CARB-X
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Human Subject Research (HSR) Checklist

This HSR compliance checklist must be completed and approved by Boston University, CARB-X, and BARDA *before* the recruitment, consenting, and screening of subjects begins. Final approval cannot be granted until all applicable items below are completed.

Information Requirement	Information (Entered below or uploaded to Box)
Study Protocol The plans for the management of safety events including side effects must be stated in the protocol. **Note:** If a clinical protocol has been reviewed by an Institutional Biosafety Committee (IBC), attach the approval letter and/or any information about the review.	*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 Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator (CARB-X) at Boston University. CARB-X is funded by a global consortium of governments and foundations including the Biomedical Advanced Research and Development Authority (BARDA) within the United States Government Department of Health and Human Services, and the Wellcome Trust, a biomedical research charity based in London, United Kingdom. Additional funders may include, and are not limited to, the Bill and Melinda Gates Foundation, the world's largest foundation dedicated to improving the quality of life for individuals around the world, the UK Government's Department of Health and Social Care (DHSC), through its Global Antimicrobial Resistance Innovation Fund (GAMRIF), a UK aid	*Upload document to Box. In file name please specify if draft or final version*

fund that supports research and development around the world to reduce the threat of antimicrobial resistance in low and middle income countries, and the Federal Ministry of Education and Research (BMBF), a cabinet-level ministry of the Federal Republic of Germany."	
Office for Human Research Protections (OHRP) Federal wide Assurance (FWA) and Registration: NOTE: By obtaining a FWA and Registration the CRO and/or Study Site agrees that they will comply with at least one of the human subject protection regulations identified on OHRP's website.	Complete the sections below as applicable:
FWA for the CRO performing the study, as applicable, if the CRO is engaged in the research.	*Provide number and expiration date here*
FWA for each Study Site (e.g. university, hospital, Phase I Unit) engaged in the research.	*Provide number(s) and expiration date(s) here as appropriate*
Registration for the Institutional Review Board (IRB) or Institutional Ethics Committee (IEC) that will review the study.	*Provide number(s) and expiration date(s) here as appropriate*
FWA and Registration for any other body engaged in the research, as applicable.	*Provide number(s) and expiration date(s) here as appropriate*
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 IRB or IEC. This must be the final, approved version, not conditional or provisional, or expired.	*Upload document to Box.*
A statement confirming that all country-specific and funder-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.*

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 reviewing the use of the drug, biologic and/or device in the research . **Studies conducted in the United States must have an IND/IDE from the FDA.** Documentation of the FDA's IND/IDE 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 with this checklist. **Note:** The study cannot proceed until the IND/IDE is approved by the FDA.	*Upload document to Box.*
For studies conducted in the United States: Confirmation that the following IND requirements were met at the time of application submission: • FDA Form 1572 for all investigators • Copy of medical license(s) submitted • CVs of all investigators listed on 1572(s) • Financial disclosure Form 3455 submitted	*Confirmation that these documents were submitted as part of the IND submission. If any of these documents were not included at the time of submission, please upload document(s) to Box.*
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 (CV) from all members.	*Text description or upload document to Box.*
Confirmation that a review of potential conflicts of interest for monitors/board members has been conducted as well as the outcome of that review.	*Text description or upload document(s) to Box.*
Research sponsored by BARDA requires ClinicalTrials.gov registration for Phase II-IV studies and Wellcome Trust requires registration for all HSR studies on at least one of the following platforms: • ClinicalTrials.gov	*Provide registration identifier here(e.g. ClinicalTrials.gov Identifier) and confirm that sponsors have been listed*

• ISRCTN registry • another registry listed on the WHO International Clinical Trials Registry Platform (ICTRP) For applicable clinical trials, 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. NOTE: All current funders must be listed as sponsors for this study. Your current funders are: [Insert Funders] For studies registered on ClinicalTrials.gov enter the following information under Secondary ID type: [Insert Award Numbers]	
Confirmation that the PD has the appropriate insurance. NOTE: Section B, Article 31, Section C, Article V, Section 5.03 (a) iii (and Attachment 5 as applicable) of the Portfolio Company Agreement further discusses the insurance	*Provide confirmation that insurance has been obtained*

CARB-X Team responsible for review	
BARDA Team responsible for review	
BU Administrative review	