

ENGAGEMENT DETERMINATION CHECKLIST

Location activity will occur:
 Name of Requester:
 Requester Email & Phone:
 Project Title:

Date:

Attachments Required : IRB Approved Protocol & IRB Approval Letter

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	<u>VA Facility</u>	<u>OTHER INSTITUTION</u>
Direct awardee of a federal grant, award, or contract involving human subjects research (HSR) (even if no HSR activities being carried out by institution)		NOTE: Use Other Institution, if submitting from another VA Facility.
Obtaining informed consent (do NOT check if ONLY informing prospective subjects about the study but not obtaining consent)		
Performing invasive or non-invasive procedures with ANY subjects		
Intervening, for research purposes, with ANY subjects by manipulating the environment		
Interacting, for research purposes, with any subject to collect data about them under the protocol (e.g. conducting research interviews, administering questionnaires)		
Obtaining, using, studying, or analyzing private identifiable** information from ANY source (whether from another institution or already in possession of the investigators)		
Observing or recording private behavior of ANY subject		

Form must submitted via email.
 Coatesville: VHACOAResearchAdmin@va.gov
 Wilkes-Barre: VHAWBPResearchAdmin@va.gov
 Wilmington: VHAWIMResearchAdmin1@va.gov

NOTE: Institutions are NOT engaged when their only role is:

- Performing services for non-research purposes or performing routine medical services at an institution that typically provides said services
- Providing recruitment information or investigator contact information to prospective subjects
- Obtaining de-identified PHI/biological specimens
- Obtaining coded PHI/biological specimens if they aren't able to readily ascertain the identity of the subject to whom the coded PHI pertains

**See the definition of in [45 CFR 46.102\(f\)](#) For additional guidance on *engagement*, [OHRP's Engagement of Institutions in Human Subjects Research](#)
 **In some cases the VA facility can obtain and use private identifiable information without being engaged.

FOR RESEARCH OFFICE USE ONLY:

VA is ENGAGED in RESEARCH and an IRB application must be submitted to continue with the project.

VA is NOT-ENGAGED in this research activity. **NOTE: The VA reserves the right to terminate this activity at any time with or without prior notification.**

Additional information is required before engagement can be determined; see comments below.

Comments:
