Tips to Prepare for a Human Ethics (IRB) Implementation

A note from a former IRB Research Administrator:
SO! You've been given the green-light to get a new Electronic Research Administration (eRA) software for protocol management system to help streamline your administrative processes and reduce administrative burden. FANTASTIC!

Having been through my own implementation process (that wasn't Cayuse), here are some things I wish I would have known as a research (IRB) administrator trying to implement a new electronic research administration software in the midst of ongoing submissions. These tips will help alleviate the stresses involved with migrating legacy documents and training your investigators. The more you can prepare ahead of time, the less time it will take you to get up and running so you aren't balancing two systems simultaneously while you get everyone on board.

FORMS AND TEMPLATES:
It might seem self-explanatory, but it's not something I thought about in the excitement of streamlining my efforts. If I'd had this prepared ahead of time, it would have saved me about 1-4 weeks of implementation time while I got this sorted out with the IRB committee who was already looking at the checklists and form templates to look for improvements:

- **WHAT:** *Save all potential notification, letter, reminder, and expiring/expired study templates in a "repository" Word.doc. Go back through your "sent" folder and find at least 1 of each type of notification, reminder, approval, administrative check-in language and collate in a word.doc or multiple word.docs to organize it.*

  WHY: This will allow for the ability to quickly copy/paste these into templates that our implementation team will be asking you for. Take an hour and put together a word.doc that provides:

  - Who the email/letter should go to
  - The subject line
  - Where you want "merge" information from the protocol to go (i.e., study title, protocol number, PI name, respective dates, and submission type (amendment, initial, etc.) to go in your template and put [brackets] around that information.
  - JPG signatures of your Chair and Co/Vice Chairs

- **WHAT:** *If you are considering updating any of your forms that require committee vote and approval, ensure this is done prior to implementation.*

  WHY: Even though you have the ability to manage your Smartforms and make tweaks on a whim, your "Go Live" will be seamless if your forms are the most up-to-date at the time you implement. We know purchase agreements and contracts take some time to get through business service and legal review. Take that time to check in with your

committee to ensure the forms you are using capture the most updated regulatory requirements.

Consider the following:

- ❖ Any consent/assent templates
- ❖ Letters of support guidelines
- ❖ Recruitment flier templates
- ❖ Institutional policies/procedures (i.e., with respect to sIRB or Revised Common Rule).
- ❖ Reviewer checklists (analyst, reviewer, full committee, etc.)

GO LIVE PLAN

- **WHAT:** *How will you handle closeout studies? Will you decide to not migrate in legacy information from those studies and continue with your existing process to close out (i.e. Exempt/Expedited studies pre-2018 common rule? OR do you want to migrate everything that is active and have them submit electronically?*

  WHY: I, personally, found it easier to pursue closeout, outside of the chosen eRA system so that it was:
  1) Less work to migrate data into the system since it was going to close out anyway.
  2) Alleviate some of the burden on your PIs to plug old information in, just to close it out in a few months.

  If you can, survey your Exempt study PIs to determine what studies will be closing out in the next year and audit them to see where they are in their study. Is the study in a place where it can be closed out before implementation? If so, try to have this done prior to Go Live so that the only submissions you're managing are modifications, continuing reviews, and/or incidents/protocol deviations/adverse events associated with active studies within the system.

- **WHAT:** *A few weeks prior to implementation, provide an institution-wide announcement of change to an eRA system. Let them know that change is coming and that you are there to support them. Provide them with the plan PRIOR to "Go Live" so they know what to expect.*

  WHY: PIs (and upper administration) don't like surprises when it comes to research compliance since they also have to be trained on new software. Some institutions think that by making changes without the PIs' awareness, that they'll just have to get on board. I assure you this is NOT the way to approach this kind of change.

  Engage your PIs (and committees) early! While they don't have to be involved in every administrative decision, provide a forum/in-service/presentation outlet for them to voice concerns with a new eRA system (and record it) so that when you Go-Live, they have

something they can reference. You'll be surprised at how many PIs don't support change like this, but if you can give them assurance that you're there for them to support them as they move forward, that migration to an eRA will give them more transparency into the review process that they have been wanting for a long time.

- **WHAT:** *Ensure you have what you need with external integration points and vendors. This involves conversations with your I.T. department and training partners–such as CITI–to ensure you have the right subscriptions in place. Cayuse has a variety of integration options with outside CTMS, training, and HR management systems that have a list of these integration points and vendors ready during I.T. discovery sessions with you and implementation is imperative to a seamless transition to an eRA.*

  WHY: I was not educated as a research admin to the fact that "Automatic Downloads" from CITI was a required component to integration with our eRA (again, my eRA was not Cayuse). The eRA vendor did not disclose at the time of demo or contract negotiation phase that CITI required a subscription to their automatic downloads service (a one time fee and annual subscription) that we needed to include in our budget to make it happen.

  This lack of transparency at the beginning put us back 5+ months in implementation while we handled getting approvals and activating this subscription that CITI was able to provide to us.

I hope the tips I have shared above will help you as you consider an eRA system and what it takes to successfully migrate to an eRA system without surprises.

I wish you the best of luck as you move forward with your implementation (if you are in the midst of one).

Warm regards,

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Cayuse