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| **GENERAL INSTRUCTIONS** – delete this box from the completed form. Red text represents instructions to you – to be deleted from the final version.  **NOTE: This form is designed to be a starting point on drafting either a Manual of Procedures or Standard Operating Procedures. Update it as necessary for your specific study.**   * While used interchangeably, Manual of Procedures (MOP) and Standard Operating Procedures (SOP) have two different purposes. Generally speaking, an MOP is written for one study while an SOP is written to guide practices across multiple studies.   + MOP: A much more detailed set of instructions to standardize and organize all the study procedures that are included in the protocol or IRB application. It should be viewed as a supplement to the protocol and should not include any study procedure not already IRB-approved. It supplements the study protocol by detailing a study’s organization, operational data definitions, recruitment, screening, enrollment, randomization, intervention procedures and follow-up procedures, data collection methods, data flow, case report forms (CRFs), and quality control procedures.   + SOP: Usually not study-specific but could be team, division, or department specific. These can be used to define standard practices and daily processes conducted to assure execution of research tasks in accordance with institutional, state and federal guidance. * Study teams can format this document in the way they see best with different bullets or numbering systems. This is not meant to be used as a template and rather is only giving examples of section headers and what to include. * Many NIH centers also have MOP templates available that can be used as a reference regardless of study funding. It might be helpful for a study team to review various templates to see examples of different layouts and what sections could be included. * Before writing either an MOP or SOP, study teams should think carefully about the utility and appropriateness as it is possible that monitors or auditors will require them to follow those documents and could incur additional deviations or non-compliance findings. * When writing this document, it might be helpful for the study team to complete a few dry-runs of each study visit and procedure to understand what the actual steps are that will need to be completed. * MOPs or SOPs are usually not submitted to an IRB for approval but version history should be maintained. These documents should not be updated without good cause or a clear historical record. * When amendments are made to the protocol and approved by the IRB, this document should be updated as necessary for the specific changes. * No study procedure or event should be included in this document without first being approved by an IRB. No instruction or process in an MOP or SOP should contradict what is in the protocol. * Delete the CRRO template version date and add in the study-specific version date of this document. |

1. **Purpose**
   1. This section should include a brief description of why the MOP/SOP is being written. It may be useful to include a brief summary of the study but should not repeat in too much detail what is in the protocol.
2. **Procedures**
   1. This section is where each visit should be explained in detail.
      1. Visits should include what happens during recruitment and screening.
      2. It might be helpful to include a chronological flow of events if it is important that certain things happen before others. For example, if a blood pressure should be done prior to a blood draw or if a urine sample needs to be collected before any other assessments happening. Sometimes it might be important for a specific questionnaire to be completed prior to others and that information should be included as well.
   2. This section could also include any major procedures and explain them in more detail as appropriate.
   3. Explaining visits and procedures might also include information about who should be completing them but study teams should be careful that this does not contradict what is included on the Delegation of Authority log and does not restrict staff responsibilities in such a way to make deviations likely to occur. Specific responsibilities should be tasked to a specific role only when absolutely necessary.
3. **Drug or Device Procedures**
   1. Studies with a drug or device intervention will likely find that there are very specific procedures that need to be included that are not in the protocol. This could include the process for how a drug order is placed with Investigational Pharmacy Services, how it is provided to a participant including who is allowed to provide dosing instructions, and if drug will be requested to be returned by the participant. This section could also include device storage locations.
4. **Biospecimen Procedures**
   1. For studies that have multiple biospecimen collection events or complicated processing or shipping, it might be helpful to have a separate section specifically for these procedures. For example, if urine is shipped to a specific lab but blood is shipped elsewhere. This section can also be used to indicate storage locations for each biospecimen and labeling procedures.
5. **References**
   1. This could include links to institutional policy or regulatory guidance that might be applicable to what is included in this document.
6. **Appendix**
   1. This could include a list of any relevant forms or other documents. It is recommended that these other forms and documents are not maintained as part of a MOP or SOP as that can make updating difficult. But they can be referenced here in list format.

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| **Version History** | |
| *Version # and/or Version Date* | *Summary of Changes* |
|  | Not applicable, original version. |
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