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| --- | --- |
| **Date of Hand-off** |  |
| **Name of Current Coordinator** |  |
| **Name of New Coordinator** |  |
| **Sponsor** | *If IIT, note funding source* |
| **Protocol ID/SpartaIRB #**  **Short Name** |  |
| **Velos #**  **REDCap PID** |  |
| **Principal Investigator** |  |
| **Sponsor** |  |
| **CRO** | *If applicable* |
| **CRA** | *Name, location and contact details (email and mobile phone)* |
| **Site Number** | *Include Investigator Number if this is applicable* |
| **Internal Monitoring Process** | *If it is monitored by a UH employee, last time reviewed using Internal QA tools, monitoring frequency in protocol, etc* |
| **Study Status** | *Open to Recruitment, Awaiting SIV, In Follow up, etc* |
| **Patient Population** |  |
| **Number of Patients** | *Currently enrolled: #*  *Patients enrolled overall: #*  *Enrollment Goal: #* |
| **Primary Endpoint** |  |
|  |  |
| **Amendments** | *Include details of amendments received and progress such as submission dates, approval dates and reasons why we haven’t yet submitted (eg waiting for hard copies of the protocol).* |
| **Annual Report** | *Next report due: MM-DD-YYYY*  *Last report submitted: MM-DD-YYYY* |
| **Last Monitoring Report** | *Copy of last monitoring Report if applicable or scheduled date of visit.* |
|  |  |
| **Pharmacy** | *Include name of pharmacy and contact details of trial pharmacist* |
| **Investigational Product** | *Include name, route of administration, dosage, how often dispensed, dispensing procedure (if different from standard). Include most common adverse events, any prophylactic medication required (eg antiemetic’s) and location of important safety information (eg dosing modification guidelines, prerequisites for dosing etc).* |
| **IXRS** | *Provide details of system, location of manual and how to contact the helpdesk. For IWRS, include website address.* |
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| **SAEs** | *Include method of reporting SAEs (eg eCRF, paper form), location of form and completion instructions with submission email or fax number if not on the form.* |
| **AEs of Special Interest** | *List any AEs of special interest and summarize reporting timelines, how to report and other relevant information.* |
| **SUSARs** | *Provide SUSARs format and location (if electronic, who has access to these, website address etc).* |
|  |  |
| **Local Lab** | *Include name, contact details of lab staff. Include any study specific information that might be important (eg list of tests performed at local lab).* |
| **Central Lab** | *Include name, location of lab manual, contact details of lab staff, location of lab kits, how to order more kits, how reports are received (eg fax, web portal, email), date of last kit order or if automatic resupply.* |
| **Central Lab Courier** | *Include name of courier, how to book, fax/phone/email for booking, location of waybills, shippers declarations, packaging material etc* |
|  |  |
| **Radiology** | *Name of radiology provider, location, contact details, booking procedure* |
| **Central Radiology** | *Include name of radiology provider, location of radiology manual, contact details of central radiology, how to transmit images, how reports are received (eg fax, web portal, email) etc* |
| **Interventional Radiology** | *Scheduling person, number of cores needed, gauge of needle used, how cores are processed post biopsy, etc.* |
| **Other Departments Utilized** | *Contact information and any pertinent details from other departments utilized in protocol (ie Ophthalmology, Pathology, Audiology, etc)* |
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| **eCRF** | *Website address of eCRF, location of eCRF guidelines, timelines for eCRF entry, any tips and hints not included in the guidelines* |
| **Screening/Randomization** | *Include any study specific requirements for screening or randomization such how and when to enroll patients in the study, details of eligibility forms, explanations of anything that is not clear from reading the protocol.*  *Current ICF: Version x dated MM-DD-YYYY*  *Approved on: MM-DD-YYYY* |
|  |  |
| **Patient #*XXXX***  ***(add each patient)*** | *DOB:*  *Treating Doctor:*  *Date of IC:MM-DD-YYYY*  *Date of Randomization: MM-DD-YYYY*  *Last Visit: Name and date*  *Next Visit: Name and date*  *Allergies/Intolerances: No known*  *Brief narrative explaining any concerns with this patient such as work schedule, communication issues, requirements for transport, SAEs, ongoing AEs, problems with compliance, scenarios you had with patient, documentation was limited, etc* |
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| **Badge Access Needed** | *Building and doors where access is needed* |
|  |  |
| **Study Supplies and Storage** | *lab kits*  *subject binders*  *regulatory binder*  *investigational products*  *investigational devices,*  *study supplies*  *sponsor-provided equipment*  *etc..* |
|  |  |
| **Other Comments or Information** |  |