Use this form for research that involves a reliance agreement. The form provides a snapshot of the research as it will be conducted by a Participating Site or “pSite.” The Reviewing and Relying IRBs can use this form to help ensure that pSites meet their local requirements.

When study teams ask UMass Chan Medical School to rely on an external IRB (NCI CIRB, WIRB, Advarra, IRB at another academic institution, etc.), UMass Chan is the pSite. When study teams ask UMass Chan Medical School to review for an outside institution or collaborator, the outside institution or collaborator is the pSite. This form should be submitted to the UMMS Chan IRB in each case. The UMMS Chan IRB will accept similar forms from other institutions.

**Recommended process when study teams are working together across sites:** The study team at the lead site completes the form in consultation with its IRB before sharing the form with the pSite. The pSite adds its site-specific information and shares the form with its own IRB or HRPP (Human Research Protection Program). The final completed form is provided to both study teams, the Reviewing IRB, and the pSite IRB/HRPP office.

**Recommended process when the study is multi-site, and UMass Chan operates as an independent site, as is often the case for multi-site industry-sponsored trials using a commercial IRB:** The UMass Chan study team completes the form to describe its local context and shares the form with the UMass Chan IRB.

**Part 1: pSite Supplement**

1.

|  |  |
| --- | --- |
| Reviewing IRB: |  |
| Participating Site (pSite): |  |
| Study Title: |  |
| Funding Sources for Lead Site (include any federal funds even if pending): |  |
| Additional pSite Funding Sources (if any): |  |
| UMMS Investigator: |  |
| Other Site’s Investigator: |  |

2. Briefly describe the study and how the pSite is involved.

|  |
| --- |
|  |

3. What is the age range for the study subjects? (e.g., any, 18 to 65, 6 to 21; please do not say “adult” or “child” or “pediatric” as the meaning of these terms can vary by state and funding source)

|  |
| --- |
|  |

4. Does the research for the pSite involve any of the following:

|  |  |  |  |
| --- | --- | --- | --- |
|  | YES | NO | Optional Notes |
| Children |  |  |  |
| Neonates of uncertain viability |  |  |  |
| Nonviable neonates |  |  |  |
| Wards |  |  |  |
| Pregnant women |  |  |  |
| Prisoners |  |  |  |
| Purposeful enrollment of the pSite’s students or employees |  |  |  |
|  | YES | NO | Optional Notes |
| Testing for communicable diseases or other test results that require mandatory reporting; Note: see the UMass Chan consent template for suggested consent form language at our site |  |  |  |
| Pregnancy testing of minors; Note: see the UMass Chan consent template for suggested consent form language at our site |  |  |  |
| Proposed access to sensitive records through a waiver of consent or authorization (e.g., mental health, substance use, HIV test results, genetic testing); Note: federal and state law may restrict or prohibit such a waiver |  |  |  |
|  | YES | NO | Optional Notes |
| Obtaining consent from speakers of languages other than English |  |  |  |
| Obtaining consent with a short form rather than a translated form |  |  |  |
| Obtaining consent to enroll adults who lack capacity to consent for themselves |  |  |  |
| Obtaining assent from children or from adults who lack capacity |  |  |  |
| Obtaining signatures on informed consents and/or HIPAA authorization forms electronically |  |  |  |
|  | YES | NO | Optional Notes |
| Biospecimens |  |  |  |
| Ancillary review from: Biosafety; Note: if yes to biospecimens and no to biosafety review, Optional Notes should explain how this is possible |  |  |  |
| X-rays, CT scans, DEXA scans, fluoroscopy, etc. |  |  |  |
| Ancillary review from: Radiation Safety; Note: if yes to radiation and no to radiation safety review, Optional Notes should explain how this is possible |  |  |  |
| Financial interests related to the research for pSite personnel or the pSite as an institution |  |  |  |
| Ancillary review from: Conflict of Interest |  |  |  |
| Conflict of interest mitigation plan at the non-pSite (lead site) |  |  |  |
| Any other ancillary reviews; if yes, describe here or in the final column for optional notes: |  |  |  |

**If the protocol or study plan provides a complete and accurate description of the pSite processes, we recommend citing the page number/section when answering the questions below and copying the information into this form.**

5. Will pSite subjects be recruited to the study? If yes, describe the pSite processes or SOPs. For example, who invites subjects to participate? When and where will this occur? Are particular steps taken to ensure subject privacy?

|  |
| --- |
|  |

6. Will pSite subjects provide informed consent? If yes, describe the pSite processes or SOPs. For example, who obtains informed consent? Who provides informed consent? If the pSite involves enrollment of children or adults lacking capacity, are there any pSite policies or SOPs related to assent or assessment of cognitive capacity? When and where will the consent process take place? Are particular steps taken to ensure subject privacy?

|  |  |  |  |
| --- | --- | --- | --- |
| YES | NO | NA |  |
|  |  |  | The study team will follow HRP-090 SOP: Informed Consent Process for Research |
|  |  |  | The study team will follow HRP-013 SOP: Legally Authorized Representatives, Children, and Guardians |
|  | | | |

7. Will pSite subjects sign consent forms and/or authorization forms in writing? If yes, describe the pSite process to obtain these signatures. For example, are these paper forms that are handled in person? Will subjects provided a “wet signature” through REDCap or use a particular e-consent system?

|  |  |  |  |
| --- | --- | --- | --- |
| YES | NO | NA |  |
|  |  |  | The study team will follow HRP-091: Written Documentation of Consent |
|  |  |  | The study team will apply [HRP-803 Investigator Guidance: Documentation of Informed Consent – Temporary exceptions for research requiring written documentation of consent during the COVID-19 pandemic](https://www.umassmed.edu/ccts/covid-19/) (posted 03/25/2021) |
|  | | | |

8. The main protocol or study plan is unlikely to describe the specific pSite setting where primary research procedures or subject interactions will occur. Describe the local pSite setting where research procedures will be conducted.

|  |
| --- |
|  |

9. How will data be handled at the pSite? For example, does the pSite have to obtain some or all of the data through specific channels, such as the [UMCCTS Recruitment Core](https://www.umassmed.edu/ccts/research-resources/recruitment-resources/) and [Research Informatics Data Science Core](https://www.umassmed.edu/research-informatics/data_services/how-to-obtain-data/)? Where will data be stored at the pSite? How will data be transferred to and from the pSite? When and how will data at the pSite be destroyed?

|  |  |  |  |
| --- | --- | --- | --- |
| YES | NO | NA |  |
|  |  |  | Data will transfer from the lead site to the pSite. |
|  |  |  | Data will transfer from the pSite to the lead site. |
|  |  |  | The study involves [protected health information (PHI)](https://www.umassmed.edu/research-informatics/resources/hipaa-identifiers/). |
|  |  |  | PHI (including at least one of the [HIPAA identifiers](https://www.umassmed.edu/research-informatics/resources/hipaa-identifiers/)) will transfer from the lead site to the pSite. |
|  |  |  | PHI (including at least one of the [HIPAA identifiers](https://www.umassmed.edu/research-informatics/resources/hipaa-identifiers/)) will transfer from the pSite to the lead site. |
|  | | | |

10. Indicate how HIPAA applies to the pSite for the proposed research:

|  |  |  |  |
| --- | --- | --- | --- |
|  | YES | NO | Optional Notes |
| For the purposes of this research, HIPAA applies at the pSite |  |  |  |
| The pSite needs a HIPAA waiver to aid recruitment |  |  |  |
| The pSite needs a HIPAA waiver to obtain verbal authorization |  |  |  |
| The pSite needs a HIPAA waiver to collect data |  |  |  |
| The pSite will use the HIPAA waiver from the Reviewing IRB |  |  |  |
| The pSite will use a compound consent and authorization |  |  |  |
| The pSite will use a stand-alone HIPAA authorization |  |  |  |

11. Does the research at the pSite involve the use of approved or unapproved drugs? If yes, list the drugs, their regulatory status in the research, how they will be handled at the pSite, and any relevant ancillary reviews not mentioned earlier.

|  |  |  |  |
| --- | --- | --- | --- |
| YES | NO | NA |  |
|  |  |  | The study is conducted under an IND and a copy of the UMMS PI’s Mass Controlled Substances Registration is attached (MCSR Type: Researcher, Schedule: IND) |
|  |  |  | The Investigational Pharmacy will control the IND drug(s). |
|  | | | |

11. Does the research at the pSite involve testing the safety or effectiveness of any medical devices? If yes, list the devices, their regulatory status in the research, how they will be handled at the pSite such that they are used only by authorized investigations in subjects, and any relevant ancillary reviews not mentioned earlier (e.g., clinical engineering).

|  |
| --- |
|  |

12. Is there any information the Reviewing IRB needs because it would affect the research or informed consent documents?

|  |
| --- |
|  |

**Part 2: SMART IRB Communication Plan**

This information was obtained from the Template Communication Plan for SMART IRB as part of SMART IRB, which is funded by the NIH National Center for Advancing Translational Sciences through its Clinical and Translational Science Awards Program, grant number 3UL1TR002541-01S1.

*Definitions*

* REVIEWING IRB - Point of Contact (POC): Main person responsible for addressing questions related to the Reviewing IRB’s policies and procedures and review status for a ceded study
* LEAD STUDY TEAM - POC: Main person responsible for communication with the Reviewing IRB and facilitating communication between relying site study teams and the Reviewing IRB regarding the ceded study
* RELYING SITE - POC: Main person responsible for communication with the Reviewing IRB and local study team regarding the ceded study (e.g., personnel in the local IRB office or local human research protection program personnel)
* RELYING SITE STUDY TEAM POC: Main person responsible for communication with the Lead Study Team regarding the ceded study

***The UMass Chan Study team should review the selected Responsible Parties listed below for each Communication Responsibility and revise as necessary.***

| **Communication Responsibility** | **Responsible Party** | **Notes** |
| --- | --- | --- |
| COI: Providing applicable conflict of interest management plans for relying site study teams to the Reviewing IRB | Reviewing IRB  Lead Study Team  Relying Site Study Team(s)  Relying Site(s) POC(s)  Other, specify: |  |
| STUDY TEAM TRAINING & QUALIFICATIONS: Providing confirmation to the Reviewing IRB that relying site study teams have completed relevant training and are qualified to conduct the proposed research | Reviewing IRB  Lead Study Team  Relying Site Study Team(s)  Relying Site(s) POC(s)  Other, specify: |  |
| LOCAL CONTEXT INFORMATION: Providing local context information to the Reviewing IRB regarding state laws and institutional requirements that pertain to the review of the ceded study | Reviewing IRB  Lead Study Team  Relying Site Study Team(s)  Relying Site(s) POC(s)  Other, specify: |  |
| IRB APPLICATION – STUDYWIDE: Preparing and submitting the studywide application for initial IRB review and studywide amendments to the Reviewing IRB | Reviewing IRB  Lead Study Team  Relying Site Study Team(s)  Relying Site(s) POC(s)  Other, specify: |  |
| IRB APPLICATION – SITE-SPECIFIC: Preparing and submitting the site-specific applications and site-specific amendments to the Reviewing IRB that address site variations in study conduct, informed consent language, HIPAA Privacy Rule requirements, subject identification and recruitment processes (including recruitment materials), and any other applicable components of the research | Reviewing IRB  Lead Study Team  Relying Site Study Team(s)  Relying Site(s) POC(s)  Other, specify: |  |
| IRB DETERMINATIONS: Providing documentation of IRB determinations to relying site study teams | Reviewing IRB  Lead Study Team  Relying Site Study Team(s)  Relying Site(s) POC(s)  Other, specify: |  |
| IRB-APPROVED DOCUMENTS: Providing copies of IRB-approved materials to the lead study team | Reviewing IRB  Lead Study Team  Relying Site Study Team  Relying Site POC  Other, specify: |  |
| IRB-APPROVED DOCUMENTS – RELYING SITES: Providing copies of the most current versions of IRB-approved materials to relying site study teams in a timely manner | Reviewing IRB  Lead Study Team  Relying Site Study Team(s)  Relying Site(s) POC(s)  Other, specify: |  |
| CONSENT FORM TEMPLATE: Providing the consent form template to relying site study teams | Reviewing IRB  Lead Study Team  Relying Site Study Team(s)  Relying Site(s) POC(s)  Other, specify: |  |
| CONSENT FORM LANGUAGE: Incorporating site-specific language into consent form(s) and providing these consent form(s) to the Reviewing IRB | Reviewing IRB  Lead Study Team  Relying Site Study Team(s)  Relying Site(s) POC(s)  Other, specify: |  |
| REVIEWING IRB POLICIES: Providing relevant Reviewing IRB policies to the lead study team | Reviewing IRB  Lead Study Team  Relying Site Study Team(s)  Relying Site(s) POC(s)  Other, specify: | Indicate location: |
| CONTINUING REVIEW INFORMATION: Obtaining and collating studywide information for continuing review to the Reviewing IRB | Reviewing IRB  Lead Study Team  Relying Site Study Team(s)  Relying Site(s) POC(s)  Other, specify: |  |
| CONTINUING REVIEW SUBMISSION: Submitting continuing review progress report to the Reviewing IRB | Reviewing IRB  Lead Study Team  Relying Site Study Team(s)  Relying Site(s) POC(s)  Other, specify: |  |
| REPORTABLE EVENTS: Reporting reportable events to the Reviewing IRB (e.g., unanticipated problems, noncompliance, subject complaints) | Reviewing IRB  Lead Study Team  Relying Site Study Team(s)  Relying Site(s) POC(s)  Other, specify: |  |
| CLOSURE REPORTS: Providing the Reviewing IRB with required information when a study is closed. | Reviewing IRB  Lead Study Team  Relying Site Study Team(s)  Relying Site(s) POC(s)  Other, specify: |  |

**PART 3: Acknowledgment**

The UMass Chan IRB requests that the UMass Chan study team submit redline versions of pSite consent and authorization forms, if any, to the Reviewing IRB after the pSite IRB or HRPP conducts an administrative review of the documents and clears them for submission.

As Principal Investigators, primary individuals handling the IRB submission, and IRB/HRPP contacts assist in preparing this form, enter each individual’s printed information and a date of acknowledgment. Signatures are not required.

|  |  |  |
| --- | --- | --- |
| Name | Role and Institution | Date Acknowledged |
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