Centers for Disease Control and Prevention

Additional Requirement – 1: Human Subjects Requirements

If the proposed project involves research on human subjects, the applicant must comply with the Department of Health and Human Services (DHHS) Regulations (Title 45 Code of Federal Regulations Part 46) regarding the protection of human research subjects, unless that research is exempt as specified in the regulation (45 CFR 46.104). All awardees of CDC grants and cooperative agreements and their performance sites engaged in research involving human subjects must obtain (1) Federalwide Assurance (FWA) of compliance with the Regulations, and (2) initial and continuing approval of the research by an appropriately constituted and registered institutional review board (IRB) unless exempt from continuing review (45 CFR 46.109(f)).

An FWA is required for all applicants conducting human subjects research, regardless of whether the research is subject to the U.S. Federal Policy for the Protection of Human Subjects (also known as the Common Rule). An institution must have a valid FWA to receive HHS support for research involving human subjects. Each FWA must designate at least one IRB registered with the Office for Human Research Protections (OHRP). Before obtaining an FWA, an institution must either register its own IRB (an "internal" IRB) or designate an already registered IRB operated by another organization.

In order to obtain a FWA for the Protection of Human Subjects, the applicant must complete an on-line application at the Office for Human Research Protections (OHRP) website or write to the OHRP for an application.

To obtain a FWA, or for more information, contact the OHRP at: https://www.hhs.gov/ohrp .

Institutions must submit all FWAs, including new FWAs, electronically using the electronic submission system available through the OHRP website , unless an institution lacks the ability to do so electronically. If an institution believes it lacks the ability to submit its FWA electronically, it must contact OHRP by telephone or email (see https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/contact/index.html) and explain why it was unable to submit its FWA electronically.

If an Institution lacks the ability to submit its FWA electronically, after consulting with OHRP, it must send the FWA application to OHRP in writing, by: FAX ((240)453-6909; email (IRB@hhs.gov or FWA@hhs.gov); or mail (Division of Policy and Assurances, Office for Human Research Protections, The Tower Building, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852).

Note: In addition to other applicable committees, Indian Health Service (IHS) institutional review committees must also review the project if any component of IHS will be involved with or will support the research. If any American Indian community is involved, its tribal government must also approve the applicable portion of that project.

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