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| This survey is intended for use when Drexel will be the IRB of record for external sites. The Drexel lead study team will distribute this survey to relying site study teams to gather information about particular regulatory and/or institutional requirements. The completed surveys should be submitted by the lead study team to Drexel IRB with the additional required documents for a reliance agreement. | |
| **General Information** | |
| Name of Study: | |
| Overall PI: | |
| Name of Relying Institution: | |
| Site PI Name, Degree, and Contact Information: | |
| Relying IRB Contact Information: | |
| **Financial Conflicts of Interest** | |
| Have any study personnel indicated a significant conflict of interest for this protocol?  Yes  No  If yes, please provide a summary of the management plan to the Overall PI. | |
| **Special Procedures and Populations** | |
|  | The study team may enroll subjects with impaired decision making capacity.  *If selected, describe how the study team will verify someone is qualified to be the potential subject’s Legally Authorized Representative.* |
|  | The study team may enroll prisoners.  *If selected, describe below how the study team will verify someone is qualified to be the potential subject’s Legally Authorized Representative, when applicable.* |
| For studies that involve a drug, biologic, and/or device, describe:   1. The specific location where study drugs/devices/biologics will be stored 2. How storage location will be secured 3. Who is responsible for study drug or biologic preparation 4. Who will dispense subject drug or biologic to the subject | |
| **Site Specific Protocol Information** | |
| Describe any differences between what is stated in the protocol and what activities will or will not be conducted at your site (e.g., Arm B of the protocol will not be conducted at our site). | |
| Describe how and when people will be recruited to participate in the study. Specify who and how investigators will be involved in recruitment and the consent process. Explain how people will be approached, what recruitment material will be used, and how long the person has to decide to participate. | |
| Describe the consent process (include who conducts the process and where). | |
| How many subjects do you intend to enroll at your site? | |
| **Medical Records** | |
| Will medical records be accessed prior to written consent, or with a waiver of consent?  Yes  No  Not applicable – no medical records will be accessed for this study  *If the study does not involve medical records, please skip to Data Handling and Storage section.* | |
| Describe how the PI will gain access to the records. | |
| **Data Handling and Storage** | |
| How and where will data (e.g., electronic, paper, audio) be stored at your site? | |
| Who will have access to the data? | |
| How is subject confidentiality protected? | |
| **Ancillary Review Confirmation** | |
| Please list any ancillary committee reviews that your site requires for this study, and indicate if the review is complete. | |
|  | All study personnel have completed local required research trainings. |
| Please list any other state or local context issues that may be applicable for this protocol. | |

Local IRB representative: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Local IRB representative signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_