**Relying Individual Investigator Information Sheet**

|  |  |
| --- | --- |
| **Section 1: Study Information** – UChicago Study Team | |
| **Study Title** |  |
| **UChicago Study #** |  |
| **UChicago Amendment # (If applicable)** |  |
| **UChicago PI name** |  |

|  |  |
| --- | --- |
| **Section 2: Individual Investigator Information** – Relying Individual | |
| **Name of Individual** |  |
| **Contact Phone Number** |  |
| **Contact E-mail** |  |
| **Are you an employee or agent of University of Chicago Medical Center/University of Chicago?** | YES NO  *If YES, an Individual Investigator Agreement cannot be considered.* |
| **Are you conducting collaborative research activities outside the facilities of University of Chicago Medical Center/University of Chicago?** | YES NO  *If NO, please specify what facilities of the relying site you will be conducting research activities?* |
| **Are you acting as an employee of any institution with respect to your involvement in the research being conducted by University of Chicago?** | YES NO  *If YES, an Individual Investigator Agreement cannot be considered and an IRB Authorization Agreement will need to be executed.* |
| **If identifiable health information or PHI will be shared as part of the study, please confirm where it will be sent offsite. If not applicable, please state as such.** |  |
| **Indicate any human subjects protection training (HST) course(s) you have completed**  (such as CITI, GCP, [OHRP Training](https://www.hhs.gov/ohrp/education-and-outreach/human-research-protection-training/index.html)). | *Please ensure to provide a copy of your HST certificate.* |
| **Please indicate whether you have any financial interest related to this study, funder or sponsor.** NOTE: Any financial compensation or interest greater than $0 must be disclosed per institutional policy. If this relationship changes throughout the course of the study, this must be disclosed. | YES NO  If Yes, explain: |
| **Individual Investigator Specific Activities**  Will you complete all activities described in the protocol or is participation limited to specific activities? | Full protocol Limited protocol  Describe limited protocol activities for this site: |

|  |  |
| --- | --- |
| **Section 5: Relying Investigator Attestation and Signature**  By signing the below, I confirm that the information provided is accurately reflected in this document. By signing the below, I additionally agree to the following: | |
| I agree to conduct the study in accordance with the relevant, current protocol(s) and will only make changes in a protocol after notifying the overall study/lead UChicago PI, except when necessary to protect the safety, rights, or welfare of subjects.  I agree to provide any requested training and a current resume or CV.  I agree to sign a confidentiality agreement, if applicable.  I agree to inform (as applicable) any potential subject, or any persons used as controls, what activities are research activities and/or standard of care procedures.  I will ensure that the requirements relating to obtaining informed consent approved by the UChicago BSD IRB are followed, as applicable.  I agree to follow UChicago BSD IRB requirements to report promptly reportable events to the overall study/lead UChicago BSD IRB that occur in the course of the research.  I have read and understand the research protocol, including the potential risks of the research.  I agree that I have been informed about obligations in meeting the above commitments.  I agree to maintain adequate and accurate records in accordance with regulatory requirements and to make those records available for inspection by regulatory oversight agencies, including the University of Chicago.  I agree to provide pertinent information, including the progress report to the overall study/lead UChicago BSD IRB in a timely manner to comply with continuing review requirements (if applicable) and any other requests related to IRB oversight of this research.  I agree to promptly report to the overall study/lead UChicago PI all changes in the research activity and all unanticipated problems involving risks to human research participants or others, which would be communicated to the UChicago BSD IRB.  I confirm the work proposed does not involve any data, materials, drugs or devices from a company in which I have a financial interest, or in the case of a corporate sponsor, I have not received any payments, stock or equity from this sponsor in the past 2 years. If I have a financial interest, this has been appropriately disclosed and applicable management plan has been provided.  I will not make any changes in the research without prospective UChicago BSD IRB approval, except where necessary to eliminate apparent immediate hazards to human research participants.  I agree to comply with all other requirements regarding the obligations of principal investigators as a participating PI and all other pertinent requirements that I must adhere to, including local and state laws.  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Relying Individual Investigator Signature Date |