

# Human Research Protections Program

## March 2026

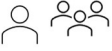





### Tip of the Month



## Data Safety Monitoring Plans (DSMP)

A well-described Data Safety Monitoring Plan (DSMP) helps set the foundation for safe and well managed research. To support investigators as they prepare their submissions, this Tip of the Month highlights the key elements the IRB looks for when reviewing these plans.

### Key Elements

	<p><b>Responsible Entity</b></p> <ul style="list-style-type: none"> <li>The DSMP should indicate who will be responsible for monitoring participant safety, such as the PI, a Medical Monitor, or a DSMB.</li> </ul>
	<p><b>Monitoring Framework</b></p> <ul style="list-style-type: none"> <li>Provide an overview of how safety oversight will work in practice.</li> <li>Include the types of information you plan to review, such as safety data, recruitment progress, or early signs of benefit.</li> </ul>
	<p><b>Frequency</b></p> <ul style="list-style-type: none"> <li>Describe how often you plan to review study data.</li> <li>This may include routine check-ins, interim analyses, or scheduled safety reviews.</li> </ul>
	<p><b>Adverse Event (AE) Reporting</b></p> <ul style="list-style-type: none"> <li>Explain how your team will identify and respond to AEs, Serious Adverse Events (SAEs), and Unanticipated Problems (UPs).</li> <li>Include when these reports will be submitted to the IRB, NIH, or FDA, and outline the expected timelines.</li> </ul>
	<p><b>Stopping Rules</b></p> <ul style="list-style-type: none"> <li>Clarify the conditions that could pause a participant’s involvement or stop the study entirely.</li> <li>These stopping points may relate to safety concerns, lack of benefit, or other predefined criteria.</li> </ul>
	<p><b>Data Integrity</b></p> <ul style="list-style-type: none"> <li>Describe how you will ensure that study data remains accurate, consistent with the protocol, and protected from unauthorized access.</li> </ul>