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

**Purpose:** This template allows the Principal Investigator and study team to fulfill their responsibilities regarding device accountability record maintenance for Devices under a full or abbreviated IDE (in the case of Non-significant risk devices). This template does not meet the needs of a University of Michigan Sponsor-Investigator sending devices to other study sites.

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

**Instructions:**

* Each type of device should have its own log. If a device has multiple components that require individual tracking, each component should have its own log.
* Complete one line for each individual device received (include in the record when the device (s) are first received. As each device is used, document its flow and storage. Before using this template modify the column headings for the realistic possibilities for your device. If a column is not applicable to an individual device, enter “N/A.”
* If the device will be used by a participant and returned to the study team at a later date, add columns to track the dates of those transfers out and in and the initials of the study team member receiving the returned device.
* Record the final disposition (e.g. destroyed, returned to Manufacturer, permanently implanted, etc.) and if returned, provide the reason for return.
* This document should be used to track device accountability at each site.

**Best Practice Recommendation:**

* If a Sponsor provides a Device Accountability Log, complete as instructed. **However, if this is an FDA regulated study of a significant risk device**, investigators must maintain records for why each device is returned. Therefore, if not already included, ask the Sponsor to amend the form to include a column for the reason for return of each individual device on the log. See regulation below.
* File in an appropriate location to be easily accessible for monitoring visits, internal auditing, and in order to have complete study records. It is recommended to update this log using as a word or an Excel spreadsheet.
* If your study makes use of combination products (combination of drug or biologic and device), Research Pharmacy (RP) should be contacted and can help with product accountability. However, the RP team will not manage the accountability for device only studies.

**Template History:**

**Reference(s)**

Device Accountability Recordkeeping requirement for FDA regulated devices: 21 CFR 812. 140(a)(2)

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

**Last updated**: 5/11/2023

**Version** 1.4

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| **Study Name:** | **IRB HUM #:** |
| **Principal Investigator:** | **Location of site:** |
| **Name of Study Device or Device Component:** | **Storage Location of Study Device:** |

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| **Device Receipt** | | | | **Device Use** | | | **Device Dispositon** | | | | |
| Study Device ID/  Lot # | Date  Received | Initials of staff person who “received” device | Device expiration Date | ID # and/or initials of subject receiving device | Dispense Date | Dispensed by  (staff initials) | Device Final Disposition  RET=Returned DES=Destroyed  LOS=Lost  OTH= Other (example implanted, or keep device)  (must comment) | Disposition Date (if not permanently implanted into participant) | Comments\*\*  Be sure to include Reason for Return, if device is returned  (e.g.subject completed study, withdrew, lost-to-f/u, expired / device damaged, not functioning, or recalled) | Tracking or Shipping Number if Returned | Initials of person who “Disposed” of device |
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\*\*Please include any malfunctions, device failure, disposition of unused devices (returned to manufaturer/destroyed), or any other pertinent information concerning device.