



Human Research Protection Official Review Checklist (This applies to situations in which the OASD HA/TMA is engaged or involved in research with another institution and said research has been reviewed and approved by one or more IRBs.)

- Contact Information for PI *AND* Government Project Manager (please use “TMA Protocol Contact Information Template for Secondary Review” template found in the IRBNet library)

- Description of the PI’s affiliations and qualifications (CV/Biosketch)

- Proof of HRPP Training within the past 3 years for all researchers ([CITI Social and Behavioral Research Investigators Module](#) [we do not accept refresher training])

- Signed “[Researcher Responsibilities Form](#)” for all investigators

- IRB Documentation:
 - a. Protocol, including all attachments, approved by the primary IRB for the study
 - b. Copy of IRB approval letter(s) for the study (initial review and continuing reviews when applicable)
 - c. If the study did not qualify as exempt, a copy of the OASD HA/TMA [Institutional Agreement for IRB Review](#) (IAIR) signed by the signature authority at the primary IRB, or the [DoD Addendum to the HHS FWA](#).

- Data Use Agreement/Data Sharing Agreement (DUA/DSA) or DUA/DSA number provided by the TMA Privacy Office (if applicable)

- Approval form HA/TMA Gatekeeper Review for Duplication for all TMA-sponsored studies. The Gatekeeper Information Sheet is available in IRBNet.