

What is an FWA?

How is it relevant to Tribal Research?

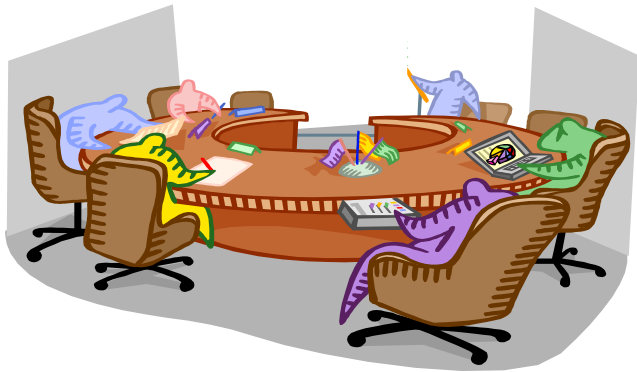
Regulatory Knowledge Core
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INTENDED AUDIENCE

- American Indian Tribal Nations involved in human subjects research
- [American Indian Tribal Institutional Review Boards](#) (IRBs) or other regulatory bodies



*Wondering about the terms,
'Institutional Review Board' and
'Research Review Board'?
Click the hyperlink above for more information.



OBJECTIVES

- Identify the relevance of the FWA to Tribal Nations and Tribal organizations.
- Distinguish between ‘Registering an IRB’ and ‘Obtaining an FWA’
- Identify requirements for obtaining an FWA and IRB registration

* See explanations of acronyms and definitions of terms at the end of the document



WHAT IS AN FEDERAL WIDE ASSURANCE (FWA)?

- A document that an 'institution' submits to the Office of Human Research Protections (OHRP). It is a written commitment to comply with the [federal regulations for the protection of human subjects](#).
- Currently the 'Federal Wide Assurance' (FWA) is the only type of assurance accepted by OHRP



WHY OBTAIN AN FWA?

- An FWA makes an institution eligible to apply for, and be a direct recipient of federal funding for human subjects research
- It is required for institutions that are in ‘engaged’* in (non-exempt*) research involving human participants - that is conducted or supported by the U.S. Department of Health and Human Services [\(HHS\)](#).

*For further information on ‘engagement of institutions’, and ‘non-exempt’, see the terms ‘engagement’ and ‘exempt’ in the [CRCAIH Glossary of Human Subjects Protections Terms](#).



CAN A TRIBE BE AN “INSTITUTION” AS DEFINED BY THE OFFICE OF HUMAN RESEARCH PROTECTIONS?

- Yes. Tribes are often treated as “public entities” or referred to as “tribal entities”.*
- For those who consider a Tribe or Tribal department to be a non-U.S. institution, the OHRP guidelines regarding non-U.S. institutions are as follows: “...Whenever non-U.S. institutions are engaged in non-exempt HHS-supported or -conducted human subjects research, the regulations apply.”**

Sources:

*“Division of Indian Self Determination” Accessed July 17, 2014 from :

<http://www.bia.gov/WhoWeAre/RegionalOffices/Pacific/SelfDetermination/index.htm>

**Federal Wide Assurance for the Protection of Human Subjects 3 (c). Accessed July 17, 2014:

www.hhs.gov/ohrp/assurances/assurances/filasurt.html#sectionb



HOW DOES AN FWA AFFECT TRIBAL LAWS GOVERNING RESEARCH?

- Having an FWA means that the Tribe is agreeing to comply with and enforce federal human subjects protections regulations as a minimum.
- Tribes (and all institutions that choose to obtain an FWA) have the right to establish regulations in addition to the existing federal regulations protecting human subjects.
- For example, Tribes can incorporate federal human subjects protections regulations into their own policy regarding research conducted on Tribal land.



DOES AN INSTITUTION APPLYING FOR A FWA NEED TO HAVE IT'S OWN IRB?

- No. An institution can list an external IRB registered with OHRP (and their IRB registration number) on its FWA application.
- However, both organizations must be agree on this relationship, and confirm the relationship to OHRP with a written 'IRB authorization agreement'* between institutions.

*For more information see the term 'IRB authorization agreement' in the [CRCAIH Glossary of Human Subjects Protections Terms](#)



OUR TRIBE DOES NOT HAVE AN IRB.

WHAT ARE OUR OPTIONS?

- Tribes that do not have an IRB can apply for a Federal Wide Assurance (FWA)
- Tribes have the option of establishing an IRB authorization agreement with:
 - another Tribe
 - a local Tribal Consortium IRB
 - regional IHS IRB, Tribal College IRB
 - or other institutional IRB

Access the page to file an FWA here:

<http://www.hhs.gov/ohrp/assurances/assurances/file/index.html>

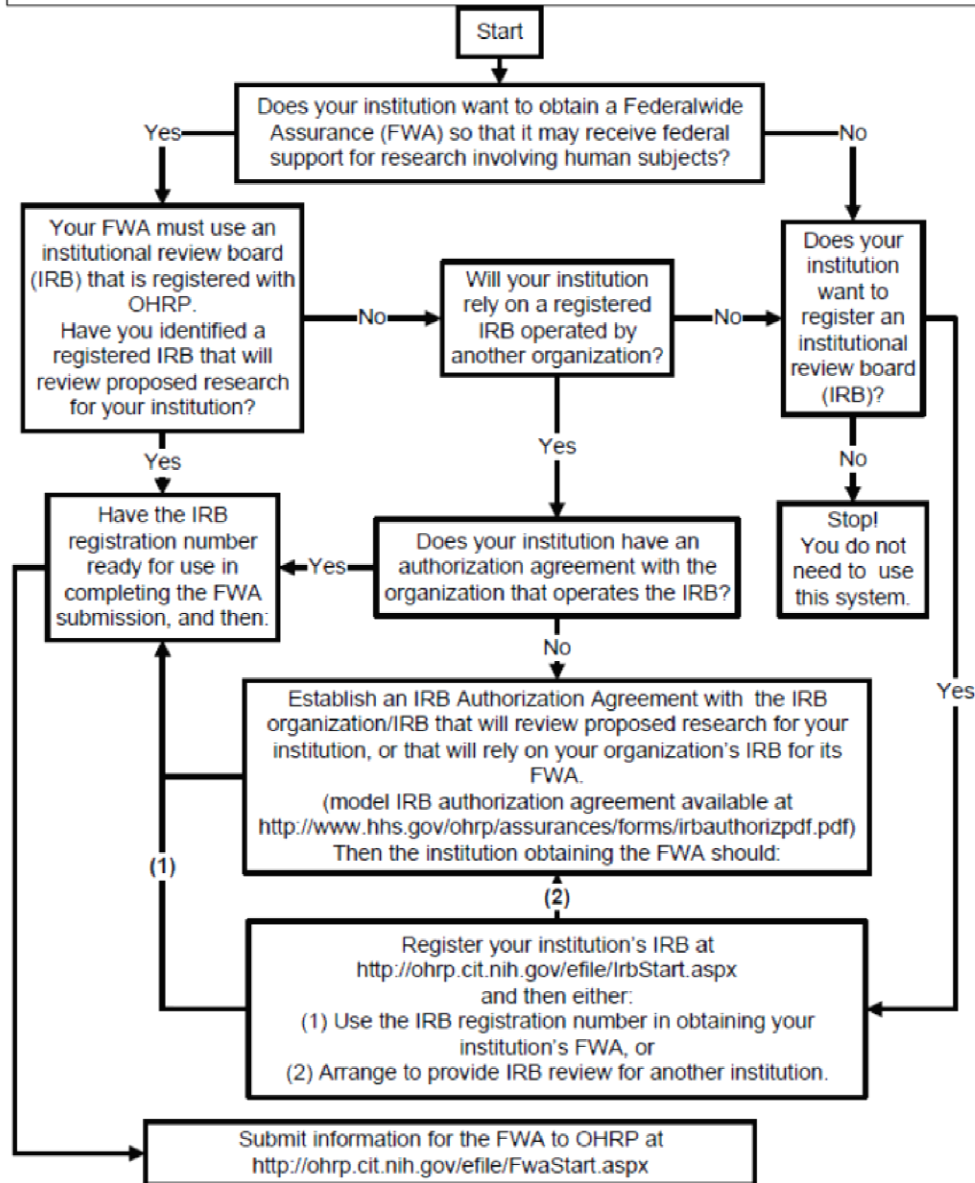


WHAT IS THE CONNECTION BETWEEN “REGISTERING AN IRB” AND “OBTAINING AN FWA”?

- They are two separate processes.
- However, in order to obtain an FWA, an ‘institution’ must designate a ‘registered’ IRB as the body responsible for the review of research.
- An institution can either :
 - ‘register’ its own IRB or
 - list another institution’s registered IRB, and submit a formal [IRB authorization agreement](#) to OHRP.



Registering an IRB and Obtaining an FWA: What to Do in What Order



Source: OHRP 'IRBs and Assurances' webpage:
<http://www.hhs.gov/ohrp/assurances/>



WHY REGISTER AN IRB?

- A ‘registered’ IRB can be listed on an institution’s Federal Wide Assurance (FWA) application.
- An institution that registers its own IRB can keep the review of research “in house” and/or serve others as a registered IRB designated on their FWA.
- Registration can also be a way to demonstrate that an institution’s IRB operates in accordance with established federal standards.



REGISTERING AN INSTITUTIONAL REVIEW BOARD

- IRBs have the option to apply for ['registration' with the U.S. Department of Health and Human Services \(HHS\), Office of Human Research Protections \(OHRP\)](#)
- Upon registration, the IRB and hosting institution, which is referred to as '[IORG](#)' by OHRP, will be placed in an OHRP database
- The institution and designated IRB will be assigned an IRB number and an IORG number respectively. These numbers are accessible to the public and can be listed in grant applications and grant correspondence.
- A registered IRB is subject to audits from OHRP



PREREQUISITES FOR IRB REGISTRATION?

- Identify number of active research protocols (or research studies 'current' or 'in process') in the past year.
- Identify number of active research protocols conducted or supported by the U.S. Department of Health and Human Services ([HHS](#)).



PREREQUISITES FOR IRB REGISTRATION? (CONT)

- The contact information for the following:
 - the institution
 - a top institutional or Tribal official
 - IRB Chairperson
 - designated contact person for the IRB
- A roster of the IRB membership and each individual's role on the IRB - in accordance with federal guidelines
- For other requirements, access the electronic application here:

<http://ohrp.cit.nih.gov/efile/Default.aspx>



ACRONYMS AND DEFINITIONS

- **FWA** – A document that an institution submits to the Office of Human Research Protections (OHRP). It is a written commitment to comply with United States federal regulations for the protection of human subjects.
- **IRB** – Institutional Review Board*, or an entity responsible for the review of research for the protection of human subjects*.
- **IORG** – IRB Organization, the organization under whose authority the IRB operates

Wondering about the terms ‘Institutional Review Board’ and ‘Research Review Board’?

Click [here](#) for more information.

*The terms ‘institutional review board’ and ‘human subjects’ are in the

[CRCAIH Glossary of Human Subjects Protections Terms](#)



ACRONYMS AND DEFINITIONS

Institution – “Any public or private entity or agency”

Public entity includes:

State and local governments and their departments and agencies

Public agency:

The government of the United States, the government of a state or political subdivision thereof; any agency of the United States, a State, or a political subdivision of a State; or any interstate governmental agency.

Sources:

42 U.S.Code § 12131 Disability Law Index, Southwest ADA Center. Retrieved July 17, 2014 from :
http://www.southwestada.org/html/topical/PublicEntities/pe_qualified.html

29 U.S. Code § 203 (s)(2)(x) Definition Retrieved July 17, 2014 from:
<http://www.law.cornell.edu/uscode/text/29/203>



ACRONYMS AND DEFINITIONS

Institution – “Any public or private entity or agency”

Private entity :

- any entity other than a State, local government, Indian tribe, or foreign public entity.

This term includes:

- (i) A nonprofit organization, including any nonprofit institution of higher education, hospital, or tribal organization other than one included in the definition of Indian tribe
- (ii) A for-profit organization.

Sources:

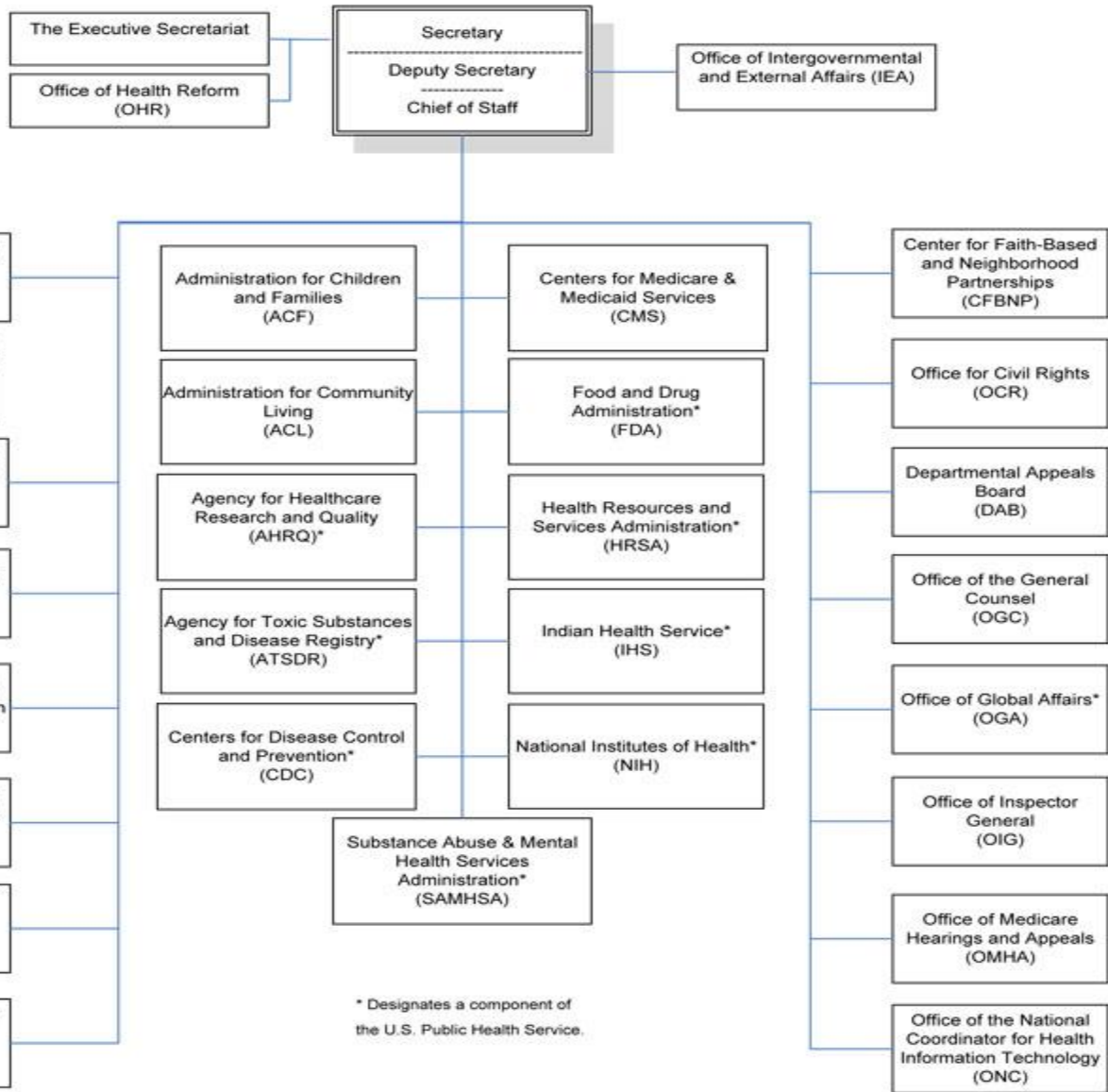
U.S. Code 2 CFR 175.25 Title 2 Grants and Agreements; Subtitle A Office of Management and Budget Guidance for Grants and Agreements. Retrieved July 17, 1014 from :

<http://www.gpo.gov/fdsys/pkg/CFR-2012-title2-vol1/pdf/CFR-2012-title2-vol1-sec175-25.pdf>



WHAT IS HHS?

HHS ORGANIZATIONAL CHART:



HHS Organizational Chart
<http://www.hhs.gov/about/orgchart/>



REFERENCES

Office of Human Research Protections (OHRP) IRBs and Assurances website.
Accessed July 17, 2014 at: <http://www.hhs.gov/ohrp/assurances/index.html>

United States Code of Federal Regulations Title 45: Public Welfare, part
46.501, Subpart E “Registration of Institutional Review Boards”. Retrieved July
17, 2014 from:
www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subparte



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