|  |
| --- |
| **Study Stage:** Conduct through Termination |



**Purpose:** This template helps track a research participant’s study visit to ensure that protocol-designated procedures for each visit are completed.

**Useful to:** Any IRB-approved research team member conducting a study participant visit.

**Instructions:**

* Customize the list of study visit requirements based on your study protocol.
* Use the checklist as a reference during the participant’s study visit in order to make sure all procedures/tests/surveys/scheduled items have been completed.
* This checklist should be kept in your participant’s study records.
* Pages may be added to the template as needed.

**Best Practice Recommendations:**

* If your study Sponsor provides a visit checklist, complete as instructed by study Sponsor.
* When using the template below, revise the checklist according to your specific protocol and use one line for each visit component.
* When protocol requirements for visits at different time points vary, create a distinct visit checklist template for each study visit (e.g. Screening, Baseline, Week 0, etc.).
* Carefully review the protocol to verify that your checklist(s) are complete.
* If the study protocol is amended to change protocol-designated visit requirements, revise the participant visit checklist(s) accordingly.
* When there are study visit requirements that must be completed in a specific order, or requirements that are time-sensitive, include this information on the checklist.
* Review the checklist prior to the participant’s departure to ensure that all items on the checklist are complete.
* If any visit requirements are not complete, provide an explanation on the checklist of why they were not completed. Please note, if a study requirement is not completed, this may be a deviation per the protocol.

**Template History**

**Reference(s):**

n/a

**Last Updated:** 6/07/2022

**Version:** 2.2

Please use this template as a reference for contact information of any personnel who is involved in the study activity.

All templates can be modified for your protocol

|  |  |
| --- | --- |
| **Study Name:** | **IRB HUM #:** |
| **Principal Investigator:** |  |

**Participant ID: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date:\_\_\_\_\_\_\_\_\_\_\_\_Visit # (or type of visit): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

|  |  |  |
| --- | --- | --- |
| **Visit Requirements:**  **(EXAMPLES)** | **Completed** | **Not Completed or Problem with Completion (describe if necessary)** |
| Vital signs | **Yes  No** |  |
| Brief Physical Evaluation | **Yes  No** |  |
| Medication Review | **Yes  No** |  |
| Adverse Event Screening | **Yes  No** |  |
| Blood Specimen Collection | **Yes  No** |  |
| Pregnancy Test | **Yes  No** |  |
| MRI | **Yes  No** |  |
| EKG (ECG) | **Yes  No** |  |
| Chest X-ray (2-view) | **Yes  No** |  |
| Questionnaire A *(must be completed prior to MRI)* | **Yes  No** |  |
| Questionnaire B *(must be completed after MRI)* | **Yes  No** |  |
| Study drug Administered | **Yes  No** |  |

**Additional Notes:**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Visit Checklist completed by:**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Name Date**