**Data Safety & Monitoring Requirements Checklist**

1. **Data & Safety Monitoring *Plan* (DSMP)-** DSMP that is 100% consistent with

* [NIA Guidance on Clinical Trials](https://www.nia.nih.gov/research/grants-funding/nia-guidance-clinical-trials)
* [NIH Policy for Data & Safety Monitoring](https://grants.nih.gov/grants/guide/notice-files/not98-084.html)
* [Further Guidance on Data & Safety Monitoring tor Phase I + Phase II Trials](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html)
* [Guidance on Reporting Adverse Events to Institutional Review Boards for NIH-Supported Multicenter Clinical Trials](https://grants.nih.gov/grants/guide/notice-files/not99-107.html)

1. **Data & Safety Monitoring *Board (*DSMB*)***: Confirmation that a formal DSMB will be established or statement that a DSMB is NOT required by confirming that this study does ***NOT***:

* Propose a **Phase III (Stage IV) Clinical Trial**

The establishment of the data safety monitoring boards (DSMBs) is required for multi-site clinical trials involving interventions that entail potential risk to the participants. Stage trials (Stage I, II, and III), a DSMB may be appropriate if there are multiple clinical sites, are blinded (masked), or employ particularly high-risk interventions or vulnerable populations. Please confirm that a DSMB is NOT required by confirming that this study does ***NOT***:

* Involve **Multiple Clinical Sites**
* Employ **Particularly High-Risk Interventions**
* Employ **Vulnerable Populations**

If a DSMB is necessary, these materials are also required:

□ Proposed DSMB members

□ Brief (2-3 sentence) justifications of their expertise/role

□ CVs of proposed DSMB member

□ [DSMB Conflict of Interest and Confidentiality Statement](https://www.nia.nih.gov/sites/default/files/2019-05/nia_dsmb_coi_nda_20190502.docx)

□ DSMB Charter, also 100% consistent with NIH and NIA policies

1. [**Clinicaltrials.gov**](https://clinicaltrials.gov/ct2/home) **Registration**: Please send the [Clinicaltrials.gov](https://clinicaltrials.gov/ct2/home) Identifier # (or the status of ClinicalTrials.gov registration) to the Program Officer. Please note that “*The* [*timeline for registration*](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-149.html) *is not later than 21 calendar days after the enrollment of the first participant*.” For [ClinicalTrials.gov](https://clinicaltrials.gov/) questions see [register@clinicaltrials.gov](mailto:register@clinicaltrials.gov).
2. [**Plan for the Dissemination of NIH-funded Clinical Trial Information**](https://grants.nih.gov/policy/clinical-trials/reporting/understanding/nih-policy.htm): Email assurance from the AOR to the Program Officer that:
   1. The clinical trial under this award is or will be registered and results information will be submitted to ClinicalTrials.gov as outlined in the [policy](https://grants.nih.gov/policy/clinical-trials/reporting/understanding/nih-policy.htm) and according to the specific timelines stated in the policy.
   2. The informed consent documents for the clinical trial(s) will include a specific statement relating to the posting of clinical trial information at [Clinicaltrials.gov](https://clinicaltrials.gov/ct2/home)
   3. The Recipient Institution (e.g., University) has an internal policy in place to ensure that clinical trials registration and results reporting occur in compliance with policy requirements
3. [**Good Clinical Practice (GCP)**](https://grants.nih.gov/policy/clinical-trials/good-clinical-training.htm): Email confirmation that all [Good Clinical Practice (GCP)](https://grants.nih.gov/policy/clinical-trials/good-clinical-training.htm) training has been completed.