

Goodbye to Paper (Mostly):

Converting IRB-approved studies to eIRB

Michael Kelley
Office for Research/OPRS
Northwestern University

Converting Studies to eIRB

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Why convert?

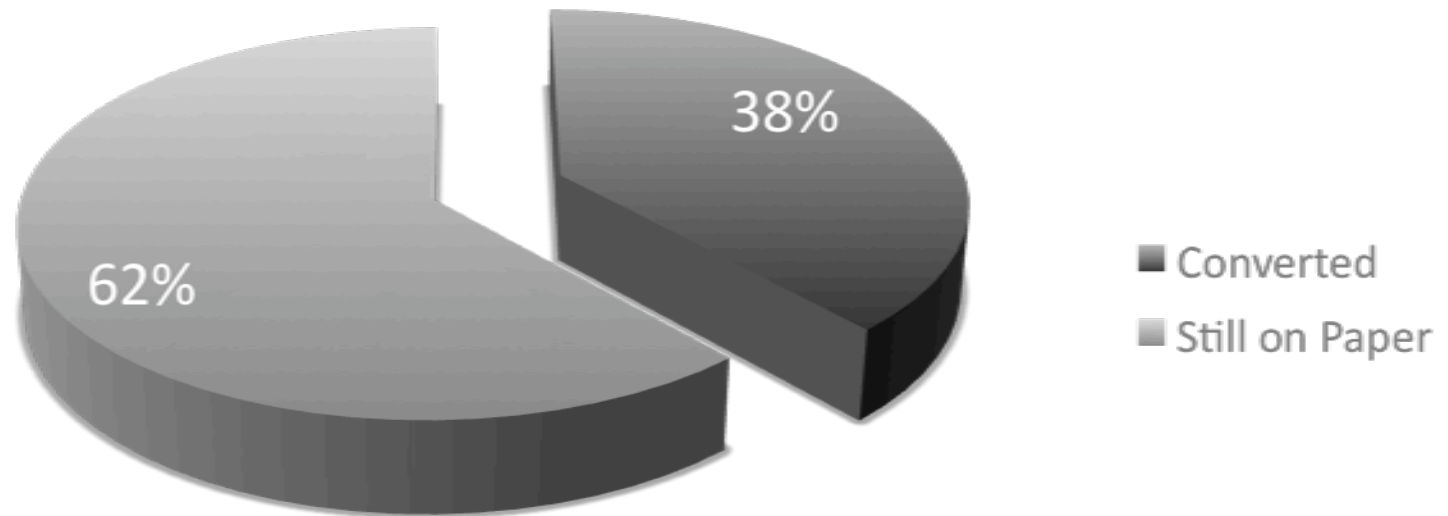
- To realize the benefits of the electronic system over the old paper system.
 - No hassling with paper
 - Electronic access to IRB submissions and IRB-approved documents
 - Monitor progress of studies on-line
- Connecting with information—not paper!

Status of the Conversion Effort

- Summer 2008
 - Designed a first version of process
 - Collaborated with ORIS to develop IT tools for the conversion
 - Worked with CRO and several other departments to test and refine the process
 - Dedicated staff to the conversion

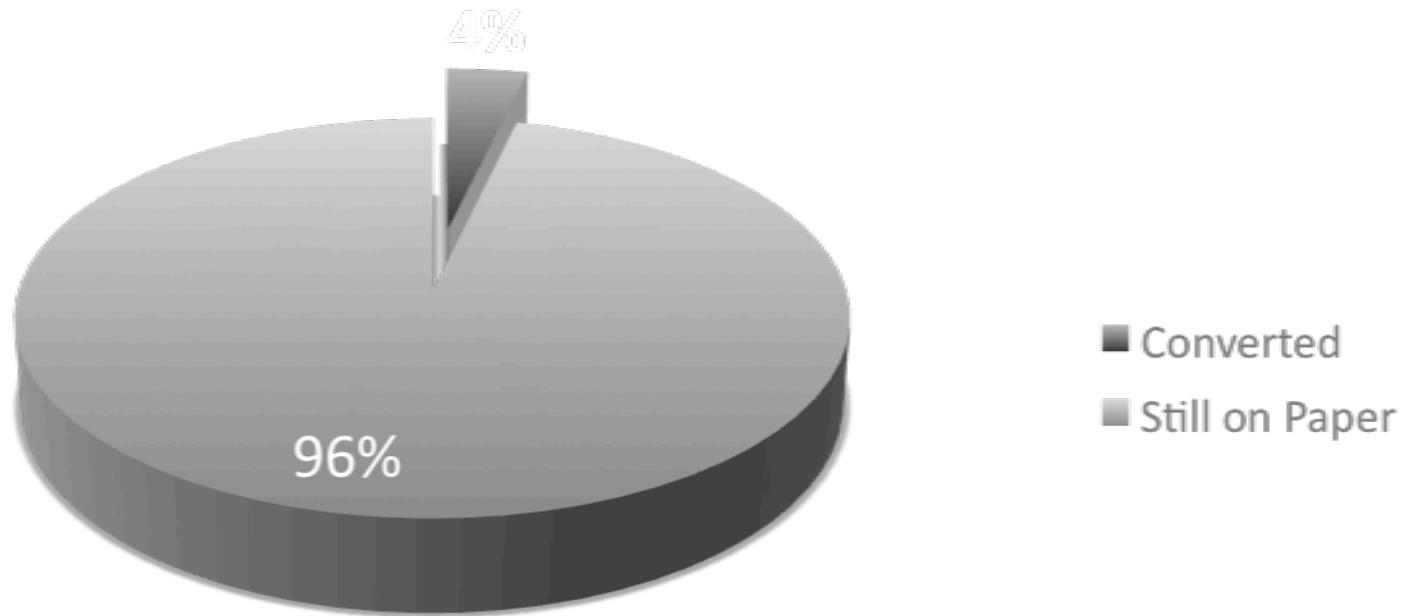
Status (cont'd)

Full Board Studies (601 total)



Status (cont'd)

Expedited Studies (1,305 total)



When Can I Convert My Studies?

- Beginning 01/19/2009, the conversion option will be made available to the research community.
- OPRS has staff dedicated to the conversion and will schedule conversions as quickly as possible.
- Email eirbsystem@northwestern.edu and indentify the PI(s) whose studies you wish to convert.
- OPRS will contact the PI/representative to begin the process.

Converting Studies

- Step 1: Identify candidates for conversion
 - Start with full board review studies. These tend to have higher submission volume, i.e., more frequent revisions and reportable events. Thus, the advantages to converting are greater.
 - OPRS will assist in selecting studies for conversion using reports from our legacy system.
 - Make sure the PI has registered in eIRB!

More tips for selecting studies to convert

- Make sure that the study is not expiring within six (6) weeks.
- If you have revisions or reportable events ready to submit, submit those on paper forms. Wait until those submissions are approved before converting the study.

Studies Not Being Converted

- Exempt
- Emergency Use
- HUD
- Studies likely to be terminated within 6 months.
- Studies where VA is a study site.
- Studies with unresolved pending/deferred issues.
 - Any IRB requests for prior submissions (Continuing Review, Adverse Events, Revisions, Promptly Reportable Events) need to be completed prior to conversion.

Converting Studies (cont'd)

- Step 2: Provide a list of studies to be converted to OPRS.
 - Base this list on the criteria listed on slides 8-10.
 - For each study, identify the following:
 - The submission preparer
 - Persons who should be included on the “Study Access List” (persons who need administrative access to the study)
 - Ensure that all these persons have registered in eIRB. Otherwise, they cannot be loaded into eIRB.
 - *Inform all study personnel who prepare IRB submissions that the study is being converted. If possible, they should wait until conversion is complete, and submit through eIRB. (See slide 21.)*

Converting Studies (cont'd)

- Step 3: OPRS closes the studies in the old system, and creates a “starter” record in eIRB.

The “starter record”

- Items loaded into the study application
 - Study Title
 - PI
 - Submission preparer
 - Study access list members
 - Other authorized personnel
 - Former NUIRBS #
 - Expiration Date
 - Currently approved consent form(s), protocol, IB

The “starter record” (cont’d)

- Background documents
 - NUIRBS project history (list of all submissions)
 - NPSF
 - Latest Continuing Review form (if a CR has occurred)
- These documents are added via a “Comment to Research Staff”.
- They are helpful in completing the conversion submission.

Converting Studies (cont'd)

- Step 4: OPRS hands off the starter record to the study staff for completion
 - Once the starter record is completed, OPRS will inform the PI/study coordinator.
 - The PI/study coordinator completes the application.
 - The PI submits the study.

Converting Studies (cont'd)

- Step 5: The Department and Site Reviewers review the conversion submission.
 - The Department and Site Reviewers review and either request changes or approve the conversion submission.
 - If the conversion submission is not reviewed within two (2) business days, OPRS will manually advance the submission to the next step.

Department/Site Review for Conversions

- Conversion submissions will be forwarded for department/site review, but...
- Reviewers will be advised that these are conversion submissions—not new studies.
- Review should be limited to confirming accuracy with department/site records and updating records to reflect the new study ID.
- In order to prevent undue delay in the conversion process, OPRS will advance the submission to the next step in the process after two business days (unless the reviewer has requested changes).

Other things to keep in mind...

- Converting studies is not effortless—but it's worth the effort!
- A little time spent completing the conversion submission will save much more time over the life of the study.
- OPRS forms have changed over time. For studies that began before 2002, a bit more “digging” may be required to complete the conversion.
- Make sure the PI submits the conversion!

Converting Studies (cont'd)

- Step 6: OPRS reviews the conversion submission, and requests changes/corrections if necessary
- Upon approval of the conversion submission, the process is complete.
- All future submissions are made electronically.

OPRS Review

- Official IRB review (under expedited procedures) ensures accuracy of the converted study record.
- Scope of review is limited to ensuring an accurate and complete eIRB record of the currently approved version of the study.

What if I need to submit a revision or reportable event *while the conversion is in process?*

- If a submission cannot wait until the conversion is complete, OPRS will work with you to submit and process the submission.
- Example: a new risk is identified and the consent form needs to be revised.
- Contact Debra Gibson Tice at 312-503-4661 or d-gibson2@northwestern.edu so that the submission will be properly processed.

