**UNIVERSITY OF CALIFORNIA, SAN DIEGO**

**PARTICIPATING SITE**

**LOCAL CONTEXT QUESTIONNAIRE**

Your site is participating in a study where University of California, San Diego (UCSD) IRB serve as the IRB of record. When relying on the UCSD IRB, relying institutions must provide the following information to assist UCSD IRB 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.
* Site-specific consent information for this study using the template provided by the UCSD PI.

The local context questionnaire contains four important sections:

* Section 1: Relying Site Study Team Information
* Section 2: Local Requirements
* Section 3: Study – Specific Local Requirements
* Section 4: Relying Site Study-Specific Information

Please review the approved protocol and the approved master template consent form and complete the local context questionnaire below. Provide any locally required consent form language using the site-specific template provided. **Please Note**: The master template consent is provided to facilitate your local context review only and is not approved for use to enroll subjects. A site-specific consent form will be created by the UCSD IRB using the approved master template consent form and the completed site-specific consent template that you provide.

We strongly recommend that the local context questionnaire be completed as a collaborative effort with your IRB/Local Context contact to ensure all necessary information is provided. **Please Note**: Signatures of both the local site PI and the Institutional Contact are required. Take care in completing this questionnaire as changes may require that the document be re-signed.

For questions about completing this local context questionnaire, you contact the UCSD Single IRB Team at irbrely@ucsd.edu.

**UCSD PI**: Click or tap here to enter text.

**UCSD IRB Protocol:** Click or tap here to enter text.

 **Study Title**: Click or tap here to enter text.

**Section 1: Relying Site Study Team Information**

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| **Relying Institution Information** |
| 1. Legal Name of Relying Institution:
 | Click or tap here to enter text. |
| 1. Name of Relying Site PI:
 | Click or tap here to enter text. |
| 1. Relying Site PI Phone #:
 | Click or tap here to enter text. |
| 1. Relying Site PI Email:
 | Click or tap here to enter text. |
| 1. Name of Relying Site Lead Study Contact:
 | Click or tap here to enter text. |
| 1. Relying Site Lead Study Contact Phone #:
 | Click or tap here to enter text. |
| 1. Relying Site Lead Study Contact Email:
 | Click or tap here to enter text. |
| FWA #: | Click or tap here to enter text. |
| FWA Expiration Date: | Click or tap here to enter text. |
| 1. Does your FWA require you apply 45 CFR 46 to all studies regardless of funding source?
 | YES[ ]  NO[ ]   |
| List all institutions that are considered components under your FWA: | Click or tap here to enter text. |
| Does your site have an IRB? | YES[ ]  NO[ ]  ***If YES,*** *provide the IRB contact information:*Add URL for the IRB/HRPP (*if applicable*):Click or tap here to enter text. |
| Does your institution require the HIPAA authorization to be separate, or can it be included in the consent form? | Must be Separate [ ]  Can be included in ICF [ ] *Provide any site-required language in the site-specific consent information template. If your site does not have any specific HIPAA authorization language requirements, the UCSD HIPAA language [already incorporated into the consent template] will be used for your site.*  |
| 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 [ ]  ***Note:*** *This form should not be submitted for sIRB review if training has not been completed.*  |
| Are all involved individuals from your institution credentialed and/or appropriately qualified and meet the institution's standards for eligibility to conduct the research as described in the approved protocol? | I confirm that all involved individuals are credentialed and/or appropriately qualified [ ]  ***Note:*** *This form should not be submitted for sIRB review unless all individuals are credentialed and/or appropriately qualified****.***  |
| Did the institution determine there is a relevant individual or institutional financial COI for this protocol? | YES [ ]  NO [ ]  ***If yes****:*(1) Provide a summary of the conflict and management plan or attach documentation:**Click or tap here to enter text.**(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]:**Click or tap here to enter text.** |

**Section 2: Applicable Local Requirements**

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| 1. Please review the protocol and template consent 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.

*Note: Only include what is 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 may include site-specific consent form language based on state law requirements [e.g. reportability of test results for infectious diseases]. This information must be considered as part of UCSD IRB review.* | Click or tap here to enter text. **Do any of the applicable local regulatory requirements noted in this section have associated consent form language requirements?**YES [ ]  NO [ ]  *If you marked ‘yes’ above, please ensure the applicable consent form language is include in the site specific consent information pages for your site.* |
| 1. Review the protocol and template consent 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.

*Note: Only include what is 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 may include changes to the consent form to include any language required based on local site requirements [e.g. any specific local site policy requirements related to consent for future use of biospecimens].* This information must be considered as part of UCSD IRB review*.*  | Click or tap here to enter text.**Do any of the applicable institutional requirements noted in this section have associated consent form language requirements?**YES [ ]  NO [ ]  *If you marked yes above, please ensure the applicable consent form language is include in the site specific consent information pages for your site.* |
| 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:* [ ]  Medical record review or other access to PHI (of potential subjects who are patients of the research team)
* [ ]  Medical record review or other access to PHI (of potential subjects who are not patients of the research team)
* [ ]  Telephone or in-person screening prior to the signing of a written privacy authorization

[ ]  N/A to the conduct of this study at this site |
| Does your site have a specific requirement for who may obtain informed consent for this research? | YES [ ]  NO [ ]  ***If yes****,* *please describe the requirement and how you will manage it.*Click or tap here to enter text. |
| Please identify the ancillary reviews [e.g., radiation safety review, review for research with biospecimens, drug/device safety review, etc.] that are applicable to this study and are required before the study may be initiated at your site.*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.N/A – no ancillary reviews [ ] Ancillary Reviews Completed[ ] *Provide the ancillary review outcome(s) and attach any relevant documentation:*Click or tap here to enter text. |
| Are there sources of support that are unique to your site?  | YES [ ]  NO [ ]  **If *yes***, Check all sources of support (pending or awarded) and indicate the source name: [ ]  Monetary[ ]  Material or Equipment (e.g., drugs or devices)[ ]  None of the aboveClick or tap here to enter text. |
| Will your site require pregnancy testing to verify eligibility for study participation? | YES [ ]  NO [ ]  NA [ ] ***If yes****,* *please include any language in your site-specific consent template.* |
| Does your institution have any policies related to data security? | YES [ ]  NO [ ]  ***If yes****,* *please describe:*Click or tap here to enter text. |
| 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. | YES [ ]  NO [ ]  Click or tap here to enter text. |

**Section 3: Study-Specific Local Requirements – As Applicable**

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| 1. *Complete if study is approved for enrollment of adults lacking capacity to consent:*

Please identify any relevant state law or local policy requirements pertaining who may serve as a legally authorized representatives (LARs) providing informed consent for subjects lacking the capacity to consent. Please confirm that you will adhere to these requirements. | NA [ ] Click or tap here to enter text. |
| 1. *Complete if study is approved for enrollment of adults lacking capacity to consent:*

Identify any relevant state law or local policy requirements for assessing the capacity to consent (and/or determining whether an individual lacks capacity) and describe how capacity to consent will be assessed. | NA [ ] Click or tap here to enter text. |
| 1. *Complete if study is approved for enrollment of adults lacking capacity to consent:*

Provide a description of any site-specific requirements regarding re-consent when using a legally authorized representative. If re-consent is required per local law or institutional policy, please be specific as to whether the re-consent must be conducted in writing. Please provide a link to any applicable local laws or institutional policies related to re-consent. | NA [ ] Click or tap here to enter text. |
| 1. *Complete if study includes research dispensed drugs/devices:*

Does your site have an ancillary committee/reviewer that has reviewed and approved your plan for drug/device management (e.g., storage, dispensation and/or handling)?  | NA [ ]  YES [ ]  NO [ ]  ***If No,*** *Please describe your institution’s plan for the storage, dispensing and monitoring of the study drug/device.*Click or tap here to enter text. |
| 1. *Complete if study is using traditional/high-efficacy drugs:*

Are any of the approved drugs in either the first-line (traditional) therapies or second-line (higher-efficacy) therapies not considered a standard of care option at your site? | NA [x]  YES [ ]  NO [ ]  ***If yes***, please explain and explain how this will be addressed at your site:Click or tap here to enter text. |

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| 1. *Complete if study is approved for enrollment of non-English speakers:*

This study is approved for enrollment of non-English speakers. Which of the following applies to your site? | [ ]   N/A - We will **not** enroll non-English speakers[ ]  We do not plan to target, but may enroll a non-English speaker[ ]  We plan to target non-English speakers**Please Note: If you plan to target non-English speakers, you are required to use a translated consent form. Please provide translated site-specific consent information sheet(s) after the English version has been approved.** |
| *Complete if study is approved for enrollment of non-English speakers and adjust the options based on whether the study allows for a short form process:* If your site will not target, but may enroll a non-English speaker, please select one of the following options: | ☐ N/A – We will **not** target non-English speakers as indicated above.☐ We plan to use our site-approved short form ☐ We plan to use the UCSD IRB short form☐ My site does not allow use of a short form. We plan to use a translated consent form [**Please provide translated site-specific consent information sheet(s) after the English version has been sIRB-approved**] |
| 1. *Complete if emancipated minors may be enrolled:*

Please identify any state law or local policy requirements pertaining to when a minor is emancipated and other requirements/conditions under which a minor can provide consent. | [ ]   N/AClick or tap here to enter text. |
| 1. *Complete if mandatory reporting is required:*

Please provide your institutional or state requirements for HIV testing and STI reporting and provide the specific required consent language related to these requirements. | [ ]   N/AClick or tap here to enter text. |
| 1. *Complete if mandatory reporting is required:*

Please identify any state law or local policy requirements pertaining to HIV testing/reporting. | [ ]   N/AClick or tap here to enter text. |

**Section 4: The Conduct of This Study at the Relying Site**

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| Please select the activities that will be performed at your site and/or performed by your site’s employees (select all that apply) | [ ]   Screening/Recruitment[ ]   Consenting[ ]   Collection of Data/Biospecimens [ ]   Data/Biospecimen Analysis[ ]   Funding Only[ ]   Other: *Click or tap here to enter text.* |
| Are there any differences to the initial contact and/or recruitment plan at your site from that described in the protocol or associated documents based on local requirements or state law?  | YES [ ]  NO [ ]  NA [ ]  ***If yes****, please describe the differences and specify whether you have attached any site-specific recruitment materials for IRB review:*Click or tap here to enter text.  |
| Please review the protocol and template consent form 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. *If any changes are required to the study plan related to the resources available at your site, please outline the required changes.* | YES [ ]  NO [ ]  ***(Please note: the answer to this must be YES prior to submission)***Click or tap here to enter text. |
| Are there any different requirements for how data will be accessed and/or stored at your site from those described in the protocol or associated documents based on local requirements or state laws? | YES [ ]  NO [ ]  N/A to this study’s conduct at this site [ ]  ***If yes***, please describe the differences:Click or tap here to enter text. |
| Are you proposing any variation from the currently approved consent process and/or process for documentation of consent at your site? | YES [ ]  NO [ ]  NA [ ]  ***If yes***, please describe the differences:Click or tap here to enter text. |
| 1. Are there any other different requirements for how the protocol will be implemented and/or conducted at your site based on local requirements or state laws?
 | YES [ ]  NO [ ] ***If yes***, explain: Click or tap here to enter text. |
| 1. Provide a brief description of your institution’s human subjects protection training requirements for researchers and study staff.
 | Click or tap here to enter text. |
| 1. If your institution has a post-approval monitoring program or other regulatory oversight for ongoing research, please provide a description of the monitoring program. The description can be attached to this document.
 | Click or tap here to enter text. |
| Review the protocol and template consent 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.[ ]  None[ ]  Characteristics/concerns have been identified. Explain: Click or tap here to enter text. |
| Select one [or more] of the following options as they relate to COVID restrictions on research activities at your site: | [ ]  I confirm that there are no COVID-related restrictions that would limit my site’s ability to begin research [ ]  My site is not currently permitting this type of research to start [ ]  My site has restrictions on specific research activities as described below:Click or tap here to enter text. |
| 1. The UCSD sIRB Team 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.Email Address: Click or tap here to enter text.Phone # Click or tap here to enter text.  |

**Signatures/Attestations**

[USE FOR SMART AGREEMENT]

By signing below, the signatories affirm that they have reviewed the SMART IRB Agreement 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.

[USE FOR NON-SMART AGREEMENT]

By signing below, the signatories affirm that they have reviewed the agreement 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: 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. |