IMPLEMENTATION CHECKLIST FOR CENTRALIZED ANCILLARY REVIEWS

The purpose of this checklist is to document any ancillary review responsibilities that one institution (i.e., a Reviewing Institution) will conduct on behalf of some or all sites participating in a multisite study. Of note, a Reviewing Institution for an ancillary review may or may not be the same as the Reviewing IRB Institution. Ancillary reviews are defined as evaluations performed to ensure compliance with institutional or funding entity policies, or by regulation, statute or law.

Who completes this checklist will vary depending on the number of ancillary reviews relevant to a study and which organization(s) will serve as the Reviewing Institution(s) for those ancillary reviews.

- If a single institution will act as the Reviewing Institution for all centralized ancillary reviews, then this institution should complete the checklist and ensure it is disseminated to all institutions relying on its review along with relevant supporting documents (e.g., additional reliance agreements when required).
- If there will be multiple Reviewing Institutions performing the different centralized reviews, then completion and distribution of this documentation is best coordinated by the Reviewing IRB, the Lead Study Team, or a coordinating center.

This checklist can be modified and tailored to a specific research study and may be used in conjunction with the SMART IRB Agreement Implementation Checklist and Documentation Tool, which covers ancillary reviews described within the SMART IRB Agreement, specifically related to conflict of interest and HIPAA Privacy Rule. Certain ancillary reviews, such as those conducted by an Institutional Biosafety Committee to comply with National Institutes of Health (NIH) requirements, may require additional documentation.

For further information, please see the SMART IRB Harmonization Steering Committee's complete guidance: *Recommendations for the Harmonization of Ancillary Reviews*.

Study Title:	
Overall PI:	
Site Investigator(s)	
Study ID No.	
Reviewing IRB:	
Relying Institution(s) for IRB review:	
Lead Study Team (if applicable):	
Date Completed:	

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Review Type	Review Option
Scientific Review	☐ OPTION 1 – Review Not Centralized: All institutions engaged in this research study will perform scientific review pertaining to overall study design, endpoints, outcomes. ☐ OPTION 2 – Centralized Review: will serve as the Reviewing Institution for this ancillary review and will perform scientific review pertaining to overall study design, endpoints, and outcomes for the study. The other institution(s) engaged in this research study will only make determinations at the institutional level of study feasibility, local study team qualifications, etc. ☐ OPTION 3 – The institutions engaged in this research study have agreed on an alternate plan for scientific review (this may include some but not all institutions relying on centralized review). PLEASE DESCRIBE THE ALTERNATE PLAN:
Institutional Biosafety Committee (IBC) Review *NOTE: Ceding IBC review to another institution requires an IBC Authorization Agreement.*	☐ OPTION 1 – Review Not Centralized: All institutions engaged in this research study will assess research involving recombinant or synthetic nucleic acid molecules for compliance with the NIH Guidelines and potential feedback on informed consent language and non-IRB related environmental health and safety issues for personnel (e.g., biological safety cabinet and blood borne pathogen training), adequacy of laboratory space and facilities, and compliance with institutional requirements. ☐ OPTION 2 – Centralized Review: will serve as the Reviewing Institution for this ancillary review and will assess research involving recombinant or synthetic nucleic acid molecules for compliance with the NIH Guidelines and potential feedback on informed consent language, while the other institution(s) engaged in this research study will only assess non-IRB-related environmental health and safety issues for personnel (e.g., biological safety cabinet and blood borne pathogen training), adequacy of laboratory space and facilities, and compliance with institutional requirements. ☐ OPTION 3 – The institutions engaged in this research study have agreed on an alternate plan for IBC review (this may include some but not all institutions relying on the centralized review). PLEASE DESCRIBE THE ALTERNATE PLAN:

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Review Type	Review Option
Radiation Safety	☐ OPTION 1 – Review Not Centralized: All institutions engaged in this research study will assess radiation risks posed by the overall study and adequacy of consent form language (taking into account potential variation in device radiation emission across sites). ☐ OPTION 2 – Centralized Review: will serve as the Reviewing Institution for this ancillary review and will assess radiation risks posed by the overall study and adequacy of consent form language (taking into account potential variation in device radiation emission across sites) while the other institution(s) engaged in this research study will only assess implementation of the study at the local institution, such as personnel expertise, training and licensing requirements; compliance with institutional requirements, procedures, and practices; and state law. ☐ OPTION 3 – The institutions engaged in this research study have agreed on an alternate plan for radiation safety review (this may include some but not all institutions relying on the centralized review). PLEASE DESCRIBE THE ALTERNATE PLAN:
Information Technology (IT) Security	☐ OPTION 1 – Review Not Centralized: All institutions engaged in this research study will review overall approach to ensure adequacy of any centralized data storage, expectations for data storage and transmission to ensure confidentiality, and security of any device or software required by or evaluated as part of the overall study. ☐ OPTION 2 – Centralized Review: will serve as the Reviewing Institution for this ancillary review and will review overall approach to ensure adequacy of any centralized data storage, expectations for data storage and transmission to ensure confidentiality, and security of any device or software required by or evaluated as part of the overall study, while other institution(s) engaged in this research study will only review local data storage and transmission systems' compliance with institutional requirements. ☐ OPTION 3 – The institutions engaged in this research study have agreed on an alternate plan for IT security review (this may include some but not all institutions relying on the centralized review). PLEASE DESCRIBE THE ALTERNATE PLAN:

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Review Type	Review Option
Clinicaltrials.gov	☐ OPTION 1 – Review Not Centralized: All institutions engaged in this research study will assess whether a study meets the definition of an applicable clinical trial and who is responsible for posting relevant information. ☐ OPTION 2 – Centralized Review: will serve as the Reviewing Institution for this ancillary review and will assess whether a study meets the definition of an applicable clinical trial and who is responsible for posting relevant information. ☐ This review does not apply to this study.
Coverage Analysis	☐ OPTION 1 – Review Not Centralized: All institutions engaged in this research study will identify and document whether a study is a Qualifying Clinical Trial that allows for billing certain study required items/services to insurance pursuant to applicable laws and regulations and determine and document billing designations for all patient care costs required by the study (i.e., identify Routine Costs that may be billed to a study participant and/or their insurer(s) vs. Study Costs for items/services that are primarily required for research purposes that should be paid for by research funding and/or support). ☐ OPTION 2 – Centralized Review: will serve as the Reviewing Institution for this ancillary review and will identify and document whether a study is a Qualifying Clinical Trial that allows for billing certain study required items/services to insurance pursuant to applicable laws and regulations and determine and document billing designations for all patient care costs required by the study (i.e., identify Routine Costs that may be billed to a study participant and/or their insurer(s) vs. Study Costs for items/services that are primarily required for research purposes that should be paid for by research funding and/or support). The other institution(s) engaged in this research study will only identify and assess any site-specific procedures not included in the study-wide coverage analysis. ☐ OPTION 3 – The institutions engaged in this research study have agreed on an alternate plan for coverage analyses (this may include some but not all institutions relying on the centralized review). PLEASE DESCRIBE THE ALTERNATE PLAN:

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