**Summary Sheet**

Site Initiation Visits (SIVs) occur prior to site activation/enrollment for a specific protocol. These visits have several objectives:

* To outline the protocol-specific activities required to facilitate the research site initiation process
* To orient and train staff on the protocol and study related processes *(sign the Protocol Training Log)*
* To ensure the study team understands their delegated duties/roles *(sign the Delegation of Authority Log)*
* To confirm the site is prepared to initiate the research. The SIV may identify additional requirements that must be satisfied before site activation/subject recruitment (e.g., obtaining appropriate clinic space, equipment, storage, etc.)

All members of the study team listed on the Delegation of Authority Log and IRB-approved application should attend the SIV (e.g., principal investigator (PI), sub-investigator(s), study coordinator(s), pharmacist(s), other specialized individuals/groups with a study-specific role and protocol-specified task). The meeting should lay the ground work for the study and allow all team members to ask any questions they may have prior to subject recruitment.

Supporting ancillary departments that are involved in the study, including the Investigational Drug Service (IDS), as applicable, also need to participate.

**Best Practice Considerations:**

* Define who is responsible for coordinating the SIV, and ensure all relevant parties are informed of the meeting date/time well in advance.
  + The SIV is typically conducted by the study sponsor or sponsor representative.
  + The SIV should occur after IRB approval of the study and before any study-related research procedures occur ([*see UUSOP-03, 1.1*](https://qualitycompliance.research.utah.edu/_resources/documents/uusop/uusop-03_protocol_training_17aug2020.pdf)).
* For Investigator Initiated Trials (IIT), identify who will prepare the agenda, create any presentation slides (if applicable), and conduct the SIV.
  + For IITs, the initial protocol training should be conducted by the principal investigator (PI) ([*see UUSOP-03, 1.2*](https://qualitycompliance.research.utah.edu/_resources/documents/uusop/uusop-03_protocol_training_17aug2020.pdf)).

IIT research should follow a similar plan as below.

* Customize a list of topics, order of presentation, and duration of each discussion item to the specific needs and requirements of the study, and provide the agenda to all study team members prior to the meeting (in case some members cannot attend the entire SIV, they can plan to be present during the sections pertinent to them)
* Study personnel unable to attend the SIV, or who are added to the research team after study initiation, must complete and document training before performing any study-related research procedures.
  + Initial training excludes self-training. Training must be conducted by the PI, sub-investigator, clinical research coordinator, or other appropriate study personnel who attended the SIV or has otherwise been previously trained ([*see UUSOP-03, 1.1-1.3*](https://qualitycompliance.research.utah.edu/_resources/documents/uusop/uusop-03_protocol_training_17aug2020.pdf)).

The following pre-requisites should be completed prior to the site initiation visit: protocol and consent have been approved by the IRB; the case report form and data collection system have been finalized; the Manual of Procedures (or set of study specific Standard Operating Procedures have been prepared); and all necessary site staff have been identified.

**Site Initiation Visit Agenda/Checklist**

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| **SCHEDULING THE SIV** | | | |
|  | **In Progress** | **Completed** | **Notes** |
| Maintain contact with the Regulatory and Grants & Contracts teams as you move closer to IRB approval and execution of the study contract. Begin planning the date of the site initiation visit (SIV) (ensure IRB approval has been obtained). |  |  |  |
| Establish a suitable date/time/location for the SIV:   * Can the SIV be conducted remotely/virtually? * Is a conference room with projector, internet, or other audiovisual aids needed? * What time will the SIV start, and what is the time commitment required for the attendees? (esp. for PI, Sub-I(s), pharmacy other special roles) * Who should all be in attendance? * Will a tour of the study facilities be necessary? And if so, what? |  |  |  |
| Send an Outlook invitation to all attendees (including Investigational Drug Services, if applicable) to make sure it is on everyone’s calendar. |  |  |  |
| **WEEK BEFORE THE SIV** | | | |
| Identify any sponsor-provided supplies needed once enrollment begins (e.g., CRFs, lab kits, shipping supplies, etc.). |  |  |  |
| Copy/obtain any study materials from the designated study staff member or sponsor that will be used during the SIV, so attendees can review the info. prior to the SIV and compose any questions/concerns for discussion at SIV. |  |  |  |
| Prepare any necessary logs to document SIV training and delegation (e.g., DOA and protocol training).  *\*Templates are available here:* [*https://qualitycompliance.research.utah.edu/toolkit.php*](https://qualitycompliance.research.utah.edu/toolkit.php) |  |  |  |

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| **CONDUCTING THE SIV** | | | |
| **REGULATORY:** | **In Progress** | **Completed** | **Notes** |
| Complete a staff signature sheet to document SIV training for the study records. |  |  |  |
| Complete the Delegation of Authority Log (DOA) to ensure that study team responsibilities are clearly assigned.  *\*Refer to* [*UUSOP-05, Delegation of Authority*](https://qualitycompliance.research.utah.edu/clinical-research-sops.php) *for University of Utah procedures re: the DOA.* |  |  |  |
| Confirm all key study personnel have the necessary training and access to fulfill the study requirements to which they are assigned (i.e., CITI/GCP training, HIPAA, COI, Biosafety training, if applicable, EDC/EDC certification, EMR access, etc.). |  |  |  |
| Review the plan for maintenance of the regulatory binder.  *\*Refer to* [*UUSOP-06, Study Records Management*](https://qualitycompliance.research.utah.edu/_resources/documents/uusop/uusop-06_study_records_management_17aug2020.pdf) *for detailed University of Utah procedures.* |  |  |  |
| Discuss the disposition of any participant compensation and the reconciliation of this information on any logs or in any study specific systems (i.e., gift cards, cash, checks, gifts, parking or meal vouchers, etc.). |  |  |  |
| Review instructions on study-specific activities, such as diagnostic tests, lab kits, study-required software, and/or any related recordkeeping requirements (i.e., temperature logs, calibration logs, etc.). |  |  |  |
| Identify important sponsor and/or monitoring body contacts and corresponding timeframes (i.e., enrollment logs, deviation reporting, safety reporting, etc.).  *\*Refer to* [*UUSOP-07, Deviations: Documentation and Reporting*](https://qualitycompliance.research.utah.edu/_resources/documents/uusop/uusop-07_documentation-and-reporting-deviations_17aug2020.pdf) *and* [*UUSOP-14, Safety Assessment and Reporting*](https://qualitycompliance.research.utah.edu/_resources/documents/uusop/uusop-14-clinical-trial-safety-assessment-and-reporting-14jan2022.pdf) *for details re: University of Utah procedures.* |  |  |  |
| **RECRUITMENT:** | **In Progress** | **Completed** | **Notes** |
| Confirm locations where enrollment will occur, study visits will be conducted, and discuss the study staff logistics of executing study procedures at those locations (study start date/end date).  Discuss:   * project timelines/recruitment goals * study population * screening/identification of potential participants * recruitment methods (ads, social media, radio, print, scripts, etc.) * subject retention procedures |  |  |  |
| **INVESTIGATIONAL PRODUCT, DEVICES, SPECIMENS:** | **In Progress** | **Completed** | **Notes** |
| Discuss test article shipment, receipt, inventory, administration, accountability, reconciliation.  Review:   * Description of Product * Investigator Brochure (IB) or Package Insert * Status of initial drug shipment (has drug been ordered/received at the study site?) * Storage * Dosing/Handling Instructions * Dispensing * Accountability * Return/Destruction Considerations * Unblinding Procedures (if applicable) * Documentation and use of Investigational Drug Services (IDS)/or exemption (if applicable) |  |  |  |
| **SAMPLE PROCESSING AND SHIPPING:** | **In Progress** | **Completed** | **Notes** |
| Review appropriate documents (e.g., protocol, lab manual, Manual of Procedures (MOP)) for all laboratory and specimen procedures, shipping requirements, and validations and certifications, if applicable.  Ask questions:   * Is there a set centrifugation time for blood samples? * How should the study blood be stored (i.e., temp)? * What labs will be used * What supplies are provided by the sponsor |  |  |  |
| **PROTOCOL:** | **In Progress** | **Completed** | **Notes** |
| Confirm the current version of the protocol. |  |  |  |
| Discuss type of study (design). |  |  |  |
| Review the study objectives/purpose. |  |  |  |
| Are any amendments expected in the near future? |  |  |  |
| Review the following:   * Informed Consent process * Enrollment goals (recruitment plans) * Visit Schedule/Schedule of Events (including visit windows) * Inclusion/Exclusion Criteria * Study Procedures   *\*Refer to* [*UUSOP-08, Obtaining Informed Consent*](https://qualitycompliance.research.utah.edu/_resources/documents/uusop/uusop-07_documentation-and-reporting-deviations_17aug2020.pdf) *for detailed University of Utah procedures.* |  |  |  |
| Review the risks associated with study participation and the steps to minimize any potential risks to study participation. |  |  |  |
| Discuss Safety Documentation and Reporting, including:   * Adverse Events (AEs) requirements; and ensure a study communication plan is in place * Serious AEs (SAEs) * Unanticipated Problems (UPs) * Protocol Deviations * Queries resulting from the above   *\*Refer to* [*UUSOP-07, Deviations: Documentation and Reporting*](https://qualitycompliance.research.utah.edu/_resources/documents/uusop/uusop-07_documentation-and-reporting-deviations_17aug2020.pdf) *and* [*UUSOP-14, Safety Assessment and Reporting*](https://qualitycompliance.research.utah.edu/_resources/documents/uusop/uusop-14-clinical-trial-safety-assessment-and-reporting-14jan2022.pdf) *for detailed University of Utah procedures.* |  |  |  |
| Discuss/Review the Manual of Procedures or SOPs, if no MOP exists |  |  |  |
| Document protocol training completed at SIV. Every attendee must sign the Protocol Training Log.  *\*Subsequent training of any study staff must also be documented on a Protocol Training Log. Refer to* [*UUSOP-03, Protocol Training*](https://qualitycompliance.research.utah.edu/_resources/documents/uusop/uusop-03_protocol_training_17aug2020.pdf) *for detailed University of Utah procedures.* |  |  |  |
| **DATA MANAGEMENT** *(Collection, Data Entry, Good Documentation Practices):* | **In Progress** | **Completed** | **Notes** |
| Review the data and record keeping plan for:   * Source Documentation (paper or electronic) * Electronic Data Capture (EDC) / Electronic Case Report Form (eCRF) training, access, and use (as applicable). * Electronic Medical Record Use and Access. * Query process (creation, review, and resolution).   *\*Refer to* [*UUSOP-06, Study Records Management*](https://qualitycompliance.research.utah.edu/_resources/documents/uusop/uusop-06_study_records_management_17aug2020.pdf) *and* [*UUSOP-09, Case Report Form Completion Standards*](https://qualitycompliance.research.utah.edu/_resources/documents/uusop/uusop-14-clinical-trial-safety-assessment-and-reporting-14jan2022.pdf) *for detailed University of Utah procedures.* |  |  |  |
| **MONITORING PLAN:** | **In Progress** | **Completed** | **Notes** |
| Review the monitoring plan, internal QA/QC plans, DSMB plan (if applicable) (e.g., frequency, scope, communications, etc.).  \**Refer to* [*UUSOP-10, Monitoring Visits for Externally Sponsored Clinical Trials*](https://qualitycompliance.research.utah.edu/_resources/documents/uusop/uusop-03_protocol_training_17aug2020.pdf) *for additional considerations.* |  |  |  |
| **RESOURCES, MATERIALS AND SUPPLIES** | **In Progress** | **Completed** | **Notes** |
| Are facilities, materials and supplies for clinical assessments available and in good working order (Review study logistics and inventory of supplies - i.e., clinic/exam rooms, equipment etc.)? |  |  |  |
| Conduct a site/facility tour (including IDS if applicable).  *\*Confirm what supplies are being provided by the sponsor vs. study site.* |  |  |  |
| **AFTER THE SIV** | | | |
|  | **In Progress** | **Completed** | **Notes** |
| File completion of the SIV visit (SIV completion Report) in the Regulatory Binder; and follow up/review any action items. |  |  |  |
| File the SIV signature sheet, Protocol Training log, and completed DOA log in the regulatory binder. |  |  |  |
| Make sure all outstanding questions or concerns are addressed prior to the first participant placed on study.  Examples:   * What is the turnaround time for ordering study supplies? * Is there a sponsor contact list for study questions? |  |  |  |
| Make sure all essential documents (CVs, licenses, and certifications) are on file. |  |  |  |
| File all training certificates in the regulatory binder. If the sponsor doesn’t provide a record of training, record the timing and details of any training sessions and file in the reg binder. |  |  |  |
| Assemble screening/enrollment materials; activate recruitment plan per IRB approval. |  |  |  |