How to add xForms in IRBManager

There are 2 reasons to add xForms:

- Beginning a new study: Complete the *New Protocol Submission* form (See Page 2)
- Adding on to an existing study: Examples would be entering a modification, continuing review, study closure, etc. (See Page 4)

To begin this process, you must already have a username and password. If you need to acquire a username, password, and IRBManager system training, please contact *Linda Zerby (zerbyl@etsu.edu)* to begin the access process.
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Begin a new study

1. After logging into IRBManager system, choose “Start xForm” under Actions.
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2. **Select xForm by clicking on the blue link**

<table>
<thead>
<tr>
<th>Action</th>
<th>Form (Click to start)</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Form 200 Humanitarian Use Device (HUD) Initial Submission</td>
<td>Submit this form to request initial approval for a HUD. Note: If the HUD is the subject of a clinical investigation (one in which safety and effectiveness data is being collected to support a FDA), this form may not be used. Instead, you must submit the new protocol submission form.</td>
</tr>
<tr>
<td></td>
<td>New Protocol Submission V5</td>
<td>ETSU or MSK researchers, submit this form for a NEW protocol. <strong>THIS FORM IS ONLY TO ASK IF AN EXTERNAL IRB MAY BE UTILIZED, PLEASE CONTACT THE IRB OFFICE TO DISCUSS BEFORE USING THIS FORM.</strong></td>
</tr>
<tr>
<td></td>
<td>Request to Rely on an External IRB V2</td>
<td><strong>VA INVESTIGATORS ONLY</strong> VA Investigators Only. Use this form to submit a New Protocol Submission</td>
</tr>
</tbody>
</table>

Use the description to choose correct affiliation.

3. **Complete form and submit.**
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Add xForms to an existing study

1. After logging into IRBManager system, select the blue link for the study you want to add a form to under My Studies.
2. Choose “Start xForm” under Actions.
3. Since you are adding a form to an existing study, the pop up box provides many form choices to select from.

4. Choose any xForm by clicking the blue link

5. Complete form and submit.
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