Community Healthcare System

The Review

Community Healthcare System Central IRB (CHS CIRB)
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Federalwide Assurance Process

Health and Human Services (HHS) human subject protection regulations require that any institution engaged in non-exempt human subjects research conducted or supported by HHS must submit a written assurance of compliance to the Office of Human Research Protections (OHRP). The Federalwide Assurance (FWA) is the only type of assurance of compliance accepted and approved by OHRP and other departments and agencies that have adopted the Federal Policy for the Protection of Human Subjects (the Common Rule or 45 CFR part 46). The FWA is effective for 5 years and must be renewed every 5 years, even if no changes have occurred.

An institution is considered to be engaged in human subjects research when its employees or agents:

1. Obtains information or biospecimens through intervention of interaction with the individual, a uses, studies, or analyses the information or biospecimens; or
2. Obtains, uses, studies, analyzes, or generated identifiable private information or biospecimens

Employees and agents, including students, are individuals performing institutionally designated activities and acting on behalf of the institution or exercising institutional authority or responsibility.

The key features of the FWA are;

1. The identifying information of the institution, the Human Protections Administrator (Jana L. Lacera) and the Institutional Official signing the FWA;
2. A list of the institutions' legal components that will be covered by the FWA. The Community Healthcare System Central IRB (CHS CIRB) lists Community Hospital, St. Catherine's Hospital, St. Mary Medical Center and the National Cancer Institute IRB (NCI CIRB);
3. A statement of ethical principles to be followed in protecting human research subjects;
4. A statement indicating that the FWA applies whenever the institution becomes engaged in human subjects research conducted or supported by any United States federal department or agency that has adopted the Common Rule;
5. An assurance of compliance indicating that the institution will comply with the Terms of the FWA;
6. The designation of all internal and external IRBs that will review the research covered by the FWA; and
7. Whenever the institution relies upon an IRB operated by another institution or organization for review of research not covered in the FWA, The institution must ensure that this arrangement is documented by a written agreement.

The Signatory Official (SO) must assure that human subject's research to which the FWA applies is conducted in accordance with the Terms of the Assurance. Elizabeth Yee, Vice President of Clinical Ancillary Services has been designated by CFNI as the Signatory Official.

FWA#0000184 Expires 09/14/2021
IORG#0003947 Expires 09/16/2019

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