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| **Study Stage:**  Start-up through Termination |

**Purpose:** This template can be used to document study-specific telephone conversations with the or about a study participant.

**Useful to:** Principal Investigators, Study Coordinators, other research study team members, as well as study monitors.

**Instructions:**

* Each consented participant should have their own, separate call log.
* Record telephone calls as they occur to ensure the most accurate recall of the information.
* Complete all columns of the log to ensure the sequence of participant phone interactions.
* Columns may be added in order to customize the log for your study’s needs.

**Best Practice Recommendation:**

* If your Sponsor provides you with a telephone contact log, complete according to the instructions of the study Sponsor.
* To document telephone discussions with the Sponsor you can use a separate “Sponsor Communication log ” that is described on the MICHR website under Guidance Documents.
* Note: If your IRB approval does not allow for the use of participant names, modify the form to use an alternate identifier, such as participant ID.
* If the conversation occurs with someone other than the participant, i.e. legally authorized representative, state their relationship to the participant/study.
* Other sources of communication, such as email contact, should be documented appropriately and included in the participant study files as well, e.g. printing out emails from the participant.

**FDA** recordkeeping and record retention 312.62 <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=312.62>

812.140(a)(3)

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.140>

**Template History:**

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

**Version:** 2.3 **A section of 312 re: subject case histories**

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| **Study Name:** | **IRB HUM #:** |
| **Principal Investigator:** | **Participant ID:** |

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| **Call Date / Time** | Call Made By\* | Call Made To | Summary of Telephone Call Conversation |
| Date:  Time: | Name: | Name: |  |
| Phone Number: | Phone Number: |
| Date:  Time: | Name: | Name: |  |
| Phone Number: | Phone Number: |
| Date:  Time: | Name: | Name: |  |
| Phone Number: | Phone Number: |
| Date:  Time: | Name: | Name: |  |
| Phone Number: | Phone Number: |

\* For incoming calls to the study team, include phone number of caller.