  - the option of voluntarily electing to apply either the CR or the CR and subparts B, C, D, E of 45 CFR part 46 to all of its non-exempt human subjects research regardless of source of support, except
  - for research that is covered by a separate assurance issued by another CR federal department or agency.

FWA Process
Information Collected, cont'd

Institution's assurance to comply with the Terms of the FWA

- The institution assures that whenever it engages in research to which its FWA applies, it will comply with the Terms of the FWA (contained in a separate document on OHRP's website at http://www.hhs.gov/ohrp/assurances/forms/fwatermsjun14.pdf)
- Each non-U.S. institution provides at least one of the listed procedural standards that it applies to human subjects research to which it FWA applies.

FWA Process
Information Collected, cont'd

- Designation of all internal IRBs that will review the research covered by the FWA.
- If the institution has no internal IRB, designation of the external IRB that reviews all research covered by the FWA.
- If the institution relies upon multiple external IRB, designation of the external IRB that reviews the largest percentage of the research covered by the FWA.
- Note: external IRB reliance requires written reliance agreement, e.g., IRB authorization agreement

FWA Process
Information Collected, cont'd

- Name and contact information for the Human Protections Administrator (HPA), the person who serves as the institution's primary point of contact.
- Signature of an official authorized to represent the institution identified on the FWA as Signatory Official (SO).
- The SO must assure that human subjects research to which the FWA applies is conducted in accordance with the Terms of Assurance.
- Note: the Terms of the FWA are contained in a separate document located on OHRP's website: http://www.hhs.gov/ohrp/assurances/forms/index.html

FWA Process
Tracking Submitted Application

Can an Institution track OHRP's receipt of its FWA submission and its status?

- Yes, at: http://ohrp.cit.nih.gov/search/
- Here an institution will find information about when the FWA was received and which OHRP Assurance Coordinator is reviewing its application and how to contact that person.

FWA Process
OHRP Approval Notification

How will an institution know its submitted FWA application has been reviewed and approved by OHRP?

- HPA, SO, and the person who submitted the FWA application each will receive an automatically generated email notifying them their FWA has been approved.
- A copy of the approved FWA will also be attached to the email.

FWA Process
Update/Renew

When must a FWA be updated or renewed?

- An institution must update its FWA within 90days after the legal name of the institution, the HPA or SO changes.
- A FWA approval is effective for 5 years and must be renewed every 5 years even if no changes have occurred, in order to maintain an active FWA.
- Any FWA renewal or update electronically submitted to, and approved by, OHRP begins a new 5-year effective period.

Poll 3

- What % of U.S. Institutions "check the box"?

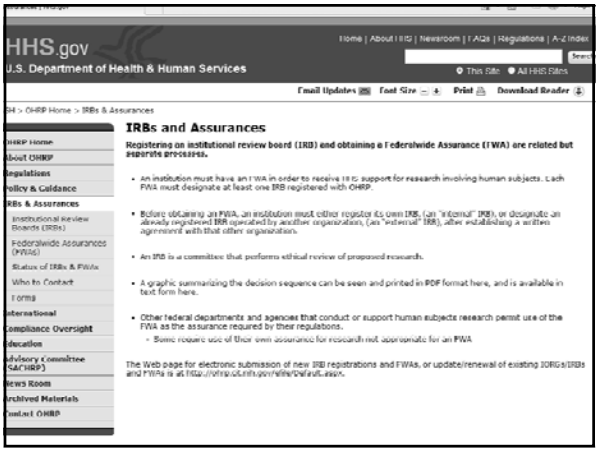
33%

66%

75%

FWA and IRB Registration Resources

- http://www.hhs.gov/ohrp/assurances/index.html



OHRP Contact Information

- OHRP website: http://www.hhs.gov/ohrp
- OHRP e-mail: ohrp@hhs.gov
- Toll free telephone number: 1-866-447-4777
- Main telephone number: 240-453-6900
- Join Listserv: http://www.hhs.gov/ohrp/newsroom/