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| **Question** | **UAB-specific response** |
| ***Regulatory Questions*** |
| Is your site affiliated with a Site Management Organization (SMO)? | No |
| Does your site have a local IRB/IEC? | Yes |
| Can your site utilize a central IRB/IEC? | Yes. **If we are given the choice, the preference is WCG IRB, as UAB IRB holds a master reliance agreement with them.** However, we are allowed to use any IRB of record, both commercial (e.g., Advarra, Sterling, etc) and another academic medical center. |
| How does your site complete reliance agreements for central IRB/IEC? | UAB IRB are members of SMART IRB, IREx, and TIN. |
| If your site can utilize a central IRB/IEC, are there any other regulatory requirements (e.g., institutional review, departmental review, etc?) | Yes. We have an institutional pre-review process that requires internal reviews by various ancillary departments (Pharmacy, Lab, Clinical Billing Office, Radiation Safety, Institutional Biosafety Committee [IBC], etc) as applicable. **IBC reviews (if applicable) must be completed locally via UAB IBC – we cannot use a central IRB’s IBC**. UAB IRB will only provide institutional signoff to use a central IRB once this process has been completed.  |
| In the past 5 years, has the FDA, OHRP, or other organization involved with the Protection of Human Subjects audited your site or affiliates? | Site – NoUAB IRB – NoPrincipal Investigator – Dependent on PISub-Investigator – Dependent on investigator |
| In the past 5 years has the FDA, OHRP, or other organization involved with the Protection of Human Subjects issued an FDA 483 letter or similar sanction following an audit? | Site – NoUAB IRB – NoPrincipal Investigator – Dependent on PISub-Investigator – Dependent on investigator |
| What is the initial IRB submission timeline? | 4-6 weeks, inclusive of reviews required for institutional signoff; may be longer if protocol is complex or requires certain ancillary reviews (e.g., Radiation Safety, IBC, etc) |
| ***Budget Questions*** |
| Can the budget/contract be negotiated at the same time as the initial IRB submission? | Yes |
| Does a contract have to be executed before IRB approval is granted, or vice versa? | In general: no, although this may be dependent on the IRB (some do require an executed contract before granting full IRB approval). **We do require an executed contract AND IRB approval prior to scheduling the SIV.** |
| What is the contract negotiation timeline? Are any separate agreements needed? | <<Site specific answer>>  |
| ***Monitoring & Electronic Medical Records*** |
| How are patient data captured at your site? | Both electronic medical records (EMR) & paper research charts |
| Name of EMR system: | Cerner IMPACT |
| Is your EMR 21 CRF Part 11 compliant? | Yes. A memo from UAB HSIS is available if requested. |
| Will monitors have direct access to EMR? | Yes. Monitors will be given a login with a unique ID to access a list of patient records curated by study coordinator. Site staff will submit access request on Monitor’s behalf. Monitor will undergo training before being allowed to access EMR. Monitor’s access will be limited only to the days of the monitor visit, and will be inactivated between those dates. It generally takes 4-6 weeks for requests to be completed by UAB HSIS (both initial and reactivation). Monitors will be required to give an employee ID number in order to receive a username. |
| ***Consent Forms & Processes*** |
| How does your site consent subjects? | <<Add your site specific informed consent process here>> |
| Do you have a Standard Operating Procedure (SOP) for consenting subjects? | <<Site specific answer>> |
| Are you able to obtain consent from a subject’s Legally Authorized Representative (LAR)? | Yes |
| ***Other commonly requested documents for PSVs:*** |
|  | * You will most likely be requested to supply the following SOPs:
	+ Informed Consent Process
	+ Record Retention
	+ IP Maintenance and Accountability – IDS Pharmacy can provide
* Signed and dated CVs (within last 2 years) for PI and Sub-Is
* Medical licenses for PIs and Sub-Is
* ICH GCP training reports for PIs and Sub-Is
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