CARB-X

Combating Antibiotic Resistant Bacteria

Checklist of Documentation for Human Subjects Research Compliance

Information Requirement	Information (Entered below or uploaded to Box)
Study Protocol	*Upload document to Box. In file name please specify if draft or final version*
Investigator Brochure	*Upload document to Box. In file name please specify if draft or final version*
Informed Consent Form (ICF) **The following statement must be included in every ICF**: "This trial is funded by the Biomedical Advanced Research and Development Authority (BARDA) within the United States Government Department of Health and Human Services, and by the Wellcome Trust, a biomedical research charity based in London, United Kingdom."	*Upload document to Box. In file name please specify if draft or final version*
Office for Human Research Protections (OHRP) Federalwide Assurance (FWA) and/or Registration:	Complete the sections below as applicable:
FWA for the CRO performing the study, as applicable. FWA is not required of the CRO unless the study is being conducted at the CRO's facilities (e.g. Phase I Unit).	*Provide number and expiration date here*
FWA for each Study Site (e.g. university, hospital, Phase I Unit.	*Provide number(s) and expiration date(s) here as appropriate*
Registration for the IRB or IEC that will review the study.	*Provide number here*
FWA and/or Registration for any other body directly involved in the research, as applicable.	*Provide number here*
IRB Authorization Agreement (IAA) between BU and reviewing IRB/IEC for studies conducted in the **United States only.**	*Upload document to Box.*

Commented [THC1]: This statement may need to be changed depending on the funders for each particular company.

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The name and contact information for the primary physician at the study site and/or CRO that will be primarily accountable for managing a subject/AE/SAE/etc. at the study site	*Provide name and contact information here*
The Approval letter from an Institutional Review Board (IRB) or Institutional Ethics Committee (IEC). This must be the final, approved version, not conditional or provisional.	*Upload document to Box.*
Documentation that the Principal Investigator and all study staff responsible for the design or conduct of the research have received training in the protection of human subjects. This should include a list of staff along with a list of the modules/topics included in the training.	*Upload document to Box.*
An approval letter (or equivalent) from the relevant regulatory agency in the United States or any other country involved. **Studies conducted in the United States**: Studies of investigational drugs that are conducted in the US must have an IND from the FDA. Documentation of the FDA's IND approval is required. If the FDA does not approve and either has additional questions/comments or puts a clinical hold on the study, this documentation must be submitted. **Note:** The study cannot proceed until the IND is approved by the FDA.	*Upload document to Box.*
A statement confirming that all country-specific regulatory requirements are met and that the study will be conducted in compliance with these requirements for the duration of the study.	*Provide statement or upload statement document to Box.*
Evidence of appropriate insurance	

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Data Safety Monitoring (DSM) Process: description of the process, its charter or operating procedures (including a proposed meeting schedule and plan for review of adverse events), and roster and curriculum vitae from all members	*Text description or upload document to Box.*
Registration of the clinical trial on at least one of the following: • ClinicalTrials.gov (https://clinicaltrials.gov/) • ISRCTN registry (http://www.isrctn.com/) • another registry listed on the WHO International Clinical Trials Registry Platform (ICTRP) (http://www.who.int/ictrp/en/). Per NIH and FDA policies, trials have to be registered "no later than 21 days" after enrollment of the first participant. Please see BU's IRB informational page for more information. If you have questions if your study is an "applicable clincal trial" or is being conducted outside the US you can contact Heather Tobin (hctobin@bu.edu) for further guidance.	*Provide registration identifier here, e.g. ClinicalTrials.gov Identifier*
Plan for external sharing of clinical trial context: protocol, statistical analysis plan (SAP), etc. You must publish the trial protocols and SAPs before trial recruitment is complete. You can use Wellcome Open Research (https://wellcomeopenresearch.org/), along with other journals and platforms such as Trials (https://trialsjournal.biomedcentral.com/) and Protocols.io (https://www.protocols.io/), to do so.	

NOTE: This HSR compliance checklist must be completed and approved by Boston University, CARB-X, and BARDA *before* the screening of subject begins. Final approval cannot be granted until all the items above are completed.