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EXEMPT RESEARCH DETERMINATIONS

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In our continued efforts of supporting the research community, Mount Sinai School of Medicine PPHS Office is announcing a change in the process to receive an exempt research determination. This applies only to human subjects research where all research activities fall under one or more categories designated as exempt from The Common Rule (45 CFR 46 Subpart A) as stipulated in 45 CFR 46.101(b).

1. The PPHS Office is launching a new Request for Exempt Determination Form that replaces the need to submit forms HRP-211 and HRP-503, and CVs for study personnel. If HIPAA applies, the HIPAA waiver request or authorization form must still be submitted to the PPHS office.
2. At the suggestion of the research community, the PPHS office has created a one-page research information sheet template to be used for exempt research in which interaction with subjects will take place (typically under category 1 if a survey is being used as the evaluation tool; or under category 2). Similar to a consent template, this includes the elements that can be provided to potential subjects before they participate in exempt research. This information sheet can be used as a telephone script for studies involving phone interviews or phone calls to ask potential subjects to take part in a focus group; as an introduction to an online survey; or can be provided to potential subjects for studies in which in-person interactions are taking place.

Note: Although the PPHS Office will not check for completion of human research education requirements, it is expected that the PI has completed these courses before conducting the research. It is the responsibility of the PI to ensure that research staff are adequately trained; it is strongly recommended that the completion of the human research education is included in that training.

NOTE: EXEMPT from the Common Rule does not mean exempt from HIPAA regulations.
If Protected Health Information (PHI) will be accessed, even if identifiers are not recorded, HIPAA regulations may apply.
In some cases, a request for Waiver of HIPAA authorization (for exempt category 4) or Alteration of HIPAA may be granted (for online surveys).
Studies requiring review for HIPAA considerations require Level 3 review (see below) as only the PPHS office or the HIPAA Privacy and Security Program office are authorized to approve HIPAA for research forms.

3. Review Options:

Level 1) Unofficial determinations: A department Chair can designate one or more faculty from their department to review human research and make exempt determinations for a project that meets the Federal Office of Human Research Protection's exemption criteria. All designees will receive training and a certificate from the PPHS office prior to being authorized to make determinations. Level I will permit an investigator to proceed with their project once reviewed by the department's designee. The department designee will not generate an official letter from the PPHS indicating that the project is exempt but will provide concurrence that the research meets the criteria for an exempt determination. If such concurrence cannot be made, the information will be provided to the PPHS for further evaluation. Since these are unofficial determinations, and the IRB cannot retroactively approve research, there is no way of receiving an official letter for a journal submission, etc. once the research is conducted.

Level 2) Official departmental determinations: The PPHS office will train IRB members to make these determinations for their departments. IRB members will report determinations they've made to the PPHS office, and the determinations will become part of the official PPHS office records. The PPHS will then issue an official Exempt

Research Determination letter to the PI of the study. This will apply for projects that require an official letter for journal submission. For this level, the PPHS office will require an appointed IRB member from any department seeking to make its own official determinations.

Level 3) The PPHS official determination: The PPHS office and the IRB members within the office will continue to make exempt determinations and issue official Exempt Research Determination letters upon receipt of the Request and accompanying project information.

Note: It is institutional policy, and guidance from OHRP, that no one involved in the research makes an exempt determination for the study. If the department designee is on the study, call the PPHS Office for guidance.