Huron Webinar Series: Data Migration Dates, Revised Documents for New Submissions, and Other News!

September 12, 2019
Topics to Cover

- Data Migration Dates
- Importance of New Templates
- New Protocol Templates
- New Checklists
- Other News
- Questions
Important Notice

All the following dates are subject to change depending on technical issues we may find along the way!
Anticipated Schedule during Data Migration

- Continuing reviews for studies **expiring January/three first weeks in February**
  - Submit renewal application in **November**

- **Strategic slowdown of submissions** (new and amendments): January 7 through go-live January 31
  - **New Studies:** Limited to interventional studies with these criteria:
    - Competitive enrollment or contractual obligation for quick start-up (e.g. NCI grant)
    - IRB is limiting factor in start-up (i.e. do not submit if contract, etc. will not be ready)
  - Others: hold until new system go-live (consult IRB leadership if special concerns)
  - Any studies submitted: **need to wrap up within 90 days of go-live, else must resubmit in new system**
Anticipated Schedule during Data Migration

- Strategic slowdown of submissions (new and amendments): January 7 through go-live January 31—Continuation...
  - Amendments: only if updating protocol, IB, consents, or other study document when immediate change is required by Sponsor or affects safety/welfare of subjects. Amendments for non-urgent changes should be held until go-live
- Reportable events: Submit as usual in the current eIRB system
- Continuing Reviews: hold until new system go-live
- WIRB and other External IRB-Reviewed Studies: we will have another workflow available outside eIRB
Anticipated Schedule during Data Migration

General Recommendations

- Make sure to save your **recruitment materials**! Studies will be migrated and snapshots of the information will be kept but recruitment materials will **not** be migrated to the recruitment section in the new Smartform. Those will need to be added back in after go-live.

- Save copies of your **consent forms** before the go-live. The system will have a copy but we want to make sure you have what you need in case there are any technical issues during that period.

- Use our new protocol and consent form templates and smart-form template to **work on your submission during the slowdown**
CR submission for studies expiring in January/three first weeks of February


Emory Winter Recess

Start of New Submission/AM Slowdown

7 Jan, 2020

31 Jan. 2020

New System Go live
Importance of New Templates

Several questions in the current submission forms will not appear in the new eIRB.

The protocols will need to cover those areas that are no longer in the submission.

Critical: you must use our templates!

For external protocols: you must use our addendum.
New Protocol Templates

- We have saved these templates at http://www.irb.emory.edu/eirb_project_huron_saas/New_Templates.html
- Our revised templates are as follows:
  - Biomedical Protocol
  - Socio-behavioral Protocol
  - Site Supplement to Sponsor Protocol
  - Retrospective Chart Review Protocol
  - Secondary Analysis Protocol
New Checklists

Terminology update!
“Checklists” = need to be filled out as part of the IRB submission (some by study team, some by IRB staff or reviewers)
“Worksheets” = for IRB staff reference primarily

Used to capture important regulatory information

Some checklists will be familiar, some will be new or updated
These are the current checklists on our website that will **not** be updated:

- Mobile Medical apps worksheet *(will be called “checklist” moving forward)*
- Department of Defense Study Checklist
- ICH-GCP E6 Checklist
- Mobile Medical apps worksheet *(will be called “checklist” moving forward)*
- REMS Checklist
- Dietary Supplements and/or Medical Foods Worksheet *(will be called “checklist” moving forward)*
- Humanitarian Use Device (HUD) Checklist
- Investigator Justification for IDE Exemption
- Investigator Justification for IND Exemption
- Investigator Checklist for the Use of Schedule I Controlled Substances
- FERPA_Guidance_and_Checklist
New Checklists

- Updated Checklists for IRB staff use available for study team reference:
  - HRP-415 - CHECKLIST - Prisoners
  - HRP-416 - CHECKLIST - Children
  - HRP-417 - CHECKLIST - Cognitively Impaired Adults
  - Subpart B worksheet
Other system upgrade updates

Study-Staff Change Requests:
- Currently: using online tool, no need for eIRB amendment
- New eIRB: all staff changes will require an amendment
  - Good news: only one form, so easy to complete
  - It will not require PI sign off if he/she identifies a proxy for submission
  - With this type of amendment, another amendment can be open at the same time!