## SOP 2: Study Initiation Meeting

### Overview:

1. The Consortium Lead Organization (CLO) Investigator, Site Coordinator, and/or their designee(s) are responsible for conducting the study initiation meeting for each study.
2. The purpose of the study initiation meeting is to meet with key staff who will be conducting the study at each Participating Organization (PO) and:
   1. Provide an orientation to the study and review study-specific details, such as the procedures for enrollment, randomization, investigational agent management, reporting requirements, and data and specimen management;
   2. Confirm all roles and responsibilities, and performance expectations;
   3. Confirm that all regulatory requirements are complete for the PO(s);
   4. Ensure that the PO(s) is/are ready to begin enrollment.
3. Key staff members from each PO are responsible for attending the study initiation meeting before the PO may enroll participants.

### Responsibilities:

The CLO Investigator, Site Coordinator, and/or their designees will:

1. Schedule the study initiation meeting:
   1. The meeting is typically scheduled after:
      1. DCP issues a “Notice of Study Approved on Hold” letter to the CLO; and
      2. The CLO has submitted the protocol to its Institutional Review Board (IRB/CIRB).
   2. The meeting may be held at the CLO site, PO site, or other location and may include remote conferencing for participants unable to attend in person.
   3. The meeting is typically accomplished in one business day.
   4. Schedule a meeting date that is mutually convenient for the CLO staff and key staff from each PO attending. Consider the following list of key staff from each PO, as applicable to the study:
      1. Investigator(s) and Site Coordinators
      2. Study pathologist
      3. Study statistician
      4. Study pharmacist
      5. Data management team
      6. CLO Monitor(s)
      7. Other staff with study responsibilities
   5. The DCP Medical/Scientific Monitor and other DCP representatives, including DCP monitoring contract staff, may also elect to attend the meeting and should be included during the scheduling process.
   6. Send an email confirmation of the meeting date to all participants, including [DCP Help Desk](mailto:dcphelpdesk@dcpais.com).
   7. Schedule a separate meeting for PO(s) that are unable to attend or are added as a new enrolling site at a later date.
2. Prepare for a study initiation meeting:
   1. Prepare an agenda prior to the meeting determining all relevant discussion topics and designating a facilitator for each topic. Refer to the [SOP 2a: Study Initiation Meeting Report](https://prevention.cancer.gov/sites/default/files/uploads/clinical_trial/SOP2a-Initiation-Report-Template.docx)to review the list of topics that may be applicable.
   2. Prepare meeting materials (hard copy and/or electronic) and distribute to participants.
   3. Confirm with the DCP Regulatory Contractor that all or most regulatory documents are on file and complete for each accruing organization.
3. Conduct a study initiation meeting:
   1. Complete an attendance record to document name/institutional affiliation/study role for all meeting participants. Maintain the original attendance record in the CLO study files and provide a copy to PO staff for their records.
   2. During the meeting, record items that are identified as action items or requiring follow up. Review the action items with the meeting participants prior to concluding the meeting.
   3. Complete the [SOP 2a: Study Initiation Meeting Report](https://prevention.cancer.gov/sites/default/files/uploads/clinical_trial/SOP2a-Initiation-Report-Template.docx), including a description of action items.
      1. Distribute the completed report via email to the [DCP Help Desk](mailto:dcphelpdesk@dcpais.com) **within 15 business days of the meeting date**. The DCP Help Desk will forward the report to all applicable DCP representatives.
      2. Distribute the completed report via email to each PO site.
      3. Document the resolution of all action items prior to participant enrollment.
      4. Email documentation of action item resolution to the [DCP Help Desk](mailto:dcphelpdesk@dcpais.com).

### Documentation Requirements:

The CLO site is responsible for maintaining the following documentation related to the study initiation meeting: attendance record, meeting agenda, study initiation meeting report, and any other related communications such as resolution of action items. This documentation should be readily accessible and may be requested by DCP, the DCP Regulatory Contractor, and/or the DCP Monitoring Contractor at any time during the duration of the study.

### Additional Information:

Refer to the [DCP Acronym List](https://prevention.cancer.gov/sites/default/files/uploads/clinical_trial/DCP-Acronym-List.docx) to see the description of commonly used acronyms in this SOP.

**Please send questions and comments to the DCP Help Desk at:**

**1-844-901-4357 or** [**dcphelpdesk@dcpais.com**](mailto:dcphelpdesk@dcpais.com)