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| Adapt the monitoring plan based on the risk. Use the following information as guidance only.  Check with the IRB for final risk assessment. | | |
| **Risk Level** | **Examples:** | **Considerations:** |
| **Minimal:** Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (45 CFR 46.102i). | Blood sampling, physical exams, volunteers participating in low-risk procedures. | Principal risk in this research is risk of a breach of confidentiality  Complete **Sections I and II** below. |
| **Moderate:** Moderate risk studies exceed the minimal risk, but constitute less risk than studies with the potential for serious risks to subjects. | Use of study drugs with moderate side effects for indicated use, study interventions with documented human safety data indicating reasonably acceptable risks, insulin pumps, endoscopies, studies using drugs for their indicated use, and studies that use invasive hemodynamic monitoring with arterial lines. | Consider whether an outside medical monitor is required.  Complete **Sections I and II** below. **Section III** may or may not apply. |
| **High:** Research procedures with high likelihood or incidence of serious risks or adverse events; increase probability for a related SAE that is prolonged or permanent, or significant uncertainty about the nature or likelihood of AE’s. | Interventions with known substantial risks, high risk of SAE’s based on subjects underlying disease, trials involving drugs or devices with little available safety data in humans or the study population, gene therapy studies. | **Sections I, II, and III** are **required**. |

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| **Section I. Subject Safety**  For each of the sections below, provide a comprehensive narrative. | | | | |
| If already described in a Sponsor’s Protocol, provide Protocol Section number and describe any local differences in the appropriate spaces below. | | | | Answer here: |
| Specify the procedure(s) you will be conducting to assess safety on an ongoing basis.  *\*You may use the* ***optional table*** *at the end of this form*  Examples include: ECG, vital signs, safety blood tests, DEXA, MRI, study specific signs/symptoms, AE logs, etc.  *Group procedures together as applicable* | | | | |
|  |  | Answer here: Describe plan here | | |
| Monitoring: How often are you collecting the safety data listed above?  *\*You may use the* ***optional table*** *at the end of this form* | | | | |
|  |  | Answer here: Describe plan here | | |
| Assessing: **How often** and **who** will assess results of the safety data? Describe your plan to ensure that all safety data is timely and appropriately assessed for reportable events (e.g., prompt reports, UPIRSO, SAE’s).  Reportable events should be submitted to the IRB according to IRB Policies:  [UPIRSO Policy](https://www.uthscsa.edu/sites/default/files/Services/forms/upirso_uade_policy.pdf)  [Noncompliance Policy](https://www.uthscsa.edu/sites/default/files/Services/forms/noncompliance_policy.pdf)  [Deviations and Violations Policy](https://www.uthscsa.edu/sites/default/files/Services/forms/deviations_policy.pdf) | | | | |
|  | Describe plan for reviewing safety data including **how often** it is assessed? | | | |
|  | Describe plan here | | |
| Who is responsible for assessing data for safety?  (check all that apply) | | PI  Research Team Member  Independent Safety monitor  Data safety Monitoring Board or Committee (DSMB/DSMC)  Other: | |

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| **Section II. Data Integrity**  For each of the sections below, provide a comprehensive narrative. | | | |
| Monitoring: For each time point below, describe the specific **data elements** to be reviewed (e.g., inclusion/exclusion criteria met, accuracy of data transcription, units of measure are appropriately recorded, accuracy of calculations). Also, include who is responsible for confirming the data is correct. | | | |
|  | Time point:  *(Check all that apply)* | Information to be reviewed:  *(Complete as applicable)* | Who will review the information?  *(Check all that apply)* |
| Each study visit |  | PI  Research Team Member  Independent Safety monitor  Data safety Monitoring Board or Committee (DSMB/DSMC)  Other: |
| Monthly |  | PI  Research Team Member  Independent Safety monitor  Data safety Monitoring Board or Committee (DSMB/DSMC)  Other: |
|  | Quarterly |  | PI  Research Team Member  Independent Safety monitor  Data safety Monitoring Board or Committee (DSMB/DSMC)  Other: |
|  | Every # subjects |  | PI  Research Team Member  Independent Safety monitor  Data safety Monitoring Board or Committee (DSMB/DSMC)  Other: |
|  | End of treatment/ intervention |  | PI  Research Team Member  Independent Safety monitor  Data safety Monitoring Board or Committee (DSMB/DSMC)  Other: |
|  | Other: |  | PI  Research Team Member  Independent Safety monitor  Data safety Monitoring Board or Committee (DSMB/DSMC)  Other: |

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| **Section III. Interim Analysis**  Describe the plan for interim analysis, if any, for safety or efficacy monitoring. | | |
| If already described in a Sponsor’s Protocol, provide Protocol Section number and do not answer the following questions. | | Answer here: |
| *If not already included in protocol:*  Describe the statistical approach for interim analysis? | | |
|  | Answer here: | |
| When will the interim analysis occur? | | |
|  | Answer here: | |

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| **Section IV. Study Stopping Rules**  Specify any conditions that would necessitate early termination of the study or individual subject participation (i.e. some clinical trials require documentation of stopping rules that might be used if the participants are found to be exposed to excessive risks in relation to anticipated benefits). | | |
| If already described in a Sponsor’s Protocol, provide Protocol Section number and do not answer the following questions. | | Answer here: |
| *If not already included in protocol:*  Under what conditions will study treatment be stopped on a **single subject**? | | |
|  | Answer here: | |
| **Who** will make the decision to stop treatment on a **single subject**? | | |
|  | Answer here: | |
| Under what conditions will the **entire study** be stopped? | | |
|  | Answer here: | |
| **Who** will make the decision to stop the study? | | |
|  | Answer here: | |

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| **Table to illustrate the timing of safety procedures**  ***(Optional)***  Use the following table to specify the procedure(s) you will be conducting to assess safety on an ongoing basis.  Examples include: ECG, vital signs, safety blood tests, DEXA, MRI, study specific signs/symptoms, AE logs, etc.  *Group procedures together as applicable* | | | | | | | | | | |
|  | **Time points (revise as necessary)** | | | | | | | | | |
| **Procedure(s)** | Baseline | Week 1 | Week 2 | Week 3 | Week 4 | Month 6 | Every Year | Time point | Time point | Time point |
| Insert procedure(s) here |  |  |  |  |  |  |  |  |  |  |
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