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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Draft Policy Update to the NIH Policy for Data and Safety Monitoring**

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Request for Information.

**SUMMARY:** The National Institutes of Health (NIH) is committed to ensuring risk-based monitoring for participant safety and to upholding the quality and integrity of data for all NIH-supported clinical research. To further this goal, NIH is seeking public input on proposed updates to the 1998 NIH Policy for Data and Safety Monitoring and on what supplemental resources would benefit the research community.

**DATES:** To ensure consideration, comments must be submitted in writing by January 6, 2027.

**ADDRESSES:** Comments may be submitted electronically to: https://osp.od.nih.gov/comment-fom1-draft-policy-update-to-the-nih-policy-for-data-and-safcty-monitoring/. Comments are voluntary and may be submitted anonymously. You may also voluntarily include your name and contact information with your response. Other than your name and contact information, please do not include in the response any personally identifiable information or any information that you do not wish to make public. Proprietary, classified, confidential, or sensitive information should not be included in your response. After the NIH Office of Science Policy (OSP) has finished reviewing the responses, the responses may be posted to the OSP website without redaction.

**FOR FURTHER INFORMATION CONTACT:** Adam Berger, Ph.D., Office of Science Policy, at (301) 496-9838 or SciencePolicy@od.nih.gov.

**SUPPLEMENTARY INFORMATION:**

**Background:** NIH is proposing to update its 1998 Policy for Data and Safety Monitoring. The 1998 Policy established NIH requirements for data and safety monitoring in clinical trials (as defined in Section V), including the requirement to develop and implement a data and safety monitoring plan. The draft update would expand those expectations to all NIH-supported clinical research (as defined in Section V), while using risk-based data and safety monitoring approaches to focus oversight where it is most needed, and reduce administrative burden for research with lower risk.

NIH is proposing this update because clinical research and study designs have advanced significantly since 1998. Valid scientific results are necessary to replicate and extend research findings and translate findings from clinical trials and other clinical research to health improvements. In addition, almost two thirds of NIH's clinical research portfolio is not clinical trials, and data from clinical research that are not clinical trials often support future clinical trial research. Updating the policy would promote a consistent NIH-wide approach to participant safety and the quality and integrity of data, better reflecting NIH's broad and diverse clinical research portfolio.

Key features of the draft updated policy include expanding the scope of the 1998 Policy from clinical trials to encompass all NIH-supported clinical research, clarifying the requirements that data and safety monitoring plans be based on the risk of the study and that NIH Institutes, Centers, and Offices (ICOs) approve those plans. By focusing on study-specific, risk-based monitoring, the draft updated policy would allow greater flexibility in monitoring approaches by removing the requirement for Data and Safety Monitoring Boards for all phase 3 or multi-site clinical trials.

**Draft Policy Update to the NIH Policy for Data and Safety Monitoring**

## I. Purpose

The purpose of the updated National Institutes of Health (NIH) Policy for Data and Safety Monitoring (DSM Policy) is to establish risk-based data and safety monitoring (i.e., monitoring) in all NIH-supported clinical research. This Policy establishes the requirement to develop and implement a NIH Institutes, Centers, and Offices (ICO)-approved data and safety monitoring plan (i.e., monitoring plan) and Policy compliance expectations. Data and safety monitoring provides risk-based oversight of (1) the quality and integrity of data and (2) participant safety and well-being (i.e., data and safety) to ensure the study is conducted ethically and progress is consistent with producing valid scientific results that accomplish the NIH-approved scope of work. Requirements of this policy are calibrated to ensure that oversight roles are non-duplicative with that of Institutional Review Boards (IRB).

## II. Background

As stewards of the world's largest public investment in biomedical research, NIH is entrusted to ensure the rigor, safety, and transparency of its clinical research. NIH endeavors to ensure that studies are conducted safely, ethically, and in accordance with approved study documents. In support of this goal, NIH issued the NIH Policy for Data and Safety Monitoring (see https://grants.nih.gov/grants/guide/notice-files/not98-084.htm1) in 1998 (1998 Policy) to ensure clinical trials had monitoring procedures for data and safety. NIH provided Further Guidance on Data and Safety Monitoring for Phase I and Phase II Trials (see https://grants.nih.gov/grants/guide/notice-files/not-od-00-038.html) in 2000 (2000 Guidance). NIH continued these efforts (see https://osp.od.nih.gov/building-better-clinical-trials-through-

enhanced-stewardship-and-transparency/) in 2016 to strengthen clinical trial stewardship, accountability, and transparency.

Significant research advancements toward increasingly data-driven, patient-centered research (e.g., real-world data research, [see https://www.fda.gov/science-research/science-and-research-special-topics/real-world-evidence] implementation science, machine learning, genomics, point-of-care clinical studies) and more efficient, adaptive, and fit for purpose study designs (e.g., decentralized, adaptive, quasi-experimental designs) have highlighted the need to continue to modernize NIH data and safety monitoring practices for all clinical research to support the ethical conduct of research and produce valid scientific data.

In-line with gold standard (see https://www.nih.gov/sites/default/files/2025-08/2025-gss.pdf) science at NIH, valid results are necessary to replicate and translate research findings to accelerate scientific discovery and improve American health. Almost two thirds of NIH's clinical research portfolio consist of studies that are not clinical trials. Research advancements in these areas necessitate that NIH require data and safety monitoring in all clinical research to ensure that these studies meet NIH's standards for valid scientific data (see https://grants.nih.gov/policy/reproducibility/guidance.htm) and ethical study conduct. Data from clinical research studies that are not clinical trials often support future clinical trial research, underscoring the need to ensure high-quality data in all research stages.

This draft updated DSM policy is distinct from, but complements, the data management and sharing practices to enable data accessibility, reuse, reproducibility and reliability of study results outlined in NIH's Data Management and Sharing Policy (see https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-013.html). NIH maintains that data monitoring and management practices support improved data validity and study outcomes,

including future reproducibility, replication, and sharing for the next generation of research. NIH's draft updated Data and Safety Monitoring policy ensures the clinical research data shared in accordance with the Data Management and Sharing Policy are monitored for participant safety and are of the highest quality, building trust in the research and its disseminated results. Accordingly, NIH proposes an updated DSM Policy that expands the goals of the 1998 Policy to require all clinical research to have plans to monitor data and safety using approaches proportionate to study risk. Risk-based monitoring approaches allow for more effective mitigation of risks to participants and to the quality and integrity of the data while allowing for tiering of oversight to reduce administrative burden. Risk-based monitoring focuses on risks that are most likely to critically affect data and safety, and, in turn, enhances ethical study conduct and the validity of scientific results. The extent and nature of risk-based monitoring is proportionate to those risks. This approach also directly supports dynamic, continual improvement in study oversight, monitoring, and conduct to ensure that studies accomplish the NIH-approved scope of work. Risk-based monitoring supports rigor, transparency, and accountability, builds public trust in NIH research, and advances the NIH mission of funding studies that advance American health.

**III. Policy Scope and Effective Date**

The policy will be effective for applications submitted on or after 6 months from when the final policy is published. This updated DSM policy applies to the following NIH-supported clinical research:

- All competing award applications, applications for competitive revisions, proposals for contracts, and other funding agreements (e.g., Other Transactions, Cooperative Agreements).

- All intramural research projects approved by an IRB.

**IV. Compliance and Enforcement**

All institutions conducting NIH-supported clinical research defined in Policy Scope and Effective Date, will be required to comply with this Policy, which will be included in the applicable te1ms and conditions of the award or agreement, or as outlined in the NIH Grants Policy Statement, or Other Transaction agreement. Compliance will be reviewed and evaluated by NIH during regular reporting intervals (e.g., at the time of monitoring reports, during study progress reviews) or more frequently by the awarding NIH ICO.

Monitoring plan amendments must be reported to and approved by the awarding NIH ICO. The monitoring plan and its amendments must be consistent with Requirements.

- Changes that require prior approval, consistent with the NIH Grants Policy Statement 8.1.2 Prior Approval Requirements (see https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.1 .2_prior_approval _requirements.htm? Highlight=Changes%20That%20Involve%20Human%20Subjects) or the Terms and Conditions of the Notice of Award, and that result in amendments to the monitoring plan, require NIH ICO review of the revised monitoring plan and NIH ICO approval prior to implementation.
- Changes that don't require prior approval, but result in monitoring plan amendments, require reporting a summary of the monitoring plan amendments during regular reporting intervals.

Failure to comply may provide a basis for remedies for noncompliance (see https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.5.2_remedies_for_noncomplianc

e_or_enforcement_actions-_suspension_termination_and_withholding_of_support.htm), which could also result in enforcement actions, including, but not limited to, specific award conditions or termination, consistent with applicable grant regulations; applicable NIH policies and procedures, including NIH intramural policies and procedures; the Federal Acquisition Regulations; and/or other authorities, as appropriate. Enforcement actions may affect future funding decisions for the recipient institution, as authorized in the NIH Grants Policy Statement. In cases where NIH proposes to suspend, limit, or terminate financial assistance because of noncompliance with this Policy, applicable HHS and Public Health Service procedures shall govern.

NIH IRP research subject to this policy will be addressed, as applicable within NIH IRP policies and procedures.

## V. Definitions and Terminology

For the purposes of the draft updated NIH DSM Policy, terms are defined or explained as follows:

**Clinical Trial**

A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes (for the complete definition of Clinical Trial, see https://grants.nih.gov/grants/glossary.htm#ClinicalTrial).

***Clinical Research***

Research with human subjects that is:

1) Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) for which an

investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. It includes: (a) mechanisms of human disease, (b), therapeutic interventions, (c) clinical trials, or (d) development of new technologies.

2) Epidemiological and behavioral studies.
3) Outcomes research and health services research

(see https://grants.nih.gov/grants/glossary.htm#ClinicalRescarch).

***Data and Safety Monitoring Plan (DSMP)***

A prospectively written document that describes the strategy, methods, responsibilities, and requirements for monitoring (1) quality and integrity of data and (2) participant safety and well-being.

***Data and Safety Monitoring (DSM) Reports***

Documentation of monitoring activities, their results, actions taken in response to monitoring results, and the outcomes of those actions. The DSM report is provided to .the individual(s) monitoring the study.

***Independent Monitor***

An individual, committee, or board who, based on their roles and responsibilities defined in the monitoring plan, review the monitoring plan, study data, and/or monitoring reports as the study progresses. The independent monitor provides assessments of whether the study's human subject activities should continue or be stopped (i.e., suspension or discontinuation) based on data, safety, and if the study is conducted ethically and progress is consistent with producing valid scientific results that accomplish the NIH-approved scope of work. Independence means that the

monitor is not directly involved in the study and real or perceived conflicts of interest are disclosed and adequately mitigated.

***Monitoring (of the Study)***

Monitoring (see https://www.fda.gov/regulatory-information/search-fda-guidance-documents/e6r3-good-clinical-practice-gcp) is the review of study data as the study progresses to provide appropriate oversight of the processes and procedures necessary for (1) quality and integrity of data and (2) participant safety and well-being (i.e., data and safety). Monitoring includes developing and implementing a monitoring plan, along with the actions taken to identify, evaluate, mitigate, or correct risks. Data and safety are monitored to assess if the study is conducted ethically and progress is consistent with producing valid scientific results that accomplish the NIH-approved scope of work. Monitoring should be risk-based (see https://www.fda.gov/regulatory-information/search-fda-guidance-documents/oversight-clinical-investigations-risk-based-approach-monitoring). Risk-based monitoring focuses on identifying and mitigating the risks that are most likely to critically affect data and safety, and, in turn, if the study is conducted ethically and produces valid results (see https://www.fda.gov/regulatory-information/search-fda-guidance-documents/e6r3-good-clinical-practice-gcp). This is determined based on the study's risk assessment (i.e., initial or throughout the study) and ongoing review. The extent and nature of risk-based monitoring is proportionate to those risks. Monitoring is one aspect of quality assurance and control procedures in studies, (see https://www.fda.gov/regulatory-information/search-fda-guidance-documents/e6r3-good-clinical-practice-gcp) and is distinct from the routine (i.e., day-to-day) operational activities performed by the study staff for study quality assurance and control.

***NIH-Supported Research***

NIH supported research includes all research funded in whole or in part by NIH. This includes research conducted by the NIH intramural research program and funded or conducted by extramural grants, contracts, other transactions, or other funding agreements regardless of NIH funding level or awarding instrument.

***Program Director/Principal Investigator (hereafter Investigator)***

The individual(s) designated by the applicant organization to have the appropriate level of authority and responsibility to direct the project or program to be supported by the award. (See https://grants.nih.gov/grants/glossary.htm#ProgramDirector/Principallnvestigator(PD/PI).

***Quality and Integrity of Data***

Quality and integrity of data include the degree to which the data are generated, recorded, and reported throughout the study are fit for purpose, such that the data fulfill the criteria needed for the study to be ethically conducted and produce valid scientific results.

***Recipient***

An entity that receives a Federal award directly from a Federal agency to carry out an activity under a Federal program. The term recipient does not include subrecipients, consortiums or individuals that are participants or beneficiaries of the award.

***Risk Assessment (of the Study)***

The risk assessment of the study is used to develop a monitoring approach that is proportionate in extent and nature to the study's risks. The study's risk assessment may be reviewed and amended throughout the study.

Critical risks are based on identification and evaluation of the study's risks to determine criticality based on the likelihood risks might occur or their possible impact on data and safety,

and, in turn, if the study is ethically conducted and produces valid scientific results accomplishing the NIH-approved scope of work. Critical risks should be monitored, mitigated, and reported.

All studies involve some measure of risk. Risks should be interpreted broadly (evidence-based, theoretical, anticipated at the start of the study, or identified during the study), then evaluated to determine if they are critical risks, and may include factors affecting:

(1) Participant safety and well-being (including privacy and confidentiality);

(2) Quality and integrity of data (including study outcomes);

(3) Complexity, processes, and procedures (including study design, operations, systems, large language models (LLMs) or super intelligence (see https://www.whitehouse.gov/presidential-actions/2026/09/inaugurating-the-era-ot.._super-intelligence/), regulatory, administrative factors);

(4) NIH financial stewardship; or

(5) Other significant risks (including data security, public trust).

***Sponsor***

A sponsor is the person or entity who takes responsibility for and initiates a clinical trial under a Food and Drug Administration Investigational New Drug (IND) application or Investigational Device Exemption (IDE). The sponsor may be an individual, company, governmental agency, academic institution, private organization, or other organization (see https://www.ecfr.gov/current/title-21/part-312/section-312.3#p-312.3(b) and https://www.ecfr.gov/current/title-21/section-812.40).

***Study Documents***

Study documents include (1) NIH-approved study documents, including, but not limited to, all components of the application, any changes made to application documents or the information described within them after initial submission, the Research Performance Progress Rep01i (RPPR) or other required reporting, or any other NIH document relevant to the study, (2) IRB approved study documents (e.g., protocol), (3) study documents reviewed by other applicable authorities (e.g., FDA), and (4) any other study documents needed to execute approved plans (e.g., statistical analysis plan, manual of operating procedures). Together, these study documents describe the approved scope of work and timelines, as well as the plans or operational procedures required to accomplish them.

**VI. Roles and Responsibilities**

***Recipient or Investigator Responsibilities***

The recipient institution is responsible for the conduct of all research under the award (see https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4.1.16_human_subjects_protections.htm?Highlight=good%20clinical%20practice), including compliance with this Policy. The recipient institution may designate the investigator(s) as responsible for carrying out these responsibilities under the oversight of the awarding NIH ICO. NIH's review and evaluation of recipient/investigator requirements does not relieve the recipient/investigator of its responsibility to satisfactorily implement requirements. The recipient /investigator is responsible for:

- Developing and receiving approval for a satisfactory monitoring plan (i.e., consistent with Requirements) from the awarding NIH ICO. The initial monitoring plan must be approved p1ior to initiating human subject activities. In developing the monitoring plan,

recipient(s)/investigator(s) should perform a risk assessment and propose a monitoring approach that is proportionate to the study's risk.

- Determining and adhering to the IRB review requirements for the monitoring plan. Please see NIH's Policy on single IRB (sIRB) for information on sIRB requirements (see https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-094.html).
- If independent monitoring is required by the NIH ICO for the study, (1) identifying possible independent monitors for the study at NIH ICO request and (2) managing real and perceived conflicts of interest to mitigate bias.
- Implementing and adhering to the monitoring plan once human subject activities begin.
- Assessing the need for monitoring plan amendments in response to study issues or changes. This may then include amending the monitoring plan to ensure it remains satisfactory, implementing amendments, and, when required by Compliance and Enforcement, obtaining approval from the NIH ICO for amendments.
- Mitigating or resolving issues identified through monitoring reports and indicated in monitoring reports if and how issues are satisfactorily mitigated or resolved. This includes corrective and preventive action plans that mitigate issues (as defined in Section V: "Monitoring" and "Risk Assessment").
- Providing monitoring reports according to monitoring plan requirements and demonstrating if the ongoing review of study data indicates that data and safety are consistent with ethical study conduct and that progress is consistent with producing valid scientific results that accomplish the NIH-approved scope of work.

- Providing the study documents that enable monitoring or monitoring reports to the parties described in the monitoring plan (e.g., the NIH ICO, independent monitor (if applicable), and regulatory authorities (e.g., IRB, FDA)).

***Sponsor Responsibilities***

In cases where there is a regulatory sponsor for studies with an IND or IDE, the sponsor should determine which responsibilities listed under Recipient/Investigator Responsibilities are to be performed by the sponsor or the recipient/investigator (see https://www.ecfr.gov/current/title-21/chapter-I/subchapter-D/part-312#subpart-D and https://www.ecfr.gov/current/title-21/part-812/subpart-C).

***Institutes, Centers, and Offices Responsibilities***

The awarding NIH ICO is responsible for the oversight of the data and safety monitoring of the NIH-supported clinical research. This is distinct from the monitoring activities performed by the recipient/investigator, sponsor, or independent monitor(s). The awarding NIH ICO is responsible for:

- Requiring that the recipient/investigator provide a satisfactory monitoring plan (i.e., consistent with Requirements) that is approved by the NIH ICO prior to the initiation of human subject activities. NIH ICO is responsible for reviewing and evaluating the plan to determine if the recipient/investigator has provided a satisfactory plan. The NIH ICO may require changes to the study or monitoring plan or, if applicable, assessment of the plan by an independent monitor prior to NIH ICO approval.

- Evaluating and approving the study to have independent monitoring. If independent monitoring is required, approving the independent monitor(s) roles, responsibilities, and selection.
- Establishing review and management processes to ensure disclosure and mitigation of conflicts of interest throughout the study.
- Reviewing, evaluating, and approving amendments to monitoring plans according to Compliance and Enforcement expectations and to require that the recipient/investigator maintains a satisfactory monitoring plan throughout the study.
- Reviewing and evaluating monitoring reports on the study's data and safety, including, if applicable, the independent monitor's assessment of these, to determine and approve whether the study should continue or be stopped (i.e., suspension or discontinuation). This includes determining from these reports, (1) if the study is conducted ethically, (2) if study progress is consistent with producing valid scientific results that accomplish the NIH-approved scope of work; (3) if the recipient/investigator has satisfactorily mitigated identified issues; (4) compliance with the monitoring plan requirements, (5) compliance with the updated DSM Policy; and (6) compliance with applicable laws, regulations, and policies.

If the NIH ICO identifies concerns when reviewing the monitoring plan (i.e., initial or amendments) or reports relevant to monitoring, the NIH ICO has the authority to require or approve actions including, but not limited to, amendments to the study or monitoring plan; increased monitoring and reporting requirements, corrective and preventive actions; suspension or discontinuation of human subject activities; suspension, withholding, or termination of funding; or special terms of award.

The NIH ICO will respond to the recipient/investigator within 30 days after receiving the NIH ICO requested plan. After 30 days, if the NIH ICO has not provided a response, the plan is deemed approved.

***Independent Monitor Responsibilities***

Independent monitors assist the PI with monitoring under the oversight of the NIH ICO based on their roles and responsibilities defined in the monitoring plan. The independent monitor is responsible for:

- The review and assessment of the (1) monitoring plan (i.e., the initial plan and amendments), (2) study documents (e.g., for data and safety monitoring and regulatory considerations), and (3) monitoring reports. This includes assessing if issues identified in monitoring reports have been satisfactorily mitigated.
- Disclosing conflicts of interest to ensure independence is maintained.
- Assessing whether the study's human subject activities should continue or be stopped (i.e., suspension or discontinuation).
- Informing the recipient/investigator, NIH ICO, and any other parties as specified in the monitoring plan (e.g., sponsor, IRB) of their assessments.
- Protecting the confidentiality of the study data and monitoring reports throughout all monitoring activities.
- Reporting any new real or perceived conflicts of interest to the NIH ICO for evaluation and review throughout monitoring responsibilities and according to NIH ICO procedures.

## VII. Requirements

### *Monitoring Approach*

The monitoring plan must describe a risk-based monitoring approach that is proportionate to the study's risks in extent and nature of monitoring and provides appropriate oversight of the processes and procedures necessary for (1) quality and integrity of data and (2) participant safety and well-being (i.e., data and safety). The monitoring plan must describe the strategies, methods, responsibilities, and requirements for study monitoring that:

- Assess data and safety to ensure that the study is conducted ethically and progress is consistent with producing valid scientific results that accomplish the NIH-approved scope of work.
- Enable the identification and management of anticipated risks or risks that may arise as the study progresses.
- Execute monitoring that is consistent with approved study documents.
- Are in accordance with applicable laws, regulations, and policies.

### *Monitoring Plan Elements*

The monitoring plan must include the following elements and their rationale:

- Result of the study risk assessment to inform the risk-based monitoring plan, including what critical risks the monitoring approach focuses on and the rationale for their selection.
- The activities, strategies, and methods needed to monitor the risks, including (1) what data, processes, or procedures are reviewed to monitor the risk, (2) evaluation criteria for the risk, and (3) how the monitoring activities are recorded.

- How critical risks will be addressed, including the processes to identify them and resolve them.
- Premature study discontinuation or temporary suspension reasons, including examples of what data are reviewed and evaluated to monitor these.
- Communication and review of monitoring reports.
- How monitoring activities are documented.

NIH encourages recipients/investigators to develop a single monitoring plan for the NIH, IRB, and any other applicable regulatory agencies (e.g., FDA) that is consistent with Good Clinical Practice (ICH GCP). Monitoring plan and reporting expectations do not duplicate RPPR requirements.

***Independent Monitoring***

Depending on the study, the monitoring plan may include an independent monitor. The recipient/investigator always monitors the study. The need for independent monitoring, which is in addition to monitoring by the recipient/investigator, should be based on the study's risk assessment, both initial and as the study progresses. Independent monitoring provides additional expertise to the review provided by the recipient/ investigator, sponsor, or NIH ICO. Monitoring that is independent may reduce bias, increase rigor, shield the study from conflict of interest, and/or undue influence on the study.

Depending on the study and the independent monitor's expertise, the monitor may perform all or a subset of monitoring activities described in the plan. The monitoring plan should describe the role, responsibilities, necessary expertise, and independence requirements of the independent monitor, including what aspects of the study's monitoring plan, study data, and/or monitoring

reports the monitor is anticipated to review and assess. The ICO must identify in writing a reason why independent monitoring is required.

*Communication and Review of Monitoring Reports*

Routine monitoring reports should be reviewed at least annually by individuals who have the necessary expertise to assess the findings, interpret the data, and determine whether follow-up action is needed.

Communication and review of monitoring reports must be described in the monitoring plan, including:

- If independent monitoring is used, the expertise and roles for the personnel (i.e., individual or group) conducting monitoring along with the plans to ensure independence is maintained.
- Report format and content that describe how data are reported and reviewed.
- Timing, frequency, and character (e.g., open or closed, public or private) of routine and ad hoc (i.e., monitoring reports that are more frequent than planned) monitoring reviews. If risks are identified that would trigger escalation, expedited reporting timelines should be provided.
- Reporting procedures for communicating among all interested parties (e.g., principal investigator, study staff, sponsor, the independent monitor(s), the IRB, the NIH ICO, and other applicable regulatory agencies). Procedures must state who receives reports (see Roles and Responsibilities).
- Process for ensuring interested parties are provided with adequate communication and information, including study documents, to cany out their duties.

- Maintaining confidentiality of the data and participants throughout the study when preparing, communicating, or reviewing reports and when discussing or responding to monitoring reports.

***Monitoring Plan Amendments***

Monitoring plans may require amendments periodically throughout the study. Reasons may include, but are not limited to, changes in study documents (e.g., protocol amendments), corrective or preventive actions, or identification of new and important risks that change the study's risk assessment and risk-based monitoring plan.

***Monitoring Costs***

Costs associated with monitoring may be allowable under the budget for the study. This may include funds for monitoring, including compensation for independent monitors. These costs may include, but are not limited to, study staff time for monitoring activities and independent monitor time for reviewing reports and participating in meetings.

**Proposed Supplemental Resources**

To assist the research community in understanding and implementing the draft updated policy, supplemental resources such as guidance documents, templates, or educational material may be created. Suggested topics for supplemental resources may include understanding how to: implement data and safety monitoring, develop effective risk-based data and safety monitoring approaches and plans, and implement data and safety monitoring to ensure ethical conduct and valid scientific results. NIH may also consider providing example plans in the approved format and SI-assisted tools for reformatting to minimize burden. NIH is seeking input on supplemental resources that may assist the research community with developing and implementing a risk-

based monitoring plan for their clinical research study. Please note that the suggested topics are proposed rather than final supplemental resource topics and this list is not exhaustive.

**Request for Input**

NIH is interested in feedback on the draft updated policy requiring risk-based monitoring plans for all NIH-supported clinical research, including clinical trials.

NIH is specifically interested in:

a. Overall feedback on the draft updated policy.
b. Appropriate calibration of oversight to risk, including removal of current burdensome requirements.
c. Comments on specific section(s) or text.

NIH is seeking feedback on specific areas that may inform policy changes and/or supplemental resources for policy implementation.

This feedback would include:

a. How factors affecting the risk of the clinical research study may impact the monitoring approach, the monitoring plan elements, and who performs the monitoring. Risks may include the study's design, quality and integrity of data, financial stewardship, and other considerations. Elements of the monitoring plan include methods for monitoring critical risks, the extent and nature of the monitoring, and other elements.
b. Determining when the addition of independent monitoring, in addition to monitoring by the principal investigator, is needed in a clinical research study. If independent monitoring is needed, consider what type of independent monitoring or expertise is most appropriate. Consider what roles and responsibilities are appropriate for the

independent monitor, and whether they should vary based on the risk assessment, monitoring approach and/or monitoring plan elements and the type of monitor(s) used.

c. What should be monitored for *quality and integrity of data* to assess whether a study is being conducted ethically and is likely to produce valid scientific results.

NIH is also seeking input that will help inform potential supplemental resources, tools, and monitoring plan guidance (e.g., required elements, page limit guidance) to assist researchers with implementing the policy to ensure ethical study conduct and valid scientific results.

Specifically, NIH is interested in:

a. Existing methods, tools, best practices, or guiding principles that would be helpful for
    1) Determining the risk-based monitoring approach; or
    2) Understanding how to do data and safety monitoring; or
    3) Navigating the use of large language models (LLMs) or Super Intelligence (SI) in data and safety monitoring (e.g., how SI is or should not be used in the monitoring process, risk mitigation strategies, reporting use of SI)
    4) Differences in monitoring approaches or considerations for different types of study designs

b. Additional topics for supplemental resources or areas for clarification needed to assist with implementation.

This notice is being published in accordance with a statement made by the NIH Director in NOT-OD-27-006, released on November 2, 2026. The statement can be found at: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-27-006.html.

Dated: November 10, 2026.

Matthew J. Memoli,

Principal Deputy Director,

National Institutes of Health.

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