Massachusetts General Hospital
Department of Biomedical Engineering
Policies and Procedures
Review and Approval of Medical Devices Used in Human Studies
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1. Policy

1.1 Medical devices intended to be used in human studies within Partners must be approved beforehand by the Institutional Review Board (IRB). MGH Biomedical Engineering reviews research protocols involving devices that fall within the scope of the MGH Medical Equipment Management Plan (MEMP) and inspects the associated devices. This document is supplemental to the MEMP and describes Biomedical Engineering's internal process for reviewing and approving devices used in protocols at MGH licensed facilities.

2. Roles and Responsibilities

2.1 Quality and Safety Manager (QSM) – Responsible for the department's overall management of the review and approval process for medical devices used in human studies at MGH. The QSM works with the Partners IRB to ensure that research protocols requiring Biomedical Engineering review, as well the devices involved (and associated technical and maintenance documentation), are received in a timely fashion. The QSM assigns protocol reviews and device inspections to staff engineers and technicians, respectively, and monitors the progress of this work to ensure that it is completed within acceptable timeframes, and that impediments to completion are identified and addressed as quickly as possible.

The QSM's role in overseeing the assessment of medical devices involved in human studies extends to all Designated Technology Management Groups (DTMGs), not just Biomedical Engineering. In protocols when a DTMG other than Biomedical Engineering manages the device(s) involved, the QSM will communicate with the Partners IRB and the DTMG representative to ensure that a thorough assessment of the device(s) is completed. The one exception to this is protocols involving ionizing radiation devices (e.g. PET/CT), in which cases the QSM cedes responsibility to the Radiation Safety Office.

The QSM will collaborate with other subject matter experts (e.g. Information Security, Wireless Communications) when applicable (e.g. if the Partners IRB has not initiated request for review with subject matter experts). The QSM may delegate further coordination to the Clinical Engineer assigned to the protocol review.

The QSM will also identify an appropriate staff member to fulfill the QSM's responsibilities on an interim basis when the QSM will be unavailable.

2.2 Clinical Engineer (CE) – Under the direction of the QSM, the CE is responsible for detailed review of research protocols, assessments of the devices involved, and formulating inspection procedures for technicians when necessary. The CE is also responsible for managing internal project documentation, including work orders and asset profiles, until the review is completed.

2.3 Biomedical Equipment Technicians – Responsible for carrying out tasks required by the approval process for devices used in human studies, including initial inspections of devices, ongoing support and re-inspection, and management of associated documentation. In cases of vendor supported devices, the technician might only perform supplemental tasks such as electrical safety checks but is still responsible for ensuring that all maintenance requirements are completed on time, including obtaining and filing the required documentation.

- Inspections should be completed and documented in TMS within one week after being assigned
- Communication via email to requesting CE and/or QSM should occur once task is complete

3. Notification and routing of IRB related reviews and requests

3.1 Most notifications to Biomedical Engineering for protocols requiring its review will be triggered by the Partners IRB via the research database Insight. An automatic alert will also be sent via Insight to the QSM.

3.2 Biomedical Engineering staff will likely receive a variety of IRB-related inquiries directly from researchers. In these situations, staff should direct the researcher to contact the QSM for assistance. The only exception to this is when a researcher contacts Biomedical Engineering to request service and/or re-inspection for a device already in the equipment database; these requests should be handled in the same manner as any other service calls for devices already in the database.

4. Protocol review and action steps for inspection of devices

4.1 Protocols involving <u>non-FDA approved</u> devices and/or <u>off-label use of FDA approved</u> devices

- The QSM will create a work order for the protocol review (see Section 5.2 for details)

- The QSM will complete a preliminary review of the protocol and contact the Principal Investigator (PI) or research coordinator with any questions and/or requests for clarification as needed. The QSM will also inform the PI that a comprehensive review of the protocol will be completed by a clinical engineer.

- The QSM will assign the protocol review and protocol work order to a CE based on the CE assignment sheet, and forward to the CE any relevant information and/or communications received from the PI to date.

- When the location for use is the operating room or peri-op environment, the QSM will contact Anesthesia Clinical Engineering team manager for assignment instead of assigning to a Biomedical Engineering CE.

- If projects and deadlines prohibit the availability of a CE, the QSM will contact the Clinical Engineering Manager or Director of Biomedical Engineering for guidance in assignment.

- The CE will access Insight to obtain a copy of the protocol as well as device manuals and other related information.

- The CE will create a project folder in L:\DBEMAIN\Clinical Engineering\IRB Reviews. The name of the project folder shall be the protocol number.

- The CE will contact the PI as needed to discuss questions and/or points of clarification.

- The CE shall always physically assess the device(s) and should also assess the environment(s) of use in unusual situations, such as monitoring and/or treatment of subjects in non-patient care areas (e.g. laboratories). The CE should confer with the QSM in determining when the environment warrants investigation.

- The CE will complete a new model evaluation form for every new model of equipment involved in the protocol, then forward the form(s) for review and approval per the New Model Evaluation process. The CE will also post a copy of the new model form(s), plus all manuals and procedures to the Documents Dropbox folder in L:\Dbemain for inclusion in the digital reference library (PBMEREF).

- After completing the assessment, the CE will forward to the assigned technician the required information for inspection. In cases where the CE develops the inspection procedure, a second CE and the QSM shall review the procedure before the CE sends it to the technician.

- The CE will complete the IRB approval template and send the document (or link) to the QSM and send the completed approval template to the PI for their records

- QSM will complete the approval steps in Insight.

- The CE will confirm that:

    - copies of all relevant documents have been archived to the project folder
    - all information in associated asset profiles is comprehensive and accurate
    - all associated incoming inspection work orders have been completed
    - the protocol work order has been completed.

4.2 Protocols involving intended use of FDA approved devices not already included in the Biomedical Engineering equipment database

- The QSM will complete a preliminary review of the protocol and contact the Principal Investigator (PI) or research coordinator with any questions and/or requests for clarification as needed.
- The QSM may, after preliminary protocol review, offer conditional approval from Biomedical Engineering in Insight while more detailed review is underway (e.g. when IRB approval is needed to release funds for purchasing a device)
- The QSM will create a protocol work order.

4.2.1 One or more models of equipment to be used in the protocol does NOT exist in the Biomedical Engineering database, the QSM will assign the protocol to a CE for a detailed review. The review should proceed in essentially the same manner as for protocols involving non-FDA approved devices, with the exception that the CE is not required to physically assess the device (owing to its regulatory status). However, as is the case with all new model reviews, the CE should pay careful attention to the application of the equipment and the environment and be prepared to investigate any unusual potential risks firsthand.

4.2.2 The model(s) of equipment to be used in the protocol already exists in the Biomedical Engineering equipment database.

4.2.2.1 Protocols involving models of equipment which are already included in the Biomedical Engineering database but for which there is little existing history: QSM assess existing inventory for device model history (e.g. quantity, locations, equipment status, ownership status, equipment class). If limited history exists, QSM assigns a CE for model review.

4.2.2.2 Protocols involving models of equipment which are already included in the Biomedical Engineering database and for which there is substantial existing history (e.g. existing standard clinical devices): The QSM will work directly with a technician to assign a control number and complete incoming inspection(s) of the device(s).

4.2.2.3 Protocols involving intended use of specific FDA approved devices that are already inventoried and tracked in the Biomedical Engineering equipment database (i.e. devices with control numbers): QSM confirms device inventory information in the database and updates as necessary (e.g., location of use, new protocol number).

- If the device is in active clinical use the Partners IRB is not required to notify Biomedical Engineering, in which case no action is required by Biomedical Engineering.

- In any other situations (e.g. an active IRB device transferred to a new protocol, a clinical device repurposed for research) the Partners IRB will notify the QSM, who will assess the circumstances and determine the appropriate course of action.

5. TMS documentation requirements for IRB reviews

5.1 Every new IRB protocol review by Biomedical Engineering will result in the following records being created in TMS:

- An asset profile for every device being used in the study (one or more)
- An incoming inspection work order for each new asset
- A “protocol” work order to document the clinical engineer’s time performing the protocol review

5.2 Project/Task Work Order for Protocol Review (aka the “Protocol Work Order”)

- The protocol work order shall be the first record created in conjunction with any IRB review, because it will serve as the “home” for most of the information about the protocol. The QSM will create a new protocol work order when assigning a protocol to a CE.

- Each protocol work order shall be created as project/task (child) work order under the project/task (parent) work order called MGH IRB SUPPORT (work order number 888747).

- By default, each child work order will have “MGH IRB SUPPORT” in the Description field when it is created. The IRB protocol number shall be added to the Description, e.g. “MGH IRB SUPPORT 2015p123456.” If the review pertains to an amendment to an existing protocol, the Description shall be ““MGH IRB SUPPORT – 2015p123456 Amendment <amendment number>.”

- Information about the Principal Investigator shall be documented in the Requester, Phone, and Email fields. Additional information, such as names of other contact persons, should go in the Requester Remarks field.

- Protocol work orders use the same statuses and sub-statuses as most device-related work orders, so the status will be Active when the review is in progress and should be changed to Complete when the review is finished. The special “Project” status should not be used in these instances; it is reserved for parent work orders only.

- Once asset profile(s) have been created for devices in the study (see below), the CE shall link the protocol work order to the assets by adding the asset numbers to the asset field in the work order (using the Multiple Assets work order form as needed).

5.3 Asset Profiles

- New asset requests in TMS for devices on new protocols will originate from the CE performing the review or the QSM. When requesting new assets:

    - The protocol number shall be added to the IRB Protocol Number field on the Details – Contacts tab of the asset profile. If the device is being used in multiple protocols at the same time, then “MULTIPLE” should be written in the IRB Protocol Number field.

- The name of the technician who will perform the Incoming Inspection (and subsequent maintenance) shall be added in the Extended Description field on the Details – Contacts tab.

- In general, the resource technician for the area where the device will be used will be assigned the Incoming Inspection. For devices that will be used in multiple areas, the CE or QSM will decide which technician will be responsible for the device, consulting with Team Leaders as needed.

- If an existing device (i.e. one already tracked in TMS) is to be used on a new protocol, the CE performing the review, or QSM, will document the change by creating a Data Management work order to update the asset profile.

### 5.4 Incoming Inspection Work Orders

- The Incoming Inspection work order will be created automatically in conjunction with the asset creation.

- The DBA will assign the Incoming Inspection work order, and any PM schedules associated with the device, to the resource technician.

- No special information about the protocol is added to the Incoming Inspection work order, since the protocol number is recorded in the corresponding asset.

## 6. Maintenance, Inspection, and Compliance Requirements

- Ongoing maintenance and support of IRB devices is handled in the same fashion as Clinical devices, i.e. the assigned resource technician is responsible for the timely completion of the necessary inspections and documentation. This applies to all IRB devices, including those supported by vendors.

- IRB device compliance is calculated in the same manner as Clinical device compliance, is of equal importance, and has the same requirements.

- The department IRB program requires an annual check on every IRB device to:

  - confirm if the device is still in use
  - confirm that the device is being used correctly, i.e. consistent with the protocol
  - determine if any changes exist related to the device, environment, or workflow
  - perform a visual inspection on the device

- This program requirement is tracked separately in the equipment database from any prescribed technical maintenance by applying a special PM schedule to every IRB device called “Annual IRB Program Inspection.” This special schedule is of type [*PREVENTIVE MAINTENANCE*] and will be the responsibility of the resource technician to complete.

7. Investigational Device Exemptions

    - For devices deemed by Partners IRB to meet the criteria for an IDE number: Biomedical Engineering reviews the protocol only after the device is assigned the IDE number (Appendix A).

8. Response Expectation

    - Biomedical Engineering cannot predict the time it will require to complete a review (Appendix A)
    - Generally, preliminary action in Insight occurs within 7 days of the protocol being triggered to Biomed via Insight.
    - A subset of protocols can be completed within 7-14 days (Appendix A)
    - Clinical Engineers and/or technicians are expected to communicate with the PI within two days of being assigned
    - Clinical Engineers and/or technicians are expected to take additional action within 7 days (determine next steps for inspection, schedule inspection, complete straight forward inspections)

9. Reporting

    - QSM is responsible for monitoring the Biomedical Engineering IRB Process through review of BME internal reports and Partners IRB generated reports

APPENDIX A – Informational Guidance for Principal Investigators: Biomedical Engineering Review and Approval of Devices Used in Human Studies

URL: http://biomed.partners.org/main/EquipmentMgmt/HumanStudiesDeviceApprovalProcess.asp

## Introduction

Devices to be used in human studies within Partners must be approved beforehand by the Institutional Review Board (IRB). In general, the IRB requires that Biomedical Engineering approve all devices. Following are the objectives of the review process:

- Ensure the PI is aware of device-related risks in order to most appropriately design study and obtain informed consent
- Assure the device(s) and accessories meet safety and performance specifications and requirements
- Ensure device labeling is sufficient to inform and caution
- Inform PI of restrictions on use and schedule and need for follow-up
- Assess fitness for use and application

Prior to Biomedical Engineering review of an IRB, any submitted devices that are not FDA approved are reviewed and classified by the IRB board as significant or non-significant risk. A Significant Risk device must have an IDE to be used in a study. A device that meets the following criteria may be classified Non-Significant Risk:

- The device is not being studied for possible manufacture, and
- The use of the device is very limited and constrained, and
- The device is virtually the same as an already marketed device in terms of its safety profile

This determination by the IRB board of a device as significant or non-significant risk does not change the overall objectives of the Biomedical Engineering review. All devices within scope for Biomedical Engineering review will be assigned an independent risk classification consistent with the hospital's Medical Equipment Management Plan (MEMP). The **MGH MEMP** can be found on the Biomedical Engineering website under Equipment Management > Committees and Programs > MGH MEMP.

## Scope of Biomedical Engineering Review

Following is a list of the types of equipment that Biomedical Engineering reviews:

- Types of devices that are or would be found in the Biomedical Engineering equipment inventory
- Any electrically powered device that comes within six feet of a patient or subject. (e.g. lasers, non-hospital inventory infusion pumps, computers, other computer-based hardware or data collection systems).
- Any non-implantable device or device accessory used to acquire a real-time physiological signal from or deliver mechanical or electrical energy or therapy to a patient or subject (e.g. investigational finger tonometer, cutaneous sensors, nerve stimulators, etc.).

Note that the above includes electrically powered Significant Risk devices with IDEs.
Following is a list of the types of equipment that Biomedical Engineering need not review and generally will not inspect or test:

- Biologically based devices or artificial organs that do not incorporate a device that meets one of the previous criteria (e.g. artificial vessels or endovascular grafts – most of these have IDEs and are reviewed as part of protocol submission to the IRB submission).

- Imaging systems that deliver ionizing or non-ionizing radiation and do not incorporate a device that meets one of the previous criteria. For these systems, the IRB assigns review by Radiation Safety.
- Clinical laboratory equipment that does not incorporate a device that meets one of the previous criteria (e.g. new meter for determining speed of blood clotting).
- Significant Risk devices that are not electrically powered or are implantable and have IDEs (e.g. cardiac catheter with no electrical component).

For studies conducted under the management of the DFCI IRB, MGH Biomedical Engineering will provide review and recommendation services. Devices that are used in non-MGH licensed facilities (e.g. in a patient's home) typically do not fall within the scope of Biomedical Engineering. Through the IRB application process, Biomedical Engineering review may be requested. However, these devices will not be inspected. Under these circumstances, Biomedical Engineering serves in a consulting role.

## Review Process

To begin the review process for a device, Biomedical Engineering generally requires a description of the intended application of the device and complete device information within the electronic IRB application. Additional information about the safety or performance of the device in the context of its application or in support of data in the form may be requested.
On completion of review, Biomedical Engineering determines what, if any, additional documentation, inspection, tests, and changes are needed for the device. Inspection and testing will be scheduled as needed to assess the following:

- Function
- Clinical application
- Required maintenance
- Likelihood of failure
- Environment of use

Devices with an IDE status that meet the above criteria will be reviewed by Biomedical Engineering. The IDE status will be taken into account in the assessment of the device. On satisfaction of all requirements, Biomedical Engineering informs the IRB and Principal Investigator of the approval via a memo. Biomedical Engineering cannot predict the time it will require to complete a review. Generally, the documentation provided by the IRB would be reviewed and first action taken within seven days of receipt. A subset of reviews can be expedited and completed within a week. These reviews meet the following criteria:

- All devices are already managed by Biomedical Engineering and there is no alteration to the clinical application, or
- The PI has worked with Biomedical Engineering before submitting the protocol, or
- The devices are outside Biomedical Engineering expertise and/or among the categories of devices that Biomedical Engineering does not review (see above).

## PI Responsibilities for Post-Biomedical Engineering Review

All IRB devices require annual routine inspections. It is the responsibility of the PI or research team to ensure compliance of devices. Biomedical Engineering must be contacted when routine inspection is due or required. Reinspection is required for the following:

- Device is being replaced by a device of the same make and model
- Modifications made to an existing device or system

A new amendment is required for the following:

- A device is being replaced with a similar device of a different make and model
- If an entirely new device is being added to a protocol

Upon completion of the study, the PI or research team must contact Biomedical Engineering when the device is being taken out of service.