Form Uploads

Issue:
Certain forms still need to be filled out and uploaded to the E-IRB application. While this will always be the case with informed consent documents, it is anticipated that other forms (e.g., Study Drug, Study Device) will eventually be incorporated into E-IRB as part of the pages.

- *There is no workaround at this time*, but Research Information Services (RIS) is aware of the concern and the long-term plan is to eliminate separate form uploads wherever possible.

Stamping and Coding ICFs

Issue:
The approval stamp on an approved informed consent form (ICF) contains only the approval begin date that applies to that ICF, not also the protocol approval end date.
Please note that for complex coding reasons that differ between determining what date to apply for the approval begin date vs. the approval end date, and the end date appearing on a consent form is not a regulatory requirement, a decision to just apply an approval begin date was made as the system was being developed.

Workaround:
- *There is no workaround within the system at this time*, but ORI, the IRB, and RIS are aware of the concern. It may be decided at some point during future refinements of the system to add the approval end date, but at this time there is not a set timeframe for when that could occur.
- The IRB permits researchers to add text that serves as an internal tracking mechanism as long as it does not affect the information in the consent document or confuse potential research participants. For example, researchers may add version numbers or consent form expiration dates in the footer of the document for tracking purposes or to facilitate compliance.

Study Personnel – My Contact List

Issue:

Under the 'Study Personnel' bar on the Researcher's Dashboard menu, there is an option to select "My Contact List". When the user clicks to view the contact list and the grid at the bottom shows the results, any list that exceeds one page gives links to subsequent pages. However, when user clicks on the "second page" and beyond, an error is thrown.

Workaround:

Open the applicable E-IRB application or ProtocolPDF of the currently approved application to view the list of personnel in the Study Personnel section.

Incorrect/Missing PI/Study Personnel Information

Issues:
- Possible "incorrect" or outdated PI Contact or Study Personnel Info;
- Possible HSP training data not displaying properly;
- Personnel Status Flag field is blank in the study personnel table;

Workaround(s):
- Personnel records are uploaded into E-IRB from Human Resources (HR) SAP on a nightly basis, however, updates to personnel information (tied to Link Blue ID and UK Person ID) sometimes take a while to be inserted across all HR systems. Once the personnel record has been updated across all HR systems, E-IRB should reflect the new personnel info on all active in-progress applications the next day.
- In some cases when a PI has a clinical department that differs from his/her academic department, the wrong department for the study being proposed may display in the PI Contact Info section. Use the dropdown box feature on the Department field to select the PI's applicable department. The Department Code field will automatically get updated based on the selection made in the Department field. These fields for PI Contact Info are maintained per protocol and will not affect contact info for that PI on other applications.
- ORI will be reviewing study personnel lists for accuracy and make note of study personnel who have completed HSP training. If someone has left UK, the HSP training field may be blank.
- Listings with a blank for the Status Flag field can be populated by clicking 'Save' in that individual's Details window. Clicking 'Save' will make that listing look like something has been changed in that cycle though (highlighted in yellow).

Web Browsers

Issue:
If you are using a web browser other than Firefox or Chrome (e.g., Internet Explorer), or you are on a device rather than a laptop, you may experience issues navigating the E-IRB system, e.g., access, formatting issues (e.g., the page is zoomed in too much to see the "save" button); functional issues (e.g., Print Protocol – doesn't produce a PDF).

Workaround(s):
- Use Firefox or Chrome. Use a laptop or desktop. See the E-IRB FAQ on web browsers and/or platforms for more details.

Inactivity

Issue:
If you are inactive in the system for more than 30 minutes (scrolling and typing don't count as activity), your session will be 'timed-out'. There is no auto-log-off feature at this time, so unless you refresh your page, it won't look like you've been logged out, and any data you enter after that point won't be saved.

Workaround(s):
- Save your work often.
- Refresh your page if you've stepped away (this can be done by pressing the F5 key on your keyboard or clicking to a different section or menu option in E-IRB).

Small Font in Printed Protocol

Issue:
There may be portions of the "Print Protocol" PDF document, approval letter, or other documents converted to PDF by the E-IRB system with font that is very small.

Workaround:
There is no workaround at this time, but Research Information Services (RIS) is aware of the concern and hopes to be able to increase the font size in the PDFs created by E-IRB.