AU RED ESSENTIALS - HREC APPLICATIONS

Adding a new application

1. Click on **Applications,** then **New**.
2. Select the **Study Type** and the **Application Type** (single or multi-site) from the drop-down lists. Note the screen will briefly refresh after making each selection.
3. If you select ***Other*** for **Study Type** please ensure you complete the **Study Type Description** field underneath.
4. Select *'**No**'* from the **Low or Negligible Risk** drop down list***.*** **Note: this field is mandatory.**
5. Click on **Register Application** and you will be taken to the **References** page where the newly created HREC reference number will appear.
6. Click on the **Major Sponsor Type** drop down list and select the appropriate value.
7. **Mode of HREC Review** defaults to ***'State'.*** If the study has been submitted under the National Mutual Acceptance initiative, click on the **Mode of HREC Review** drop-down list and select **'*National Mutual Acceptance*'.**
8. Scroll to the bottom of the screen and click **Update Details**.
9. Click on the **Details** tab and then on **Upload Online Form Data**. Enter the submission code from the NEAF and click **Get Online Form**.
10. You will be prompted to check the contact details being uploaded against any similar contacts that already exist in AU RED. It is recommended that you match contacts to existing contacts in AU RED where possible, but that you update details from the form, if the address details are similar. This will help reduce the number of duplicate contacts in your system. Leaving the default option for each contact e.g., "***The Principal Investigator shown on the form is not in my Database, please add as a new contact***" may be perfectly valid if a researcher has more than one set of contact details and the details are relevant for the particular application.
11. Once the form is successfully uploaded, the **Short Title**, **Full Research Title, Project Summary** fields and the **CTN/CTX** and **Student** tick-boxes if appropriate, will be auto-populated.
12. Click on the **Checklist** tab, locate the Application under Documents checked in, and click on **Edit** to the left of the Item Name. Ensure the **Date Received** reflects the date the HREC staff received the NEAF application from the researcher, regardless of whether or not it was complete and/or deemed valid, *not* the date the application was uploaded into AU RED. Enter the document date as needed. Keep the Reviewable checkbox selected if you wish for the application to be listed as a reviewable document in applicable standard letters generated by AU RED. Click **Save.**
13. Click on the **Validate/Start** tab, then on the radio button for **'*Valid*'** and a second option will appear to allow you to start the clock.
14. Enter the appropriate date and click on **Start Clock**. **IMPORTANT – the start date should always be the closing date for HREC submissions or if there is a separate, prior scientific review, the closing date for submissions for the scientific committee.**
15. The 'Target Date' and the number of days for review within the target period now appear in the top right hand section of the screen.

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Creating a meeting

1. Click on **Meetings** on the dark blue menu bar at the top of the screen then select **New.**
2. In the **Reference** field enter the name of the committee meeting.
3. Select the appropriate committee type from the drop-down list in the **Type** field.
4. If you wish to create a repeating cycle of meetings, click on **Enable Meeting Recurrence** and complete the necessary details.
5. Enter the **Meeting Date** or the **Start Date** (if recurring).
6. When completed click on **Save** (additional details are optional).

Assigning an application to a meeting from within the application

1. Applications can be assigned to meetings from within the application **Meetings** tab, or from within Meetings – Details under **Assign Applications**.
2. To assign an application to a meeting from within the application, click on the **Meetings** tab. All future meetings will be displayed.
3. Click on the **Assign to Meeting** tab for the meeting to which you wish to assign the application. The meeting details and a meeting link (enabling you to navigate directly to the meeting) will appear on the top left hand side of the screen under **Scheduled Meeting.**
4. To assign an application to a meeting from within Meetings – Details, click on the **Assign Applications** tab. Click on the **Add Applications** link, and search for the relevant application in the search pop-up window. Add the application by clicking **Add**, and close the search pop-up window.

Recording a decision to request further information/modification

1. Click on **Meetings** on the main menu bar and select ***Search*** from the drop-down list.
2. Click on the meeting at which the decision was made for the application you are updating, in the **Meeting Reference** column.
3. Click on the **Decisions** tab, then on the **Edit** button on the far right of the row for the application you are updating.
4. From the drop down list for **Decision Given at This Meeting**, select *'**Further information/modification requested**'*.
5. Click on **Save Decision.** A message will appear to say the decision has been successfully saved.
6. Now click on the **Clocks and Correspondence** tab.
7. Stop the clock – **IMPORTANT – enter the date the letter was sent to the investigator to advise of the decision** and then click on **Stop Clock.**
8. If you now click on the link to the application, you will see that the clock has stopped and the decision you recorded is displayed in the top right hand section of the screen.

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Receipting further information/modifications

1. When a response is received, it **MUST** be receipted in the **Checklist** tab.
2. On the **Checklist** tab for the application, click in the tick-box beside '***Response to Request for Further Information***' then click on **Enter Selected Items.**
3. **IMPORTANT – enter the date the response was received** into the **Received Date** field. You may choose to enter other details if you wish. Click on **Save Items.**
4. **NOTE – this action automatically re-starts the clock.** You will notice that the '*Target Date*' and number of days for review now appear in the top right hand section at the top of the screen.

Recording a final decision

1. Click on the **Meetings** tab for the application. Select the appropriate decision and click **Save Decision;** OR click on the **Decisions** tab for the meeting. Select **Edit** to right of the relevant application, to open the application. Select the appropriate decision and click **Save Decision.**
2. Enter the date on the final HREC decision letter that is provided to the investigator as the **Stop Clock** date. Solely clicking the "Save Decision" button does not stop the clock**.**
3. When you enter a final decision, you will see that the clock shows as stopped and the decision you recorded is displayed in the right hand section of the header section at the top of the screen with the number of days taken to complete the process.

DOs	• Only validate the HREC application once. • Validate the application and start the clock before the meeting date. • Always 'check-in' responses to requests for further information/modifications on the **Checklist** tab to automatically restart the clock.	**DON'Ts**	• Stop the clock before an HREC application has been to a full HREC meeting, unless the application has been withdrawn. • Use the meeting type **Sub-Committee** for a scientific review committee. Decisions must be recorded for Sub-Committees in AU RED and scientific committees cannot make decisions on applications; they can only make recommendations to the HREC. • Select ***"State"*** for **Mode of HREC Review** if the study has been submitted under National Mutual Acceptance.