HUMAN RESEARCH PROTECTION

IRB review of research subject to the Revised Common Rule 45 CFR 46

Number 145 Version date DEC 2020

Resource type GUIDANCE

Research subject to 45 CFR 46 that is initially approved by the IRB after January 20, 2019 will be reviewed and approved in accordance with the Revised Common Rule (RCR). Human subjects research approved prior to this date will continue to be subject to the previous requirements in effect at the time that research was approved.

The following activities are deemed not to be research, and as of 1/21/2019 newly proposed projects that fall into these categories will not require approval from the HHRI IRB.

a) scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected;

b) public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in disease, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters);

c) collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activates authorized by law or court order solely for criminal justice or criminal investigative purposes; and

d) authorized operational activities as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions; and (5) written materials specify that secondary research involving non-identifiable newborn screening blood spots is not considered research involving human participants.

IRB review for research subject to the cooperative research provision will be conducted in accordance with HRPO 2xx SOPs and applicable 7xx Worksheets.

Certificates of Confidentiality protect the privacy of research subjects by prohibiting disclosure of identifiable, sensitive research information to anyone not connected to the research except when the subject consents, or in a few other specific situations. Certificates are available by request from several federal agencies (CDC, FDA, HRSA, SAMHSA) and they are issued automatically by the National Institutes of Health for projects it funds. During the review of each project a determination will be made to clarify if a Certificate of Confidentiality has automatically been issued by identification of the sponsor. If one has been issued, the consent form will be reviewed to ensure that it appropriately informs research participants of the protections and limits of those protections under a Certificate of Confidentiality.

Effective January 11, 2019, HHRI has revised its DHHS Federal Wide Assurance filing and will no longer voluntarily extend the oversight of all of its research to DHHS's regulatory purview; however, for the sake of consistency and quality assurance, the HHRI IRB will continue to apply the same policies and procedures to all the research it oversees, irrespective of sponsor type.

Researchers may use the HRPO 410 CHECKLIST **Elements of Informed Consent** to confirm compliance with requirements for informed consent (as specified in the Code of Federal Regulations 45 CFR 46), as well as other information required by the HHRI IRB.