The follow documents are required for HRPO review. The below list is for a single site submission or for a master protocol/lead site submission for multi-site trials. NO SCANNED PDFs. HRPO NEEDS TO BE ABLE TO SEARCH PDF FILES SUBMITTED

For your Single Site Protocol submission or Master Protocol submission (for multi-site research/trials), the following documents are needed for HRPO review and approval:

1. Award#\_IRB approval letter

2. Award#\_IRB approved research protocol

3. Award#\_IRB application form

3. Award #\_IRB approved consent

4. Award #\_HIPAA form (if applicable)

5. Award #\_FDA approval/comments (if applicable)

6. Award #\_1572 (if applicable)

7. Award #\_InvestigatorBrochure (if applicable)

8. Award #\_HRPO submission form

9. Award #\_Human subject protection training\_investigatorlastname (required for PI and key personnel)

10. Award #\_studyinstruments (as applicable and approved by IRB, and break out as separate document, not one file)

11. Award #\_Other\_description

When submitting documents for a performance site, please identify the site in the description box when uploading documents. The following documents are required for each SITE submission (for multi-site research/trials):

1. Award #\_IRB approval\_sitename

2. Award #\_IRB approved application\_sitename

3. Award #\_HRPO site addendum form\_sitename

4. Award #\_IRB approved consent\_sitename

5. Award #\_HIPAAauthorization\_sitename (if applicable)

5. Award #\_Humansubjects protection training\_investigatorname (required for PI and key personnel)

6. Award #\_1572\_sitename

7. Award #\_RelianceDocumentation\_Sitename (Documentation from the local institution confirming reliance on the single IRB of record (we don't need to see the agreement, an email from the institution is sufficient)

8. Award #\_Otherapproveddocuments (Any additional local documents approved by the IRB (if applicable))

9. Award #\_Other\_description

Quick Tips for HRPO submissions:

1. Read the HRPO investigator guidance document

2. Make certain consent documents state:

a. DOD is funding the research

b. DOD may have access to identifiable research records for research regulatory oversight activities

c. DOD may have access to identifiable PHI for research regulatory activity (applicable if HIPAA authorization is necessary for the research)

3. All performance sites must have an FWA (international performance sites also!)

4. All US based multi-site studies must use a single IRB (sIRB) for review

5. Make certain all key personnel have human subjects protection training and that it is not expired

7. Make certain that if research is conducted at a Military installation or with a military population that there is a Letter of Support from the appropriate individual for the activity

8. If study population is active duty military personnel, appropriate information in the consent document regarding injury treatment

9. The IRB approval memo states the IRB risk determination (GTMR or NGTMR) and any waivers that the IRB may have approved (i.e. waiver of consent, waiver of the requirement for signed consent)

Additional information:

1. A Research Not Involving Human Subjects determination is not acceptable for study data to be submitted to the FDA (ex. IVDD that use de-identified specimens/pooled blood). All research studies where data will be submitted to the FDA must be IRB reviewed.
2. If study will be conducted at international performance sites, please set up a call with SOTR and HRPO to discuss additional requirements for submission
3. If Military personnel will be AIs on a project, please make certain that IIAs are in place for the investigator to be covered under the reviewing institutions FWA
   1. If the military installation has an FWA, and investigators are conducting research under their FWA, follow sIRB guidance.
4. If the IRB approves the use of a Legally Authorized Representative to provide permission for research on behalf of the participant, the protocol or some other documentation must describe the intent to benefit all participants in the research study, including the placebo group, e.g. additional monitoring beyond standard of care, access to approved medical interventions, etc.
   1. **If a research protocol will be using a LAR for consent, please contact HRPO to discuss prior to submission to ensure the requirements are met.**