Western Research

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WREM Quick Facts

What is a Sub-Form?

- Sub-Forms are post-approval applications required by the REB throughout the course of the study:
  - ***Amendments***: Modifications to the approved application and/or study documents. Amendments must be approved prior to implementation.
  - ***Reportable Events***:
    - *Protocol deviation/violation* = unapproved study activities
    - *Serious Adverse Event* = harmful outcome to study participant
    - *FYI* = minor updates to REB
    - *Data Safety Monitoring Committee (DSMC) and audit reports*
    - *Participant complaints/privacy breaches* *Contact REB prior to submitting reportable event.
  - ***Continuing Ethics Review (CER):*** Annual update required for studies extending beyond one year. Receipt of CER approval notice required for study continuation.
  - ***Study Closure:*** End of study report required when there is no further participant involvement, and all data collection, clarification and transfer is complete (including access to participants' medical record).

Creating a Sub-Form

- How to create a Sub-Form:
  - Select your study from your Work Area/Home project list.
  - Click 'Create Sub-Form' under Actions on the left side of the screen.
  - Select the applicable form.

Roles Tile vs. Collaborators Tab

- Roles Tile (under Actions on the left side of the screen):
  - To give study team members access to the file in WREM, click this button and add the email address and role of each member.
  - *Note: This function is in addition to adding each member to Section 1.*
  - TIP: The Roles tile will only appear when the Initial Application form is highlighted in the Project Tree.
- Collaborators Tab (located under the Project Tree and Form Status Bar):
  - Once a project team member has been given a role in the WREM application, they automatically have permissions to Read, Write, Submit, Share, Create all sub-forms, Receive notifications. The Project Owner (i.e., the person who create the application) can modify these permissions in the Collaborators tab.

Emails vs. Notifications

- Emails:
  - Emails are generated to alert select project team members of important activity in the file. Only those listed in the Roles tab as '(with email notifications)' will receive emails.
  - *Note: Emails are sent from 'wremsend' to the institutional email address associated with researchers' WREM accounts.*
- Notifications:
  - Notifications are sent within the WREM system to designated project team members when any activity occurs in the file which pertains to them.
  - Notifications are found in the Notifications tile in the Work Area/Home and function like an email inbox. Opening or deleting Notifications does not impact the file.

Personal Details
• WREM accounts are linked to researchers' personal details. These details are auto-populated when a team member is added to Section 1 of an application and must be up-to-date. • To update this information click on your name in the top navigation bar and select Personal Details from the Dropdown options.   ○ *Note: Your updated personal details will not automatically be updated into your existing applications. To update this information in previously submitted applications, re-search the project team member's name in Section 1. If the project has been approved, an amendment will need to be submitted to update these details.*
Help Dropdown Menu (top Navigation Bar) **– What can I find here?**
• Contact Information (for The Office of Human Research Ethics) • Help (Step-by-step User guides, Quick Guides and Training videos for navigating the WREM system) • FAQ (Frequently Asked Questions; check here for helpful information) • Templates (Templates and Guidance Documents to assist researchers in developing their study documents and completing their application)
Project Owner
• The individual who creates a new project in WREM. The Project Owner has additional administrative capabilities within the file. • To transfer ownership, the current Project Owner must click 'Transfer' (under Actions to the left of the Work Area/Home) and type in the individual's email address (associated with their WREM account) and select the file from the list below. To accept this transfer, the new Project Owner selects their 'Transfers' tile (at the top of the Work Area/Home). Once the ownership is transferred, the original Project Owner may be re-added (in the Roles tile) to regain access to the file, if needed.
Study Expiry Date
• A study's current expiry date can be found in the Centre tab on the right side of the screen.   ○ *Note: A CER should be submitted at least 2 weeks before the expiry date to allow for processing time. It is the responsibility of the research team to keep track of these expiry dates.*
Form Status
• The current review status of any application form can be found under Form Status (beneath the Project Tree). This status will be updated as the application moves through the review process.
Locked Forms
• Application forms cannot be modified if the application is currently under review or has been approved.   ○ *Note: If the PI signature has been requested, the form will become locked so that no changes can be made. The PI or Project Owner can unlock the form for changes if needed by clicking the Unlock tile before it is signed and submitted to our office.*
Locating Recommendation Letters and Approval Notices
• From the Project Tree of the desired study, select the appropriate application form (i.e., initial application or sub-form), and click the History tab located under the Project Tree and Form Status Bar.

For more information please visit our website:
https://www.uwo.ca/research/ethics/human/