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| **Study Stage:** Start-up, Conduct |



**Purpose:** The Withdrawal and Termination Log may be used to document the number of participant withdrawals and terminations, as well as the reasons for withdrawal or termination. A participant may withdraw their consent to participate in the study, or the Principal Investigator (PI) may terminate a participant based on safety issues or other factors.

**Useful to:** Principal Investigators, Study Coordinators, other research study team members

**Instructions:**

* Add the necessary information for any study participant who withdraws or is terminated from the study.
* Pages may be added to the template as needed.

**Best Practice Recommendations:**

* If a Sponsor provides a Withdrawal and Termination Log, study teams should use it. If a Sponsor does not provide a log for a specific study, study teams may use this template and customize it based on study-specific requirements.
* This template is recommended for all study teams.
* This template is useful for Investigator-initiated studies and Industry-sponsored studies.
* Check the study protocol to make certain you follow any process for withdrawing or terminating study participants.
* The Investigator must submit the number of study participant withdrawals to the IRB annually.
* This form can be used to prepare the information for IRB submission, reporting results in clinicaltrials.gov, etc.
* It is important to document the reason for withdrawal so the PI and IRB can identify any ethical or troubling issues that may arise in study participation.
* This form is helpful in the event of an audit and for monitors to know what happened with the participant that withdrew/terminated from the study.

**Reference(s):**

**ICH E6 4.3.4**

<https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf>

**HHS guidance** <http://www.hhs.gov/ohrp/policy/subjectwithdrawal.html>

**FDA guidance**

<https://www.fda.gov/media/75138/download>

**Template History:**

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

**Version: 2.4**

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

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| **No.** | **Participant ID** | **Date** | **Type\***  | **Detailed reason for Withdrawal/Termination/Lost to Follow-up****(note if Investigator decision or participant)** | **Entrycompleted by Study team member(Initials)** |
| 1 |   |   |   |   |   |
| 2 |   |   |   |   |   |
| 3 |   |   |   |   |   |
| 4 |   |   |   |   |   |
| 5 |   |   |   |   |   |
| 6 |   |   |   |   |   |

**\*Select all that apply: AE/SAE=Adverse event (s), T=Termination; W=Withdrawal; LTF=Lost to Follow-up; O=Other**

**Note: Lost to Follow-up may be a subset of Withdrawal or Termination, depending on the individual protocol**

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| **Principal Investigator:** |  |

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| 7 |   |   |   |   |   |
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**\*Select all that apply: AE/SAE=Adverse event (s), T=Termination; W=Withdrawal; LTF=Lost to Follow-up; O=Other**

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