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1. **What is eHIRB? (url: http://ehirb.jhu.edu)**
   The Electronic Homewood Institutional Review Board (eHIRB) is a paperless, electronic method to submit, track, and review the scientific, regulatory, and compliance information required for the safe conduct of human subjects research at Homewood. The system provides a platform for the IRB and other research compliance committees to share critical information regarding the submission and review of new applications, amendments, continuing reviews, reportable events, and study closures.

2. **How do I get an account in eHIRB?**
   Users can login with their JHEDID and password. Logging into the system for the first time auto creates an account for that person and gives them a basic Researcher role. To have an account created for a Non-JHU User, contact the HIRB Office at hirb@jhu.edu or 410-516-6580.

3. **What browsers are recommended to use with eHIRB?**
   For the best experience, use one of the following recommended browsers:

<table>
<thead>
<tr>
<th>Platform</th>
<th>Browser</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microsoft Windows (all versions)</td>
<td>Internet Explorer 7 or later, Firefox 7 or later, Chrome* 9 or later</td>
</tr>
<tr>
<td>Apple Mac OS X 10.4x or later</td>
<td>Safari 4 or later, Firefox 3 or later</td>
</tr>
</tbody>
</table>

4. **When do I need to create a new application in eHIRB?**
   You should submit a New Application to the HIRB office for any proposed projects involving human subjects, even if you are unsure if it requires IRB review. The HIRB office will review your application and determine the level of review required: Not Human Subjects Research, Exempt Review, Expedited Review, or Full Board Review, as well send you a determination letter to keep for your records.

5. **Can I save my work and come back to the application later?**
   Yes, you can save your work at any time by using the ‘Save’ button at the top or bottom of any SmartForm page. In addition, clicking ‘Continue’ also saves your work.

6. **Why do I keep getting error/warning messages when I try to submit?**
   - The system will not allow the application to be submitted to the IRB until all required items are completed on the application SmartForm.
   - To assess completeness of the form, you can **Turn on the Hide/Show Errors** feature, from the blue navigation bar (Figure 5 below), to provide a list of validation errors that the system finds along the way.
• Click the name of the section to address the required item. As required questions are answered in each section, the error/warning messages will disappear from the list.

• The hide/show errors feature is optional and can be turned on/off at any time from the blue navigation bar.

7. **How can a PI allow someone to have access to their study in eHIRB?**
   Permission can be granted by adding that user to the Study Personnel section of the application.

8. **I need to add a user to my eHIRB application but their name is not appearing in the system. What do I do?**
   Only users who have an account in eHIRB can be added to an application. If you are unable to find a user to add to your Study Personnel, and you are certain you have searched for their name with accurate spelling, contact that user and have them log into https://ehirb.jhu.edu for the first time using their JHED ID and password. An eHIRB account will be automatically created for them. Once they have an account, you can go back into the system and add them to the application.

9. **How do I know if my study was submitted successfully?**
   Once you have completely filled out an eHIRB application and clicked ‘Finish’ on the last page, the form will close and you will be brought to the application workspace, where you will have several activity buttons you can run on the left hand side. Click the ‘Submit’ button and the system will verify the form is complete, and if so, it will then send it to the eHIRB office. You will get an email confirming receipt of the application. You will also notice the Current Status of the application will change, and you will no longer have the ‘Submit’ button available to you.

10. **How do I know the status of IRB review?**
    On the application workspace, you will find the Current Status of the application located at the top left corner. For a more detailed description of what each status means, refer to the ‘eHIRB Simplified Workflow’ document located on the eHIRB Help Desk.
11. **Where can I find currently approved study documents?**
   All approved documents containing a HIRB approval stamp can be found on the application’s workspace, under the ‘Stamped Documents’ tab. (Figure 2)

   Any other documents that you have provided in the application for IRB review, which do NOT contain an approval stamp, can be found in the section of the SmartForm where you uploaded them. You would access them by clicking the ‘View/Edit Form’ button.

12. **Where can I find IRB Determination letters for my study?**
   IRB letters of determination can be found on the application’s workspace:
13. **How do I make changes to an IRB-approved application? (Amendment)**

Any changes to an IRB-approved application must be submitted as an amendment (including, but not limited to changes to the study title, PI, study team members, study procedures, recruitment procedures, advertisement materials, consent documents, privacy and confidentiality).

From your approved application workspace, select the ‘Create Further Study Action’ activity button (Figure 6) and follow the instructions for creating an amendment. The system only allows one amendment to be in review by the IRB at a time. Any study team member can create and fill out the amendment. However, only the PI can submit.

14. **How do I submit a Continuing Review?**

The PI must submit a continuing review before the study expiration date (if the study expires before the Continuing Review is submitted, a new study must be submitted). From your approved application
workspace, select the ‘Create Further Study Action’ activity button (Figure 6) and follow the instructions for creating a continuing review. Any study team member can create and fill out the continuing review. However, only the PI can submit.

15. My eHIRB application has expired. What do I do?
   If a continuing review is not submitted before the study expiration date, the study WILL expire and all research activities must stop. A new study must then be submitted in eHIRB.

16. How do I submit a Reportable Event?
   From your approved application workspace, select the ‘Create Further Study Action’ activity button (Figure 6) and follow the instructions for creating a reportable event. Any study team member can create and fill out the reportable event. However, only the PI can submit.

17. How do I submit a Study Closure?
   From your approved application workspace, select the ‘Create Further Study Action’ activity button (Figure 6) and follow the instructions for creating a study closure. Any study team member can create and fill out the study closure. However, only the PI can submit.