E-IRB: Known Issues for the Researcher

1. **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., "save" button isn't displaying); 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.

2. **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.

3. **Issue:** Research Description section and section Comments -- text boxes do not allow symbols, special characters, web addresses, email addresses, or images (characters on a standard keyboard should be ok). If something is entered that the text boxes don't allow, user will lose any unsaved information upon attempt to save, and might get an error message. This is typically encountered when copying and pasting content from another source into the text box.

   Workaround(s):
   - If copying and pasting text into a text box, review for any of the disallowed content prior to saving.
   - Save your work often to avoid losing data.
   - Use one of the attachment buttons in the Research Description section or under the Additional Information section to include the information as an attachment to your application. During the document upload process, you will be able to provide a brief description of the attachment.

4. **Issues:** PI / Study Personnel
   - Possible "incorrect" or outdated PI Contact or Study Personnel Info;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 the Human Resources (HR) hana database 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 and inactive 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).

5. **Issue:** If you log-in to E-IRB in more than one web browser, or open another web browser to try and view more than one application, there could be synchronization issues with the data that displays.

   Workaround:
   - E-IRB has been designed to prevent the user from being able to open more than one session browser, however, if you are in a platform that enables this to occur, be sure to only log-in to and work in one web browser for E-IRB.

6. **Issue:** The Protocol History "All Events" tool is not necessarily accurate. While most events logged should be reflective of what has transpired with the application, there are still a few gaps and inaccurate descriptions for logged events, primarily revolving around requested revisions.

   - There is no workaround at this time, but Research Information Services (RIS) is aware of the concern and has plans to resolve the inaccuracies.

7. **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.

   - 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.

8. **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, other forms (e.g., Study Drug, Study Device) will eventually be incorporated into E-IRB as part of the pages.

   Workaround:
   - 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.

9. **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 worry about successfully generating 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.

10. **Issue:** If the comment pop-up box in a section is the last thing you opened and your page refreshes, the comment box will pop back open; this is the nature of pop-ups and how page refreshes work. Most commonly this is an issue on the *Submission* section when you have inserted a comment then immediately want to submit. The attempt to submit automatically refreshes the page so the comment box pops-up and prevents you from submitting.

    Workaround:
    - Don't open the comments right before clicking Submit, or, move to a different section first.