Mentor Online IRB System

IRB's require lots of documentation and managing this process can get to be a burden for both investigators and the IRB committee and administrator. The Mentor IRB system is designed to provide an interactive process for investigators to submit protocols for review, for the IRB members to review these protocols and for the IRB chair and administrator to manage the data.

Although Mentor has a wide variety of features to handle the most demanding IRBs, many of these features can be switched on and off, so that your IRB can customize Mentor to meet your exact needs.

Key Features for the PI

- **IRB Info Page** - The IRB chair or admin can create an info page for all investigators with instructions, and general information, including links to key documents.

- **IRB Documents Page** - A portion of the Mentor Document Management System where the IRB chair or admin can post general interest documents. For example, the IRB SOP's, copies of the regulations, general policies, application templates, etc.

- **My Protocols Page** - A list of protocols for each principal investigator. The PI can choose to list new (unapproved), active, terminated, and exempt protocols.

- **Protocol Submission** - A simple form that collects the important information about the protocol from the PI. PI's can upload the protocol, consent form and any other documentation relevant to the IRB review process. Mentor supports all review types (full board, expedited, exempt, QI, delegated to an external IRB, emergency use, HUD).

- **Custom Forms** – add your own questions to the protocol submission template. You can add a separate set of questions for each exemption category and for expedited, full board, emergency use and humanitarian use device submissions. Multi-part forms are also supported. Form parts can be linked to specific menu options on the protocol submission form. You can also create custom forms for continuing reviews, adverse events and for assigned reviewers.

- **Research Coordinator** - PI's who have research coordinators or secretarial support can designate individuals to manage their IRB protocols in Mentor.

- **Continuing Review** - Once a protocol is approved, a continuing review (annual report) record is automatically generated with a due date. The PI can submit the report and request continuation or terminate the protocol. You can add custom questions to the continuing review form and select from a list of preset questions to include.

- **Notifications** – Mentor automatically notifies the PI of a pending continuing review date at a time pre-set by the IRB administrator. Additional reminders can be scheduled to repeat until submission is made.

- **Amendments** – You can define multiple file types to be submitted for each amendment (e.g., Revised Protocol – Track Changes, Revised Protocol – Changes Accepted, etc.). There is no limit on the number of amendments that can be filed. Revised consent form and revised protocol can then be moved onto the protocol to replace the prior documents. Mentor's version control system keeps a history of the prior versions of each document.

- **Adverse Event Reporting** - Each protocol supports an unlimited number of adverse events to be submitted by the PI. We have an advanced AE reporting feature for IRBs that wish to track AEs in detail.

- **DSMB Reporting** - Each protocol supports the submission of data safety monitoring board reports. (no limit on numbers of reports)

- **Protocol Deviation/Unanticipated Problem Reporting** – Each protocol supports the submission of protocol deviation reports. (no limits on numbers of reports)

- **Department Chair Approval** - The IRB can require department chair approval for submitted protocols. The department chair is notified of a new submission and has an interface to review protocols by their faculty and approve the submission to the IRB.

- **Administrative Approval** – the IRB can name one or more administrators in the institution who routinely have to approve protocols before the IRB does its review.

- **Supervised PI's** – IRB's often require students to have a faculty or staff member as supervisor on the student protocol. Also some staff within an institution may be required to have a supervisor. Any role within Mentor can be designated as requiring a supervisor to be selected from any other role within Mentor. When a supervisor is required, Mentor prompts the PI to name the supervisor and then notifies the supervisor of the protocol and the supervisor must formally "accept" the protocol. Supervisors are automatically cc'd on all notifications from the IRB.

- **Save and Submit** – Mentor provides an option that allows PIs to initiate the protocol submission process and save their work but not formally "submit" to the IRB. The IRB can still see the protocol and associated documents, as can any supervisor. Once the PI clicks the formal Submit button, the protocol then enters the normal workflow of the IRB.

Key Features for the IRB

- **Support for Multiple IRB's** - Mentor will handle as many IRBs as your institution has, each with its own independent interface and each with its own customizable settings.

- **Notifications to IRB** - Upon submission of a protocol or any other element related to it by the PI, a notification email is sent to IRB members (who can elect which specific notifications to receive).

- **Canned Notifications** - The IRB Chair or Administrator can customize notification templates for all the standard communications between the IRB and the PI: approval, expedited approval, exempt certification, tabled, continuing review approval, new protocol, new continuing review, etc. Notification templates support a wide array of variables that automatically insert data from the protocol. There are variables for IRB ID, Title, Approval Date, etc…over 30 variables in all.

- **Continuing Review Reminders** - Mentor will automatically send a reminder email to the PI informing them of an impending continuing review due date.

- **IRB Administrator Assignment** – Some IRBs have multiple administrators and assign individual administrators to particular protocols. Mentor supports both manual assignment of an administrator as well as automatic assignment of the administrator.

- **IRB Members** can access the full protocol and all documentation and reports.

- **IRB Chair & Designated Administrators** can access and modify all elements of the protocol as well as change the status of protocols (e.g., from new to approved, tabled, revisions required, etc.).

- **Human Subjects Training Documentation** – if your IRB requires that investigators complete human subjects training (e.g., through the NIH tutorial or CITI), investigators (and IRB members) can be required to submit their certificates of completion in Mentor to the PI Documentation page. Mentor can be set up to remind investigators when their certification requires renewal. A link appears beside the PI name on any protocol that shows the certification status. Thus one certificate will apply to all protocols associated with that individual.

  CITI Integration – Mentor can be set up to download the CITI certifications data for your institution on a nightly basis and report that data directly on the PI Documentation page.

- **IRB Forms** - IRB's may have specific questions that they ask their PI's to answer. Mentor IRB supports custom forms that allow the IRB to create a set of questions that each PI must complete on submission of a new protocol. This allows the IRB to ask for additional data not included on the protocol submission form, or it may be used as a decision tree to confirm exemption, expedited review or other protocol parameters. The IRB can in the same way create checklists for IRB Reviewers to complete. Each reviewer role can have its own checklist. The custom forms support a wide array of question types: check box, multiple choice, multiple select, short text, long text, numeric, etc…

- **Custom Document Types** – most IRBs require multiple documents from the investigator, either on submission of a new protocol, or on submission of a continuing review or amendment, DSBM report or Protocol Deviation. The IRB can define a set of file types for each of these contexts. Thus, you might ask for a Protocol Summary and an Investigator's Brochure, as well as any advertisement literature and the consent form.

- **Document Version Control** – All documents in Mentor can be "replaced". When replaced, the original document remains archived in our version control system. These older versions can be accessed at any time and you can always restore a prior version of the document. There is also a detailed log of downloads of each file.

- **Multiple Reviewer Roles** - The IRB can define reviewer roles (e.g., primary reviewer, medical reviewer, etc.) and then assign IRB members to these roles on specific protocols. Each reviewer role supports its own custom form if you have your reviewers complete a checklist or answer a set of required questions. Reviewer roles can also be authorized to approve exempt or expedited protocols.

- **Automatic Reviewer Assignments** – You can establish rules that are used to automatically assign reviewers to protocols as they are submitted (reviewers are not assigned to supervised/student protocols until the supervisor "accepts" the protocol.) Reviewers from different roles can be automatically assigned to the same protocol and you set the number of reviewers from each role. Mentor uses a "reviewer load" calculation to select the reviewer with the lowest load score. Loads are weighted by the protocol review type (exempt, expedited, full board review). You can also configure Mentor to assign reviewers from specific departments or schools to protocols that originate from those same departments or schools. Non-IRB members can also be assigned as reviewers when outside expertise is required.

- **Meeting Agenda & Minutes** - Mentor will generate an agenda automatically based on the status and dates of submission of new protocols and reports received. All protocol files can be directly downloaded from the agenda, and members can access the full protocol as well. You can add agenda notes and discussion notes, so the agenda can double as your minutes. Agendas can be custom ordered and the agenda includes an attendance function and a place for IRB members to write notes about each protocol or report.

- **Notifications to PI** - Email notifications from the IRB chair or administrator are automatically saved as PDF files and attached to the protocol record.

- **Communications** - A simple messaging service for PI's and members of the IRB to communicate about the protocol. Messages can be limited to just the IRB, or specific members of the IRB, or include the PI. Messages are archived and become part of the permanent record of the protocol. Messages are sent by email to recipients and replies to these emails are archived on the protocol before being sent out to the original list of recipients.

- **Print to PDF & Zip** - This function allows both the PI and the IRB administrator to print all the Mentor pages associated with the protocol record to PDF and then create a zip file of these PDF pages, along with all the related files that have been uploaded to the protocol.

- **Custom Labels** – You can create your own labels for the protocol tabs as well as the submission form input fields.

- **Custom Menus** – Mentor has three customizable menus: Protocol Types, Protocol Categories, and Protocol Groups. You can re-label them and populate them with options, display them to the PI or just the IRB administrators, and set them to be multiple select or single select menus. Each of these menus can be custom labeled as well. Mentor also has Regulatory Agency menu and a HIPAA menu that you can customize. Any additional menu can be added using our custom forms.

- **Reports** – Mentor provides a set of canned reports: number and type of protocols per calendar year, academic year or date range; average time to approval; reviewer load report; reviewer average time to completion.

- **Data Export** – In addition to downloading a zip file that includes a PDF of all protocol pages plus all protocol files, you can extract all protocol data to a set of csv files which can be opened in Excel or imported into any statistical package. In addition, the data from any custom form can be exported to csv as well. So you have an easy and convenient way to extract data for statistical analysis.

- **Panels** – For high volume IRBs that convene separate IRB panels, Mentor supports multiple panels. Panels include a roster, assignment of an IRB administrator and linkage to specific meeting agenda. The IRB administrators assign protocols and reports to the appropriate panels or protocols can be automatically assigned to panels based on review type and/or report type (continuing reviews, amendments, etc.).

- **Approved Consent Form & IRB Stamp** – IRBs that use an "Approved Consent Form" often embed a stamp onto that form indicating the expiration date of the current approval, and perhaps a signature or initials of the IRB chair. Mentor has a function that will convert the final approved MS Word version of the consent form to PDF and place the IRB stamp on

the PDF, including the expiration date, approval date, IRB chair name and any graphical elements you include in your IRB stamp.

Customization - Mentor is easily customizable to each IRBs needs. Don't need DSMB reporting? Just switch it off. Set your own continuing review due date schedule for all protocols, customize your notification templates and define your own reviewer roles, forms and checklists.

Custom Development – If Mentor doesn't meet your exact needs, we are generally willing to add custom features to meet them. We know that IRBs each have their own practices. While we can't guarantee to be able to make any modification you might ask for, we are pretty flexible and can generally add features that will meet your requirements. Most custom work is done without additional cost. Requests for major changes, however, would need to be negotiated.

Support – The Mentor help staff provides same day (and usually within a few hours) answers to your questions. We can help you with both the Mentor IRB system and your questions about the IRB practice and the ethics and regulation of research involving human subjects.

Included - All installations of the Mentor IRB system come with two additional Mentor features: the full Mentor document management system, which can be used for sharing and archiving documents from across the institution. Mentor IRB also includes the Surveys & Tests module within Mentor which allows the institution to conduct surveys of Mentor users or external constituencies.

Data Extraction – Mentor provides downloadable text files (csv) to extract all of your protocol related data in a format that is easily imported to a spreadsheet, statistical program or database. This feature, coupled with our Print & Zip function allows you to easily archive all your IRB data locally if that is desired.

Hosting – Mentor is offered on a Software as a Service (SaaS) model. We are responsible for all maintenance, backups, data redundancy, 99.95% uptime and security. Mentor is PCI certified by McAfee Secure. All files uploaded to Mentor are encrypted. Mentor can tie in to your institutions identity management system (LDAP, CAS, Shibboleth) and Mentor can be automatically populated with users from your institution's central data management system (via file uploads or web service). Mentor can also be populated with users by LDAP and web service lookup as well as manually by the system administrator or manual file upload.

Check out our IRB webpage at: http://www.axiomeducation.com/irb-management-software/

Check out our quick video overview of Mentor IRB and more detailed videos at:

https://www.axiommentor.com/mentor/IRB