JOHNS HOPKINS UNIVERSITY

# JOHNS HOPKINS MEDICINE (JHM) IRB LOCAL CONTEXT QUESTIONNAIRE

Your site is participating in a study where JHM IRB will be the IRB of record. When relying on the JHM IRB, relying institutions must agree to provide the following important information to help the JHM IRB conduct its review:

- The requirements of any applicable state or local laws, regulations, institutional policies, standards, or other local factors, including local site ancillary reviews, relevant to the research that would affect the conduct or approval of the research at your institution.

**Please seek guidance from your HRPP/Research Office/IRB regarding how to complete the local context review process at your institution. Most IRBs require a local submission in order to initiate the local context review process.**

The local context questionnaire contains three important sections:

- Section 1: Relying Site Study Team Information
- Section 2: Applicable Local Requirements
- Section 3: The Conduct of this Study at the Relying Site

Please carefully review the approved protocol and complete the local context questionnaire below. We strongly recommend that the local context questionnaire be completed as a collaborative effort. Often, to ensure all necessary information is captured, information from the local site PI, in addition to the IRB/institutional contact is required. **Please Note**: Signatures by both the local site PI and the Institutional Contact are required. Please be as careful as possible in completing this questionnaire so that the document does not need to be re-signed.

Study team members with questions about completing this local context questionnaire can contact [INSERT CONTACT NAME] at [INSERT EMAIL ADDRESS]. If your organization's IRB has questions about this form, please contact Janelle Maddox-Regis at jmaddox3@jhmi.edu.

Your contributions to our IRB review process are important and we appreciate your assistance in providing your local context questionnaire.

**Study Title**: National COVID Cohort Collaborative (N3C): A national resource for shared analytics

**Overall Study PI**: Christopher Chute

**JHM IRB Protocol:** IRB00249128

## Section 1: Relying Site Study Team Information

| Relying Institution Information | |
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| **1a. Legal Name of Relying Institution:** | Click or tap here to enter text. |
| **1b. Name of Relying Site PI:** | Click or tap here to enter text. |
| **1c. Relying Site PI Phone #:** | Click or tap here to enter text. |
| **1d. Relying Site PI Email:** | Click or tap here to enter text. |
| **1e. Name of Relying Site Lead Study Contact:** | Click or tap here to enter text. |
| **1f. Relying Site Lead Study Contact Phone #:** | Click or tap here to enter text. |
| **1g. Relying Site Lead Study Contact Email:** | Click or tap here to enter text. |
| **1h. FWA #:** | Click or tap here to enter text. |
| **1i. FWA Expiration Date:** | Click or tap here to enter text. |
| **1j. Does your FWA require you apply 45 CFR 46 to all studies regardless of funding source (e.g., "check the box")?** | YES☐ NO☐ |
| **1k. List all institutions that are considered components under your FWA:** | Click or tap here to enter text. |
| **1l. Does your site have an IRB?** | YES☐ NO☐<br>*If YES, provide the IRB contact information:*<br><br>URL for the IRB/HRPP (*if applicable*):<br>Click or tap here to enter text. |
| **1m. Is your site AAHRPP accredited?** | YES☐ NO☐ |
| **1n. Please review the planned list of personnel who will be engaged in human subjects research at your institution and verify that all of your institutionally-required training for the conduct of the research [including human subjects protections training, GCP training, and HIPAA training, as applicable] has been completed for each individual.** | Training Completed ☐<br><br>***Note: This form should not be submitted for central review if training has not been completed.*** |
| **1o. Are all involved individuals from your institution credentialed and/or appropriately qualified and meet the institution's standards for eligibility to** | I confirm that all involved individuals are credentialed and/or appropriately qualified ☐ |

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| **conduct the research as described in the approved protocol?** | ***Note: This form should not be submitted for central review unless all individuals are credentialed and/or appropriately qualified.*** |
| **1p. Did the institution determine there is a relevant individual or institutional financial COI for this protocol?** | YES ☐ NO ☐<br>***If yes:***<br><br>(1) Provide a summary of the conflict and management plan or attach documentation:<br>**Click or tap here to enter text.**<br><br>(2) Provide an institutional Point Of Contact for questions related to the local management plan [This person should be someone in the office/entity who prepared the management plan]:<br><br>Click or tap here to enter text. |

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## Section 2: Applicable Local Requirements

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| **2a. Please review the protocol and identify areas where there are unique state, local or federal regulatory requirements that apply to the conduct of this study at your site (e.g., legally authorized representatives, state laws regarding confidentiality of specific types of health information, emancipated minors) and describe any steps that must be taken to adhere to these requirements.**<br><br>*Note: Only include what's relevant to the conduct of this study at your site. Please outline any specific changes needed to ensure adherence with the requirements you have identified. This information needs to be considered as part of the JHM IRB review.* | Click or tap here to enter text. |
| **2b. Please review the protocol and identify any institutional requirements (e.g., policy or procedural requirements such as recruitment, data security, remuneration) that apply to this study and describe any steps that must be taken to adhere to these requirements.**<br><br>*Note: Only include what's relevant to the conduct of this study at your site. Please outline any specific changes needed to ensure adherence with the requirements you have identified.* This information needs to be considered as part of the JHM IRB review. | Click or tap here to enter text. |
| **2c. Does your organization require that the IRB grant a waiver of privacy authorization under HIPAA for any of the following recruitment activities?** | Check all that apply:<br><br>☐ Medical record review or other access to PHI (of potential subjects who are patients of the research team)<br><br>☐ Medical record review or other access to PHI (of potential subjects who are not patients of the research team) |

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| | ☐ N/A to the conduct of this study at this site |
| **2d. Please identify the ancillary reviews [e.g., radiation safety review, review for research with bio-specimens, drug/device safety review, etc.] that are <u>applicable to this study</u> and are required before the study may be initiated <u>at your site</u>.**<br><br>**Please confirm that these ancillary reviews have been completed and provide the outcome of those reviews (including any changes required to the conduct of the study).** | Click or tap here to enter text.<br><br>N/A – no ancillary reviews ☐<br><br>Ancillary Reviews Completed ☐<br><br>*Provide the ancillary review outcome(s) and attach any relevant documentation:*<br><br>Click or tap here to enter text. |
| **2e. Are there sources of support that are unique <u>to your site</u>?** | YES ☐ NO ☐<br>If *yes*, Check all sources of support (pending or awarded) and indicate the source name:<br><br>☐Monetary<br>☐Material or Equipment (e.g., drugs or devices)<br>☐None of the above<br><br>Click or tap here to enter text. |

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## Section 3: The Conduct of This Study at the Relying Site

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| **3a. Are there any differences to <u>the initial contact and/or recruitment plan at your site</u> from that described in the protocol or associated documents based on local requirements or state law?** | YES ☐ NO ☐<br><br>***If <u>yes</u>**, please describe the differences and specify whether you have attached any site-specific recruitment materials for IRB review:*<br><br>Click or tap here to enter text. |
| **3b. Please review the protocol and verify that there are sufficient resources available at your site to carry out the research as planned, including study team members with prior clinical trial experience.**<br><br>*If any changes are required to the study plan related to the resources available at your site, please outline the required changes.* | YES ☐ NO ☐<br><br>***(Please note: the answer to this must be YES prior to submission)***<br><br>Click or tap here to enter text. |
| **3c. Are there any different requirements for how <u>data will be accessed and/or stored</u> at your site from those described in the protocol or associated documents based on local requirements or state laws?** | YES ☐<br>NO ☐<br>N/A to this study's conduct at this site ☐ |
| **3d. Are there any other different requirements for <u>how the protocol will be implemented and/or conducted</u> at your site based on local requirements or state laws?** | YES ☐ NO ☐<br><br>***If <u>yes</u>**,* explain: Click or tap here to enter text. |
| **3e. Does your institution have any policies related to data security?** | YES ☐ NO ☐<br><br>***If <u>yes</u>**,* please describe: Click or tap here to enter text. |
| **3f. Please confirm that the plans for data sharing as outlined in the protocol comply with your institutional requirements. If additional requirements [e.g. agreements, data security provisions, etc.] are required for your site please provide a summary of these requirements with your response.** | Click or tap here to enter text. |

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| **3g. Does your site have a data security/governance committee that is required to review and approve this protocol prior to implementation?** | YES ☐ NO ☐<br><br>***If yes***, please indicate their review outcome and/or attach their approval letter:<br><br>Click or tap here to enter text. |
| **3h. Please review the protocol and identify whether there are any special characteristics/concerns of your community of which the reviewing IRB should be aware for this specific study. Please also outline any steps that must be taken to address these concerns.** | Click or tap here to enter text.<br><br>☐ None<br>☐ Characteristics/concerns have been identified.<br><br>Explain: Click or tap here to enter text. |
| **3i. It is possible that the JHM SIRB may have additional questions about your local community. Please include the best contact below for additional questions about local site information.** | Local Site Contact Name: Click or tap here to enter text.<br>Email Address: Click or tap here to enter text.<br>Phone # Click or tap here to enter text. |

## Signatures/Attestations

By signing below, the signatories affirm that they have reviewed the SMART IRB Agreement, Letter of Indemnification and the responsibilities of relying institutions and attest that the information fulfills the relying institutions responsibilities for the provision of local context information.

As specified in the Agreement, Relying Institution is solely responsible for consulting with its own legal counsel to determine whether research reviewed by Reviewing IRB (including but not limited to any consent process or documentation and any HIPAA documentation), meets all other applicable federal, state, and local legal and policy requirements, including but not limited to HIPAA compliance. Relying Institution is solely responsible for identifying all ancillary reviews required by applicable regulation or policy in the Reliance Application and must notify Reviewing IRB of the outcome of such reviews prior to final protocol approval.

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| Local Site Investigator Signature: | Institutional Contact [e.g. HRPP Lead] Signature:<br><br>Role/Title: Click or tap here to enter text. |
| Print Full Name: Click or tap here to enter text. | Print Full Name: Click or tap here to enter text. |
| Contact Phone Number/Email: Click or tap here to enter text. | Contact Phone Number/Email: Click or tap here to enter text. |
| Date of Signature: Click or tap here to enter text. | Date of Signature: Click or tap here to enter text. |