

# Human Subjects Research Checklist: Prerequisites to Study Start

- Study Protocol
- Investigator Brochure
- Institutional Review Board (IRB) or Institutional Ethics Committee (IEC) approved informed consent document
- Office for Human Research Protection (OHRP) federal wide assurance (FWA) number, or the IRB or IEC name and registration number, for each of the following:
  - Each Study Site (e.g. university, hospital, etc.)
  - IRB or IEC that will review the study
  - Any other body directly involved in the research
- Name and contact information for the primary physician at the center and/or CRO that will be primarily accountable for managing a subject/AE/SAE/etc.
- Approval letter from an IRB or IEC
- Documentation that the sub-recipient and all study staff responsible for the design or conduct of the research have received training in the protection of human subjects.
- Approval letter (or equivalent) from the relevant regulatory agency in the US or any other country involved, e.g. FDA approval letter for an IND application for a US trial. Written documentation from FDA regarding comments, etc.
- Statement acknowledging satisfaction of all regulatory requirements of any country involved in the clinical trial, and responsibility for ongoing regulatory compliance.
- Description of the process used for scientific review of the Clinical Trial Protocol, e.g. who reviewed it, when it was reviewed, sign-off, etc.
- Written summary of PD's plans and procedures for: (1) Management of side effects; (2) Assessing and reporting adverse events; and (3) Data and safety monitoring, and monitoring of the clinical study site, pharmacy, and laboratory.
- Existing FDA or other regulatory agency submission documentation and correspondence
- Documentation of registration on ClinicalTrials.gov

**NB: BARDA and BU must review and approve all documents before a study may begin**