Human Research Newsletter

MAY 27, 2016
VOLUME 2, NUMBER 2

INSIDE THIS ISSUE:

Filtering eMail Notifications From IRBNet

The IRB staff is in the process of changing the way that IRBNet is used. This will improve efficiency and organization in working with projects. This may result in an increase in the number of emails generated to study teams regarding projects.

As study teams know there are a lot of emails notifications from IRBNet. Some of these are important to note, and may require action on the part of the study team. Others are automatically generated by the system, are duplicative, don't require any follow-up and can be filtered out to decrease the "clutter" in your inbox.

All of the following actions and notifications are communicated via an automatic email with **"IRBNet Board Action"** in the subject line:

- A project is shared
- A package is signed
- A package is submitted
- An action is taken on a submission
- A board document is posted for a submission

These automatic notifications either require no action by the study team, or are duplicative of the notifications that are generated by IRB staff.

The following emails are generated by IRB staff when letters and documents are published following a board action and/or when follow-up action/information is required. These will have a **different** subject line.

- Approvals
- Requests for Information
- Modifications required
- Acknowledgements (these may have instructions for follow-up or questions that need to be answered, in addition to the acknowledgement, so these are important to read)
- Study closure notifications
- Reminders of upcoming continuing review

As a result, for study team members wishing to decrease the number of notifications in their inbox, you can choose to filter out any emails with **"IRBNet Board Action"** in the subject line. This will not affect notifications generated by IRB staff, so the same important information and any requests regarding projects will still make it to your inbox.

Study team members can also review all notifications and emails sent through IRBNet by logging into a project and selecting **"Messages & Alerts"** which will show all messages generated regarding a particular project throughout its history.

NOTE: if you opt NOT to filter - only those team members with **FULL** access to projects will receive automatic emails from IRBNet. **It is recommended**

that the PI always has full access to projects in IRBNet.

Links for help setting up rules in Outlook to filter email:

Office 2007
https://support.office.com/en-us/article/Manage-messages-by-using-rules-80cc1f28-533d-4879-a8cc-ef83e9af0495

Office 2010
https://support.office.com/en-US/article/Manage-email-messages-by-using-rules-50307363-0e79-4f6a-95c0-04b922a2ff13

Office 2013 & 2016
https://support.office.com/en-US/article/Manage-email-messages-by-using-rules-C24F5DEA-9465-4DF4-AD17-A50704D66C59

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Training Resources in IRBNet

IRBNet has a resources page with printable resources and videos on how to submit and manage projects in IRBNet.

For researchers, this is accessed here:
http://www.irbnetresources.org/tresources/training.html
User Name: chwi
Password: training

You can also access something called the "Sandbox" which is a practice environment for working in IRBNet. This is a place for new study team members, or those needing a refresher, to become familiar with IRBNet and how to create different submissions without affecting "real" projects.

This can be accessed here: https://training.irbnet.org/training/index.html
User Name: chwres1
Password: training

You can also contact the IRB staff with any questions or requests for assistance in working with IRBNet or putting together project submissions.

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Managing Documents in IRBNet Projects

The appropriate management of document revisions and additions within a project in IRBNet is important for establishing an accurate project history and maintaining efficiency in locating particular versions of revised documents, especially for the board members reviewing the documents.

Actions when it comes to documents in the IRBNet packages:
- Add a new document
- Update or revise a previously added document

In order for the system to work effectively, teams need to use the appropriate action for the circumstance/submission.

A **new** document should be added **only once** – the first time a particular document (consent, protocol, assent, data collection tool, brochure, IB, etc) is added to a project.

- This could be at the initial submission for a new project **OR**
- It could be at the time of an amendment if an additional, brand new document was created for the study

A document should be **revised** within a project in only 2 circumstances:

- When an **amendment** package is submitted
- When a package to respond to a **request for modifications** is submitted

The process in IRBNet is slightly different for each instance.

Adding a <u>New</u> Document:
When a new document is being added to a project, the user should upload it to the package using the **"Add New Document"** button from the **Designer** view. This adds the new document into the list of all documents submitted for the project –whether in the current package or in previous packages.

This list should contain a listing for each document type included with a project, but each particular document should only show up once in the list, with the **"Document Revision History"** attached. This history compiles all the previous versions of that particular document as a group (discussed below).

Updating and Revising Documents:
When a document is being **revised or updated**, it should NOT be added as new document. Instead, this should be managed from the list of "documents from previous packages that you revise." This is the list mentioned above generated and added to as you add NEW documents.

Users should:

- Locate the document that requires revision from the list of documents in the project
- Download the previous version (which should be the most current) from IRBNet to your computer, revise as needed, save a tracked version and a clean version to your computer
- Instead of ADDING this revision back as a **new** document, you should locate the document in the list for the project, and click on the **pencil** icon (update icon) next to it (**NOT** the Add New Document button)
- This will bring up a view similar to adding a document, where you can browse for your revision and attach by clicking the **"update"** button.
  NOTE: if this is the **FIRST** time you are adding a **revision** to a document, you should upload the **TRACKED** version as a NEW document (with a descriptor that this is the tracked version) to get this into the list of project documents. Subsequent tracked versions of the same document should be updated using the pencil icon for revisions the same way as for the subsequent clean versions.

When you revise a document in this manner, you avoid creating a long list of project documents in which each revision is showing as a separate, new document. This kind of list becomes difficult to sort through to find a particular revision or determine which is the most recent when the board is looking for documents from their view in IRBNet.

Instead, when revisions are managed in this way, all the **versions** of a particular document are "stacked" together into a **"Document Revision History"** that travels with the document into subsequent packages as revisions are made, rather than a document being repetitively listed with each package to which revisions are uploaded, as though it is a new document.

By selecting the **"Document Revision History"** icon, all versions of a particular document can be viewed together, in order, rather than trying to find them within a long list of documents from previous packages.

For step by step, printed instructions with screen shots and a video about document management:

http://www.irbnetresources.org/tresources/training.html
User Name: chwi
Password: training
R2: Post Submission Advanced Topics
Add and Revising documents starts on page 11 of the .pdf document

If you would like one on one assistance with this please contact Michelle Martin at MMartin@chw.org.

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Education Opportunity: Enhancing Ethical Decision Making for Vulnerable Populations Conference

On Thursday, June 9th from 7:30am to 3:00pm the Medical College of Wisconsin has a Continuing Education opportunity. The Division of Medical Humanities will be hosting a conference entitled "Enhancing Ethical Decision Making for Vulnerable Populations." The conference will be in the Alumni Center at the Medical College of Wisconsin.

The Keynote Speaker will be D. Micah Hester, PhD. Dr. Hester is a Professor of Medical Humanities and Pediatrics at the University of Arkansas for Medical Sciences, and a clinical ethicist at Arkansas Children's Hospital.

Program Objectives include:
- Expand the definition of "vulnerable populations"
- Understand how vulnerability influences health care providers' decisions
- Explore alternative models of care for vulnerable populations

Continuing Education credits are available.

REGISTRATION:
To register for this program, please visit:

http://ocpe.mcw.edu/content/enhancing-ethical-decision-making-vulnerable-populations

Registration Fees
$50 Regular registration
$40 MECN Members and MCW affiliated hospital staff/employees

MCW Bioethics students and alumni
Plus additional $25 fee for CME/CE certificate, if requested. Lunch is included in the registration fee.

Please call or email Diane Kramer at 414-955-8498 or dkramer@mcw.edu for more information.

Pediatric Translational Research Unit

All pediatric affiliated research coordinators and assistants are cordially invited to the Bi-Monthly Research Support Staff Networking session in the Pediatric TRU:

Wednesday, June 29 from 2:00pm – 3:00pm
in the Pediatric TRU (Center 2)
Call 266-6515 with questions
Take a break and get to know CRCs and Research Assistants from other departments/divisions
Independence Day ice cream sundaes provided!

If you have resources you would like to see here, please contact Beth Gissibl bgissibl@chw.org with suggestions and feedback..

New IRB Staff

Michelle Martin, CCRP began work with the CHW IRB on May 16th, 2016 as the new Research Quality and Education Coordinator.

This is a new position in the IRB office and will evolve as needs become apparent. The goal of this position is to provide IRB members and study teams with training and resources for questions about human subject protection and assistance with conducting research at CHW.

Some examples include:

- developing training and educational resources and materials
- providing updates on regulations, IRB policies and procedures
- assistance with process improvements, quality improvement initiatives, revisions/clarifications to IRB policies and procedures
- working with study teams individually for training and help with initiating and managing research projects

Michelle can be reached at: MMartin@chw.org 414-266-7454

IRBNet Document Library

The IRB Office is reviewing and updating the submission forms posted in IRBNet. To ensure you are using the most recent version, please use the documents posted in IRBNet when preparing a new submission.

An updated Amendment Form
The IRB staff will send out an announcement when this is available in the library

Prior issues of this newsletter are posted under Research Newsletter.

The IRBNet Document Library houses submission forms, templates, policies and guidance documents. To access, log on to IRBNet. On the left navigation bar click “Forms and Templates”. Then click the dropdown menu on top of the page and choose the second option “CHW IRB Milwaukee, WI Documents for Researchers”.

Questions, Comments, or Suggestions

Your thoughts and recommendations for future newsletter topics are much appreciated! Please send your ideas and feedback to Michelle Martin at MMartin@chw.org.