|  |
| --- |
|  |

**Initial Review and Approval of Exempt Human Subjects Research**

**Roles and Responsibilities**

**Instructions**

This tool can be used to help identify the individual(s) and/or committee(s) at your Institution that play a role in the review and approval of human subjects research that is exempt from the Common Rule in accordance with 38 CFR 16.104. Depending on your local processes and procedures for the review and approval of exempt research, additional columns and rows may need to be added to the table.

|  | Conflict of Interest (COI) Administrator  (Coming Soon) | Exempt Determination Official/Committee[[1]](#footnote-1) | IRB | Privacy Board | Privacy Officer (PO) | Information Systems Security Officer (ISSO) | Research & Development Committee | Associate Chief of Staff/Research or Coordinator for R&D |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Managing the review of potential financial conflicts of interest | **X** |  |  |  |  |  |  |  |
| Determining if the research qualifies for exemption (VHA Directive 1200.05 para 10) |  | **X** | **X** |  |  |  |  |  |
| Conducting limited IRB review for exempt categories 2(iii); 3(i)(c); 7; and 8 (VHA Directive 1200.05 para 10e) |  |  | **X** |  |  |  |  |  |
| Approving a waiver of HIPAA authorization for research involving use of protected health information (PHI) (VHA Directive 1200.05 para 23b) |  |  | **X** | **X** |  |  |  |  |
| Ensuring compliance with information security requirements for research involving VA sensitive information (VHA Directive 1200.01 para 5j) |  |  |  |  |  | **X** |  |  |
| Ensuring compliance with VA Privacy requirements, and when applicable, ensuring that the HIPAA authorization contains all required elements (VHA Directive 1200.01 para 5k) |  |  |  |  | **X** |  |  |  |
| Ensuring all disclosures and data transmission meet privacy and security requirements per VHA Directive 1605.01 and VA Handbook 6500 (VHA Directive 1200.01 para 10b(2)) |  |  |  |  | **X** | **X** |  |  |
| Approving exempt research to include:   * Ensuring that research in which the facility is engaged is consistent with the VA mission and complies with all applicable statutory and regulatory requirements (VHA Directive 1200.01 para 5h(4)) * Ensuring research in which the facility is to be engaged has been reviewed and approved for high scientific quality, the protection of human subjects and research staff,…, the safety of all involved in research, the security of research laboratories, and the security of VA data and sensitive information (VHA Directive 1200.01 para 5h(8)) * Approving recruitment of non-Veterans (VHA Directive 1200.01 para 13(a)) * For exempt research that involves the Investigator interacting with human subjects or obtaining information by educational tests, survey or interview procedures, or behavioral interventions, ensuring the following information is provided to prospective human subjects either in writing or orally in accordance with VHA Directive 1200.05 para 10c:   + The activity is research   + Participation is voluntary   + Permission to participate can be withdrawn   + Permission for use of data can be withdrawn for exempt research activities involving the collection and use of identifiable data; and   + Contact information for the VA Investigator * Determining if the facility should participate in the study * Ensuring that the appropriate IRB arrangements are in place prior to using an external IRB if limited IRB review is required (VHA Directive 1200.01 para 5h(7)) * Ensuring all committee/subcommittee non-contingent approvals are in place (VHA Directive 1200.01 para 9b(1)) * Ensuring that potential financial conflicts of interest are reported, reviewed, and managed (VHA Directive 1200.01 para 5h(9)) * Ensuring ISSO and PO review is complete before a study is given final approval (VHA Directive 1200.01 para 5h(6)) |  |  |  |  |  |  | **X**  **X**  **X** |  |
| Notifying investigators, in writing, when a research project can be initiated, and the period for which the project is approved (VHA Directive 1200.01 paragraph 5g(2)) |  |  |  |  |  |  |  | **X** |

1. The exempt determination official can be either an individual or committee that is qualified to make exempt determinations, e.g. a subcommittee of the R&D Committee or the R&D Committee itself. The exempt determination official is the individual or committee that is responsible for reviewing the research study to verify that it qualifies for exemption. ORD policy allows exempt determinations to be made by the IRB Chair, an experienced IRB member, or qualified administrative staff with expertise in applying human research exempt regulations (VHA Directive 1200.05 paragraph 10b). [↑](#footnote-ref-1)