JHM IRB COMPLIANCE GUIDE FOR DEVELOPING SITE MANAGEMENT AND STUDY PROCESS COMPLIANCE TOOLS

Table of Contents

The Compliance Monitoring Team has created example guides that will assist the Principal Investigator and study staff in developing and implementing a system to keep study-related documentation in order. In addition, the process guides will provide suggested approaches to augmenting regulatory and study procedural compliance. Example guides are available below.

*The contents these guides emerged from common findings observed from monitoring visits and audits, and represent the general suggestions made to address these findings.*

# Research Procedures Manual and Process Resources

**Table of Contents**:

REGULATORY BINDER

Table of Contents:

- Protocol
- IRB (Submissions, correspondence, amendments, advertisements, reports, approved consent forms, materials & HIPAA forms)
- Investigator's Brochure
- FDA Form 1572 (Investigator's Statement)
- Sponsor Communications (written, phone, fax, email)
- Monitoring Log (every visit, every report)
- Subject Screening Log/ Master randomization list
- Study Drug (shipping, accountability, storage, batch numbers, dates)
- AE, SAE Reports / protocol deviations and violations, IND Safety Reports
- All relevant communications (letters, e-mails, phone notes, meeting minutes)
- Study CRFs, data collection forms
- Documentation of edits (audit trail)

Protocol Title/Application Number:
Subject ID:
Date of Visit:
Time of Visit:

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# Informed Consent Checklist

| | Yes | No* |
|---|---|---|
| Consent form is verified IRB approved and current<br>Date IRB Approved: _____ Expiration Date: _____ | ☐ | ☐ |
| Subject understands the purpose, risks and benefits, and voluntary nature of study participation | ☐ | ☐ |
| The consent was signed and dated prior to any study related procedures being performed | ☐ | ☐ |
| Subject was provided a copy of the signed informed consent | ☐ | ☐ |
| Subject was given contact information to call with any questions regarding the study | ☐ | ☐ |

Comments

_____

_____

_____

_____

Consent obtained by

| Print Name | Signature | Date |
|---|---|---|
| _____ | _____ | _____ |

**INFORMED CONSENT PROCESS CHECKLIST**

**Study Application Number**

**Subject initials: _____**

**Subject Unique Identifier: _____**

**Date of Birth: _____**

**Consent Version #/Expiration Date: _____**

**Consent signed and dated by subject: YES □ NO □ Date: _____**

**Was a copy of the consent given to the subject: YES □ NO □**

**Did Subject demonstrate comprehension of consent form contents? YES □ NO □**

Comments: _____

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Consent obtained by:

_____ _____ _____

Print name Signature Date

Protocol:
Subject ID:
Date of Visit:
Time of Visit:

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# Informed Consent Source Documentation

| | Yes | No* |
|---|---|---|
| Consent form is verified IRB approved and current<br>Date IRB Approved: _____ Expiration Date: _____ | ☐ | ☐ |
| Subject Read consent | ☐ | ☐ |
| Subject understands the purpose, risks and benefits of study participation | ☐ | ☐ |
| The consent was appropriately signed prior to any study related procedures being performed | ☐ | ☐ |
| Subject was provided a copy of the signed informed consent | ☐ | ☐ |
| Subject was given contact information to call with any questions regarding the study | ☐ | ☐ |

Comments

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Consent obtained by

| Print Name | Signature | Date |
|---|---|---|
| _____ | _____ | _____ |

**ELIGIBILITY ASSESSMENT CHECKLIST**

Study Title/Application Number:

Unique Subject Identifier/Initials:

Date of Birth:

**Inclusion criteria**:

- ☐ "Criterion 1"
- ☐ "Criterion 2"
- ☐ "Criterion 3"
- ☐ …

**Exclusion Criteria**:

- ☐ "Criterion 1"
- ☐ "Criterion 2"
- ☐ "Criterion 3"
- ☐ …

Person completing eligibility assessment form:

| _____ | _____ | _____ |
|---|---|---|
| Print name | Signature | Date |

## Protocol Responsibility Delegation Table

| Staff Name and Designation | Duties | Staff Signature | IRB Approval | PI Initials |
|---|---|---|---|---|
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## RESPONSIBILITY KEY

1. Consent Designee
2. Evaluates Subject Inclusion/Exclusion criteria
3. Maintains Source Documents
4. Completes Case Report Forms
5. Administers Study Article Accountability
6. Administrative Activities
7. Obtains Laboratory Values (sample collection)
8. Interprets Medical Reports and Laboratory Results (i.e. ECGs, MRIs, etc.)
9. Adverse Event Documenting and Reporting

**PROTOCOL EVENT AND DEVIATION LOG**

Continuing Review Application Attachment

PI:

Application No.:

Date Protocol Expires:

| Date of Event | Study Participant I.D. | Description of Event/Deviation | Reason for Event/Deviation and Corrective Action Plan | Sponsor Approval? (Yes/ No/ NA) |
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**Protocol Number:** _____ **Study Material:** _____

**Location Drug:** _____ **Drug Administered:** _____

**PI:** _____

**Title:** _____

| | Date Received/ Returned/ Dispensed | Subject Initials | Subject # | Lot # | Dose | Quantity Received/ Dispensed | Balance Forward | Recorder Initials | Initials of personnel |
|---|---|---|---|---|---|---|---|---|---|
| 1 | | | | | | | | | |
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| 13 | | | | | | | | | |
| 14 | | | | | | | | | |
| 15 | | | | | | | | | |

**Notes / Comments:** _____

**Recorder Initials ____Recorder Name_____Recorder Initials ____**
**Recorder Name_____**

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Version No.1
Date

# Device Storage & Accountability Log

Principal Investigator:
Study Number #:
Study Title:
Name of Device:

| PROTOCOL INFORMATION | Y/N | COMMENTS |
|---|---|---|
| A copy of the most current IRB approved signed consent form is located in the medical chart/regulatory binder for each subject prior to device use (relevant to individual subject enrollment date) | | |
| Most Recent Version of the Protocol submitted to the IRB | | Date of Last IRB Approval_____ |
| **DEVICE RECEIPT RECORD** | | |
| Manufacturer/Sponsor | Name:<br>Address : | |
| Quantity of the device | | |
| Batch Number/Code Mark | | |
| Date of Receipt | | |
| Copies of Device Receipt Records are maintained by Investigator located inside (Check one) | Regulatory Binder:<br>Other Source: | |
| Name of Person who received this device | | |
| Any Discrepancies between the Invoice and what was actually received? | | |
| **DEVICE STORAGE REQUIREMENTS** | **Y/N** | **COMMENTS** |
| Device is kept in a locked storage area | | |

**All entries made on this record are permanent (No pencil or whiteout can be used, any changes must be done with a single line through the entry, dated and initialed)**

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Date

# Device Storage & Accountability Log

| DEVICE RETURN RECORD | | |
|---|---|---|
| Date Device Returned, Destroyed, or Transferred | | |
| Device Returned To? | | |
| How many Units were returned to the Sponsor?<br><br>What was the reason for the return? | | |
| If Device was not returned, is written documentation on file from the Sponsor for alternative disposal? | | |
| The name of the person packaging the devices for return | | |
| **GENERAL ACCOUNTABILITY** | **Y/N** | **COMMENTS** |
| The current balance in stock equals the balance recorded in the Investigator's records | | |
| The accountability records show an ongoing balance of devices received, dispensed (if applicable), and returned | | |
| **SPONSOR/INVESTIGATOR REPORTS TO/FOR THE FDA** | **Y/N** | **COMMENTS** |
| Annual report sent to the FDA | | |
| Unanticipated Adverse Device Reports sent | | |
| Current Investigator List which includes all investigative staff involved with the protocol | | |
| Final Report Submitted to the FDA with copies of the report on file | | |



**All entries made on this record are permanent (No pencil or whiteout can be used, any changes must be done with a single line through the entry, dated and initialed)**

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Date

# Device Storage & Accountability Log

| DEVICE IMPLANT RECORD | | | | | |
|---|---|---|---|---|---|
| **Device Used (ID#)** | **Date of Implant** | **Subject (ID# or Initials/Date)** | **Consent Version Date (Must be stamped IRB Approved)** | **Consent Designee (Full Name)** | **Consent Designee Date Consent Signed** |
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**All entries made on this record are permanent (No pencil or whiteout can be used, any changes must be done with a single line through the entry, dated and initialed)**

**Protocol Number:** _____ **Sample Location:** _____

**PI:** _____

**Title:** _____

| | Date Specimen obtained: | Time Sample Obtained | Date/Time Logged | Specimen type | Subject Initials | Subject # | Quantity | | |
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| 14 | | | | | | | | | |
| 15 | | | | | | | | | |

**Notes / Comments:**

**Recorder Initials ____Recorder Name_____Recorder Initials ____**
**Recorder Name_____**

Memorandum

*Note To File*

Date:

To: Regulatory Binder

RE: Protocol No. , entitled, **********"

Event: [*Description of details of a study related event or accounting of information requiring an organizational change to the protocol or needing clarification*]

Response: [*Description of the immediate response to the event referred to above and/or what steps have been taken to implement a change or to clarify a study concern*]

Corrective Action: [*Description of the general systematic response to eliminate or minimize the described event or to improved the overall quality of the study*]

_____
Study Coordinator

_____
Principal Investigator

_____
Date