Human Research Protection Program / Institutional Review Board

Standard Operating Procedure

Pre-2018 Common Rule

For Studies Initially Approved on or Before January 20, 2019

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1 "Human Subjects" and "Research" Determinations

Some MaineHealth activities involve systematic investigations, but may not generalizable (e.g., quality improvement, program evaluations, classroom research activities), and some activities result in generalizable findings, but were not conducted as systematic investigations (e.g., case studies). None of these activities are research.

The responsibility for initial determination whether an activity constitutes "research" rests with the individual with primary responsibility for the activity. This individual should make this determination based on the definitions of "research" and "clinical investigation" as provided by the Common Rule and FDA regulations, respectively. Consultation with the ORC is encouraged. Because the analysis can be complex, individuals with any questions regarding the applicability of the regulations to their activities are urged to request a determination that an activity does or does not involve research. Such requests should be submitted via the completion of a "Human Subjects Research Determination" application in IRBNet.

Similarly, the responsibility for the initial determination of whether research involves "human subjects" rests with the investigator. Under the Common Rule, information is considered identifiable, and thus involving human subjects, when the identity of the subject is or may be readily ascertained by the investigator or associated with the information. It should be noted that this definition differs significantly from de-identified in accordance with HIPAA standards. FDA regulations do not incorporate the concept of "identifiability" in the evaluation of whether an activity is a clinical investigation (or research) subject to FDA regulations. For example, the use of de-identified human specimens to evaluate the safety or effectiveness of a diagnostic device is considered human subjects research subject to FDA regulations. Investigators are urged to submit for a determination whenever they are uncertain if a research study involves "human subjects" as defined by the Common Rule or FDA. Such requests should be submitted via the completion of an MaineHealth Smartform Wizard along with the "Human Subjects Research Determination" application in IRBNet.

Investigators **may not** self-determine that research involving the use of **coded** private information or specimens does not involve "human subjects". Such determinations should only be made by ORC staff using the process described above. An exception to this policy occurs when:

- the research is not subject to FDA regulations AND
- the coded private information or specimens are to be obtained from an MaineHealth IRB-approved repository AND
- the rules of that repository forbid the release of identifiable information, the key or code that would enable re-identification, or the release of sufficient information that investigators could readily ascertain the identity of subjects.

Human Subjects Research Determinations must be submitted, and determined, prospectively (i.e., before the proposed activity or research begins). Conducting human subjects research without IRB approval or exemption is noncompliance and will be managed as described in Section 19.

Determinations whether an activity constitutes human subject research will be made by ORC staff, in consultation with others as necessary according to the definitions in Section 1.3, applicable federal

regulations, and federal guidance. A determination letter will be issued and uploaded as a board document in IRBNet to document the determination. Investigators conducting research under the auspices of MaineHealth **may not** rely upon determinations made by other organizations or through the use of electronic (or other) determination tools.