**Relying Individual Investigator Information Sheet**

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

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| **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: |

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| **Protocol Specific**  **Training:** | Describe how this individual will be trained for their role on this protocol. |
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**If the individual is enrolling, recruiting or consenting participants or will have access to study data please complete the questions below that are applicable. If they are not enrolling, recruiting, consenting participants or accessing or storing data, please skip to section 3.**

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| **Data and Specimen Storage:** | Data Should be stored and accessed according to BSD policy. Describe how the individual will access data/ study records. |
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| **Recruitment**  **Methods:** | Is this individual involved in recruitment?  YES NO  If Yes, please describe how recruitment will occur: |
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| **Consent**  **Materials:** | Please check all materials that will be used to obtain and document consent. |
| Consent Document  Letter or Information sheet containing elements of consent  Assent Document  Verbal/Phone Script  Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |

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| **Consent Process:** | Provide a step-by-step description of the enrollment and consent process for participants   * Describe each study population separately including control population * Describe who will be conducting the consent process * Include when recruitment and consent materials are used * Use THIRD person active voice. For example, "the principal investigator will identify potential participants, the study coordinator will discuss the study with participants over the telephone and schedule the first study visit, etc..." * Describe the steps that will be taken by the research team to minimize the possibility of coercion or undue influence during the consent process |
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| **Section 3: 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 |