Checklist for VAs establishing an Authorization Agreement with the NCI Central IRB

Requirements for adding NCI Central IRB as an IRB of record:

- Develop local SOPs for use of NCI CIRB and have ORO review.
- Sign and submit Authorization Agreement (VA version) to NCI.
- Make change on FWA and VA Addendum to the FWA and submit to ORO.

NCI requirements

- Complete NCI CIRB Institution Enrollment Form
- Submit two signed originals of the Authorizatin Agreement (VA version) to:
  CIRB Operations Office
  c/o The EMMES Corporation
  401 N. Washington St., Suite 700
  Rockville, MD 20850
  Then you also have to email the site enrollment form to ncicirbcontact@emmes.com
- Receive one original of the fully-executed Authorization Agreement (*NOTE: Provide a copy to ORO)*
- Complete and submit Annual Signatory Institution Worksheet about Local Context
- Receive approval letter from the CIRB confirming the Annual Signatory InstitutionWorksheet About Local Context has been approved
- Complete the Annual Principal Investigator Worksheet About local Context for each Principal Investigator who will be opening a study with the CIRB
- Receive approval letter from the CIRB confirming each Annual Principal Investigator Worksheet(s) About Local Context has been approved (at least one Annual Principal Investigator Worksheet has to be approved to complete enrollment)
- Receive approval letter from the CIRB confirming that the enrollment to the Independent Model is complete.

Local SOPs must address the following:

Responsibilities of the R&D Office

- Complete and submit the Annual Signatory Institution Worksheet About Local Context, the Annual Investigator Worksheet About Local Context, and any other worksheets/forms required by the NCI CIRB for participation.
- Use VA specific language in the consent including local contact numbers (e.g., coverage of research injury, required phone numbers for the study doctor, and a person unaffiliated with the study who can answer general clinical trial questions).
- Manage evaluation of financial conflict of interest.

Responsibilities of the R&D Committee

- Decide whether to open a study with the NCI CIRB.
- Review initial and ongoing qualifications of investigators and research staff.
- Review and have CIRB-approved Principal Investigators complete and submit the Study-Specific Worksheet About Local Context to open a study.
- Ensure ISO and PO review is complete before the study is approved. The PO must review the HIPAA Authorization to ensure it contains all required elements and is consistent with all privacy requirements. Note: VA Form 10-0493, Authorization for Use & Release of Individually Identifiable Health Information must be used.
- Oversee the conduct of the research and monitor protocol compliance.
- Provide a mechanism to receive and address concerns from local study participants and others about the conduct of the research.
- Investigate, manage, and provide notification to the NCI CIRB of any study-specific incidents, experience, or outcome that may rise to the level of an unanticipated problem and/or serious or continuing noncompliance. When notifying the NCI CIRB of a potential unanticipated problem and/or serious or continuing noncompliance, the institution must provide a plan to manage the incident, experience, or outcome, including measures to prevent similar occurrences. Incorporate procedures for reporting to ORO.
- Provide updates in a timely manner to the NCI CIRB whenever a Signatory Institution Principal Investigator is replaced. The CIRB requires submission and approval of the Annual Principal Investigator Worksheet About Local Context prior to finalizing the replacement Principal Investigator.
- Notify the NCI CIRB when a regulatory deficiency has been cited on an audit that occurred during the time that the NCI CIRB was responsible for study review.
- If the study involves pregnant women or children, get facility Director certification for inclusion of these vulnerable populations (it can also be local policy that these populations will not be included in NCI studies).
- Determine if non-Veterans should be enrolled in a NCI study at their facility.

Responsibilities of the Local IRB

- Act as Privacy Board if a HIPAA waiver is needed for subject recruitment. **Note:** In the world of oncology, treatment often consists of placement in a research protocol. If a VA clinician is seeing an oncology patient as part of his or her clinical duties and during the course of that clinical visit sees that the patient could be offered a clinical trial treatment protocol, there is no requirement nor a need for a waiver of HIPAA authorization to be obtained for research purposes because no clinical data was accessed for research – the clinical data was accessed as part of the clinical visit in treating the patient. However, if the clinician evaluating the patient as part of clinical duties has to search his or her patients' medical records to determine eligibility for protocol research purposes, the authority under HIPAA must exist through either a written HIPAA authorization signed by the patient or the patient's personal representative or a waiver of HIPAA authorization approved by the IRB for that data to be accessed for research purposes. Assure that the investigator has made the correct

determination about whether a HIPAA Authorization or a Waiver of Authorization is required.

- Ensure that the HIPAA authorization, consent document, and protocol are consistent.
- Conduct full board review of any study enrolling prisoners (with a waiver by the CRADO), since the NCI CIRB is not constituted to review studies enrolling prisoners. Note: Prisoners would never be the focus of a NCI study. So, this would only be an issue if a participant became incarcerated during the study. However, it is difficult to continue therapy when a participant is incarcerated due to prison rules. Thus, in most cases, the participant would need to be withdrawn from the study.
- If the study will enroll subjects lacking decisional capacity, determine that the conditions for enrollment have been met (see VHA Handbook 1200.05).

Responsibilities of the Investigator

- Incorporate NCI CIRB-approved boilerplate language into the NCI CIRB-approved model consent form to create the consent form to use for a specific study:
  a) Make no language changes to the consent form with the exception of NCI CIRB-approved boilerplate language and approved VA specific language;
  b) Obtain NCI CIRB approval of changes to the boilerplate language prior to implementation; and
  c) Obtain NCI CIRB approval of translations of the consent form prior to implementation.
- Develop a recruitment plan. If potential subjects are to be identified from CPRS, request a waiver of HIPAA authorization to view records (see above note).
- Maintain a regulatory file for each study under NCI CIRB purview as per local institution and sponsor policy.
- Maintain compliance with state, local, or institutional requirements related to the protection of human subjects.
- For studies under a Certificate of Confidentiality, a progress note entry should indicate that an individual has been enrolled in a research study, any details that would affect the subject's clinical care, and the name and contact information for the investigator conducting the study. Subjects' informed consent forms and HIPAA authorization documents are not to be included in the health record.
- Reporting unanticipated problems involving risks to subjects or others, serious unanticipated problems involving risks to subjects or others, local unanticipated serious adverse events, apparent serious or continuing noncompliance, any termination or suspension of research; and privacy or information security incidents related to VA research, including: any inappropriate access, loss, or theft of PHI; noncompliant storage, transmission, removal, or destruction of PHI; or theft, loss, or noncompliant destruction of equipment containing PHI, in accordance with local facility or IRB SOPs and VHA Handbook 1058.01.

Responsibilities of the RCO

- Conducts audits to ensure compliance with applicable federal, VA and local policy.
- Report any study-specific incident, experience, or outcome that may rise to the level of an apparent unanticipated problem and/or apparent serious or continuing noncompliance per the requirements of VHA Handbook 1058.01. The report to the NCI IRB is sent by the Signatory Institution Principal Investigator (PI) per NCI CIRB SOPs.
- Submit audit reports to the R&D Committee. Note: According to the Authorizing Agreement, the NCI Central IRB does not oversee the conduct of the study. Therefore, the audit reports do not need to be sent to the NCI Central IRB. Only an apparent unanticipated problem and/or apparent serious or continuing noncompliance should be submitted to NCI by the PI.