Section 1: About Safety Monitoring Plans

A safety monitoring plan must be designed for greater than minimal risk studies to minimize threats to the safety and welfare of the research participants.

When appropriate the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects. ([45 CFR 46](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html))

**Data monitoring** is required for all IRB protocols, regardless of risk level, and must include methods for monitoring and ensuring the accuracy, security, and validity of the data.

**Safety monitoring** includes the methods to ensure the safety of the subjects. The details and protections for this part of the plan should be calibrated to the likely harms associated with the research.

See guidance for more details:   
<https://oprs.research.illinois.edu/forms-templates/guidance/guidance-elements-safety-monitoring-plan>

Section 2: When to Use This Form

If you answered yes to Section 9.7 (Is there SAFETY monitoring plan for this study) in the New Study Application, you need to complete this form.

If you will be using a Safety Monitoring Plan for this study, and if you did not yet select yes in Section 9.7 of the New Study Application, please update the appropriate New Study Application section and then complete this form.

Section 3: Protocol Information:

Please complete the information below.

1) Principal Investigator:

Please enter the names of the PI’s.

2) Protocol Number:

Please enter the Protocol number. (If this is a new study application, the protocol number will be assigned and completed by OPRS once the application is submitted.)

3) Project Title:

Please enter the Project Title.

Section 4: Safety Monitoring Plan - Questions:

1) Describe the safety monitoring entity for this study.

Select all that apply:

Principal Investigator (PI)

Independent Physician or Faculty Member

Safety Monitor

Data and Safety Monitoring Board or Committee

Other, please specify below.

If you selected “Other”, please detail the safety monitoring entity.

2) Describe the expertise and affiliation of the individual(s) (selected above) who will monitor the study.

Detail below:

Click or tap here to enter text.

3) Describe the data and events that will be monitored and reviewed.

For example - vital signs, safety blood labs, depression scales, neurological exams, types of adverse events, etc.)

Detail below:

Click or tap here to enter text.

4) Describe the types of reports that will be produced by the monitoring entity.

For example - study progress, interim analysis, safety, etc.

Detail below:

Click or tap here to enter text.

5) Describe the specific triggers or stopping rules for the study.

5.1) Under what conditions will a participant be withdrawn from the study?

Detail below:

Click or tap here to enter text.

5.2) Under what conditions will the study be modified or stopped?

Detail below:

Click or tap here to enter text.

6) How often will the data and events be reviewed by the monitoring entity?

For example - after every 5 subjects, monthly, quarterly, etc.

Detail below:

Click or tap here to enter text.