Checklist for DSMP for Full Board Studies

# Data and Safety Monitoring Plan (DSMP)-General Considerations

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| --- | --- | --- |
| The study team described in their protocol … | Y/N | Notes |
| A plan to review data and complete data in real-time (for example, ensuring timely review of SAEs, and reviewing signatures after IC process) |  |  |
| An SOP to review data at pre-determined intervals for safety (for example, confirmation via copies of data sources for eligibility criteria tests) |  |  |

# Monitoring Plan

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| --- | --- | --- |
| The study team described in their protocol … | Y/N | Notes |
| For medium complexity studies (at a minimum)   * A plan to review the research data using our [self-monitoring tool](http://compliance.emory.edu/documents/eu_self_monitoring_tool.doc#EU%20Self-Monitoring%20Tool) at adequate intervals. * That the completed form will be sent to CTAC for review. * For abbreviated IDE studies, if all procedures are considered minimal risk, the study can use the self monitoring tool to satisfy the FDA requirement[[1]](#endnote-1). |  |  |
| For high complexity studies (at a minimum)   * The individual(s) or group that will serve as the study data monitor and their qualifications. This person should not be collecting data for the study and, ideally, not be associated with the study. This can be delegated to a CRO. * The frequency and percentage of files to be reviewed * The monitoring schedule, that should include study initiation, early enrollment, and interim monitoring, based on the site activity, participants’ risk, and study complexity. * A plan for consent form review (should include 100% of consents) * A plan to document and review SAEs in real-time (within 24 hours for example) * A plan to review CRFs against critical data for accuracy and completion. Examples of critical data are eligibility, study end-points, safety events, etc. * A plan to review the study binder with team members' credentials, training records, the delegation of responsibility logs, etc. Should specify the review frequency. * If applicable, review of laboratory processing and storage of specimens at participants’ first and closeouts visits and at least biannually. * Drug and Device accountability procedures |  |  |
| FDA regulated studies (at minimum) - Besides all of the above, the plan should specify:   * Monitoring methods (may include centralized/remote, on-site, and self-monitoring) * Reference to any tools used (i.e. checklists) * Identification of events that may trigger changes * Identification of deviations or failures that would be critical to study integrity * Categorization of activities done centrally and those on-site if applicable |  |  |
| High-complexity clinical trials with international sites (at minimum)- Besides all of the above, the plan should specify:   * Required to engage a CRO that is working in the site country and/or to consult with Emory’s legal counsel regarding compliance with the country’s clinical research regulations. |  |  |

# DSMB Requirements[[2]](#endnote-2)

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| --- | --- | --- |
| If a DSMB is needed, [[3]](#endnote-3) the study team described in their protocol … | Y/N | Notes |
| The frequency of the meetings, who is part of the committee and their affiliations, and what triggers the DSMB meetings in case of added risks to participants |  |  |

# Definitions[[4]](#endnote-4)

* Medium-complexity: This includes behavioral interventions and studies involving sample collection or imaging done during a single interaction with a study participant or when the probability of harm is limited to the immediate circumstances of the research encounter. For example, studies involving an MRI with contrast, bone marrow sample collection for research purposes, or CSF or biopsy material collection in the context of a clinical encounter or when the remainder of the study-related activities is considered to be no more than minimal risk.
* High-complexity: (1) Phase I – III interventional studies, and all studies under an Investigational New Drug [IND] or Investigational Device Exemption [IDE] with the FDA. (2) Other studies may not be under an IND or IDE, where a participant is exposed to risk for an extended period or for which the risk might change with time.

1. [FDA guidance](https://www.fda.gov/medical-devices/investigational-device-exemption-ide/ide-approval-process#non_sig_risk): The sponsor also must comply with the abbreviated IDE requirements under [§812.2 (b)](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?FR=812.2):

   Labeling - The device must be labeled in accordance with the labeling provisions of the IDE regulations ([§812.5](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?FR=812.5)) and must bear the statement "CAUTION - Investigational Device. Limited by Federal (or United States) law to investigational use.";  
   IRB Approval – The sponsor must obtain and maintain Investigational Review Board (IRB) approval throughout the investigation as a nonsignificant risk device study;

   Informed Consent – The sponsor must assure that investigators obtain and document informed consent from each subject according to [21 CFR 50](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=50), Protection of Human Subjects, unless documentation is waived by an IRB in accordance with §56.109(c);

   Monitoring - All investigations must be properly monitored to protect the human subjects and assure compliance with approved protocols ([§812.46](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=812.46)). Guidance on monitoring investigations can be found in Guideline for the Monitoring of Clinical Investigations.

   Records and Reports - Sponsors are required to maintain specific records and make certain reports as required by the IDE regulations ([§812.2(b)(1)(v)](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=812.2)).

   Investigator Records and Reports – The sponsor must assure that participating investigators maintain records and make reports as required (see Responsibilities of Investigators); and

   Prohibitions –Commercialization, promotion, test marketing, misrepresentation of an investigational device, and prolongation of the study are prohibited ([§812.7](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?FR=812.7)). [↑](#endnote-ref-1)
2. <http://irb.emory.edu/documents/DSMB-DSMPGuidance.pdf> [↑](#endnote-ref-2)
3. DSMBs should be required when the answer is yes to two or more of the following questions:

   * Is there a large study population, or are there multiple study sites?
   * Is the trial intended to provide definitive information about the effectiveness and/or safety of medical intervention?
   * Do prior data suggest that the intervention being studied has the potential to induce unacceptable toxicity?
   * Does the trial evaluate mortality or another major endpoint, such that inferiority of one treatment arm has safety and effectiveness implications?
   * Would it be ethically important for the trial to stop early if the primary question addressed has been definitively answered, even if secondary questions or complete safety information were not yet fully addressed?

   [↑](#endnote-ref-3)
4. <http://irb.emory.edu/documents/DSMP_requirements_ver_2-2-2021.pdf> [↑](#endnote-ref-4)