Ascension Wisconsin Research Education and Quality Management

**Regulatory Binder- HUDs**

**Purpose:** The REQM HUD Regulatory Binder assists physician’s with HUDs reviewed and approved by the IRB in achieving and maintaining regulatory compliance of all essential documents. The binder also provides:

* Guidance for organizing and record keeping.
* Assistance with proper HUD documentation and successful HUD management.
* Readily accessible links to on-line resources (REQM Tools Tab) such as Ascension WI IRB policies, guidelines, and forms.

**Do I Need A Regulatory Binder?**

All HUDs approved by the Ascension WI IRB should have a corresponding Regulatory Binder. The REQM’s Regulatory Binder is available to assist physician sites who are creating their own regulatory binder.

Each binder section outlines the regulatory documents, institutional policies, and GCP guidelines for organization and record keeping. The bottom of each tab includes REQM tips, links to REQM tools, and references for applicable documents.

**How to use Binder**

The Regulatory Binder is comprised of sections which outline the regulatory requirements, institutional policies and GCP guidelines for organization and recordkeeping. At the bottom of each section are REQM tips and links to additional resources.

For additional guidance on establishing a regulatory binder contact REQM Staff.

**REQM Tips/Additional Information**

* Label the outside of the binder with the Physician’s name, protocol title, and Ascension WI IRB assigned number.
* The Regulatory Binder should be established at the beginning of the study, prior to use of the HUD.
* Keep the Regulatory Binder current and up-to-date.
* Identify individual(s) responsible for maintaining the binder. Ensure that this person is on file with the IRB as a member of the team to ensure that all IRB correspondence and documents are received/filed in a timely manner.
* Store binder in a safe and secure location, but accessible to staff at all times. If sections of the binder are stored in a separate location, write a signed and dated note-to-file indicating the location and who maintains them. File the note behind the tab to which it applies.
* Patient-specific documentation and information, e.g., signed consent forms, test results, and documentation of HUD discussion, and dispensation of patient information sheet should be maintained separately within the patient-specific file.
* Customize the binder to meet the needs of your protocol. This Regulatory Binder is a template. Include only sections pertinent to your protocol. Omit unused sections and add sections as needed. See “applicable sections” below for more information. If unsure of what sections to include/exclude, contact REQM to clarify.
* Any contracts or financial documents must be stored in a separate location from the Regulatory Binder, e.g. budget and billing statements. Documents should be filed in reverse chronological order under the appropriate tab (most recent on top).
* Use ink on all documents.
* When creating forms, include a version number or date on all documents.
* Any change or correction to a form must have a single line drawn through it, be dated, initialed, and should not obscure the original entry. Correction fluid or “white out” must not be used on study related documents.

**Applicable Sections:**

Depending on the nature of the HUD, some tabs may not be required. Use the list below to ensure that the applicable sections are maintained. Contact REQM staff with any questions.

All HUDs:

1. Protocol
2. Staff CVs
3. Staff Licensures
4. Logs
	1. Patient Identification List
	2. User and Contact Tracking Log
	3. IRB Communication Log
5. IRB Documents
	1. Submissions/Notifications/Approvals
6. Consent Forms (if applicable)/Patient Information
7. Device Documents
	1. Device Accountability
	2. Product Labeling
	3. Instructions for Use
8. FDA Correspondence
9. Correspondence (i.e. between device manufacturer and physician)

**Protocol**

**Contents**

* Current Protocol and all previously approved versions
* When applicable, a copy of the fully executed protocol signature page for original protocol and all approved versions

**REQM Tips/Additional Information**

* Outdated protocol versions may be kept either in the current binder or in a separate location. If so, write a signed and dated note-to-file indicating where previous versions are maintained.
* All versions should be dated and/or numbered
* Applicable [GCP Sections](http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6_R1/Step4/E6_R1__Guideline.pdf): 8.2.2, 8.3.2
* Applicable IRB SOP: Humanitarian Use Devices

**Curriculum Vitae**

**Contents**

* Signed and dated CVs for IRB approved Physician and HUD support staff

**REQM Tips/Additional Information**

* CVs should be signed, dated, and updated every 2 years to verify that information is accurate and current
* If CVs are filed electronically for the departments, write a signed and dated note-to-file and indicate the location
* Applicable [GCP Sections](http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6_R1/Step4/E6_R1__Guideline.pdf): 4.1.1, 8.2.10, 8.3.5

**Licensure/Certification**

**Contents**

* Valid medial licenses/professional certifications for all IRB approved staff
* HUD specific required training documentation

**REQM Tips/Additional Information**

* Monitor licensure expiration dates and add updated copies upon receipt
* Do not remove the previous versions of licensure
* If licensure/certification documentation is maintained in another location, generate a note-to-file
* Applicable [GCP sections](http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6_R1/Step4/E6_R1__Guideline.pdf): 4.1.1, 8.2.10
* Applicable IRB SOP: Human Subject Protection Education and Training for Researchers

**Logs**

**Contents**

* **Patient Log:** Captures all patients who received an HUD.
	+ User and Contact Tracking Log
	+ IRB Communication Log

**REQM Tips/Additional Information**

* To ensure accuracy, logs should be updated as soon as possible after patient receives the HUD.
* REQM Tools have been created for tracking purposes and can be found under REQM Tools:
	+ Patient Log
	+ Site Signature and Delegation Log
* Applicable [GCP Sections](http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6_R1/Step4/E6_R1__Guideline.pdf):4.1.5, 8.3.20- 8.3.25

**IRB Documents**

**Contents**

* Signed and dated submissions:
	+ HUD Application
	+ Continuing Review
	+ Amendments
	+ Adverse events
	+ Violations/Deviations
	+ Close out Information
	+ Approval letters and/or notification of IRB decision
	+ Physician response to IRB notification (if applicable)
	+ Approved patient information sheets/additional HUD information distributed to subjects
* IRB Membership Roster
* IRB Meeting Calendar
* Documentation Federal Wide Assurance number

**REQM Tips/Additional Information**

* REQM Tools have been created for tracking purposes and can be found under REQM Tools:
	+ IRB Document Tracking Log
* Applicable [GCP Sections](http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6_R1/Step4/E6_R1__Guideline.pdf): 4.4, 8.2.7-8.2.9, 8.3.2-8.3.4

**Consent Forms (if applicable)**

**And other Patient Information**

**Contents**

* Current IRB approved consent form version (s) with the IRB approval stamp
* Previous IRB approved consent forms
* Consent Templates
* Any information provided to the subject to explain the device (broducre, infomraiton sheet, device card, etc.)

**REQM Tips/Additional Information**

* As soon as the IRB approves a new version of the consent form, the previous version expires. Previously approved versions can be kept in the IRB section of the Regulatory Binder
* The HUD Consent Note assists sites with properly documenting informed consent according to federal regulations, institutional policies, and good clinical practices.
* Applicable [GCP Sections](http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6_R1/Step4/E6_R1__Guideline.pdf)**:** 4.8, 8.2.3
* Applicable Regulations:[21 CFR 50](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=50), [21 CFR 56](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=56)

**Patient Information and Data Collection Forms**

**Contents**

* Blank set of Data collection sheets (if applicable)
* Add completed forms and in source documents patient file when complete

**REQM Tips/Additional Information**

* Source documents are original recordings of patient data
* Data collection sheets can act as source documentation.
* Applicable[GCP Sections](http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6_R1/Step4/E6_R1__Guideline.pdf):8.3.14, 8.3.15, 4.9
* Applicable Regulations: 21CFR312

**Device Documents**

**Contents**

* Device shipment and receipt records
* Device Accountability Log
* Device Inventory logs
* Device Dispensing Logs
* Device Disposal Records
* Most recent version of the Instructions for Use
* Previous versions of the Instructions for Use
* Product Labeling

**REQM Tips/Additional Information**

* If the device shipment, receipt, and accountability are managed by pharmacy, indicate this in a note-to-file. If the device is not stored on site, generate a note to file and logs will not be maintained.
* The Instructions for Use provides clinical and nonclinical data on a device. Updated versions must be submitted to the IRB.
* For marketed devices, basic product information is an appropriate alternative for the Device Manual.
* Refer to the REQM website (tools) for the following forms:
	+ Device Accountability Log
	+ Device Dispensing Log
* Applicable [GCP Sections](http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6_R1/Step4/E6_R1__Guideline.pdf):4.6, 8.2.2, 8.3.2
* Applicable Ascension WI IRB Manual: [Chapter IX.G Drugs, Biologics, and Dietary Supplements](http://www.wfhealthcare.org/app/files/public/1769/IRB-Manual-C9-Drugs-Biologics.pdf); [Chapter IX.H investigational Devices](http://www.wfhealthcare.org/app/files/public/1772/IRB-Manual-C9-Investigational-Devices.pdf)

**Correspondence**

**Contents**

* FDA correspondence
* Notes to File
* Other (Miscenallanous documents)

**REQM Tips/Additional Information**

* REQM Tools have been created for tracking purposes and can be found under REQM Tools:
	+ Note-to-File Template
* Applicable [GCP sections](http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6_R1/Step4/E6_R1__Guideline.pdf) 8.3.15

**Correspondence**

**Contents**

* Notes to File
* Correspondence between sponsor and site
* Other Miscenallenous documents

**REQM Tips/Additional Information**

* REQM Tools have been created for tracking purposes and can be found under REQM Tools:
	+ Note-to-File Template
* Applicable [GCP sections](http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6_R1/Step4/E6_R1__Guideline.pdf) 8.3.15