

AU RED ESSENTIALS - SSA APPLICATIONS

Adding a new application

1. Click on **Applications** then **New**.
2. Select the **Study Type** and the **Application Type** (*Site Specific Assessment*) from the drop-down lists.
3. The screen will refresh and the **Study Type** and **Low or Negligible Risk** fields will appear greyed out.
4. A new field will appear called **HREC/LNR Reference Number**.
5. Enter the HREC Reference Number & click **Confirm**.
6. The system will search for the HREC application.
7. The message '*Found HREC/LNR Reference, please proceed and add SSA*' should appear.
8. Check the Committee name that appears in the **Pick correct Committee** drop-down list. The message '*Once the system has found a matching HREC/LNR reference, you must select the correct lead HREC as more than one HREC may have registered the reference (i.e. entered in error)*' will appear beside Committee name.
9. Click on **Register Application** and you will be taken to the **References** page where the HREC number and the newly created SSA reference number will appear.
10. The **Study Type**, **Short Title**, **CPI details**, **Major Sponsor Type** and **Mode of HREC Review** will be auto-populated from the HREC record.
11. Click on the **Details** page. The **Short Title**, **Full Research Title**, **Project Summary** and **CTN/CTX boxes**, if applicable, will be auto-populated from the HREC record.
12. Click on **Upload Online Form Data**. Enter the submission code from the SSA and click **Get Online Form**, then click **Continue**.
13. Once the SSA is successfully uploaded, 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 RGO or designee received the SSA application from the researcher regardless of whether or not it is complete and/or deemed valid, *not* the date the application was uploaded into AU RED. 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**.
14. 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.
15. Enter the appropriate date and click on **Start Clock**. **IMPORTANT – the start date should always be the date on which the SSA application has been deemed valid by the RGO**. This is the date the SSA has been received by the RGO and is confirmed to contain the following signatures: all investigators who will conduct research at the site; and the head of department (or divisional director or other authority) of each investigator at the site.
16. 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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Recording a decision to request further information/modification

1. Click on the **Meetings** tab for the application.
2. Select **Request for Further Information/modification** from the **Decision** drop-down list and click **Save Decision**.
3. Enter the date the request was/is to be sent and click on **Stop Clock**.
4. The date the clock was stopped, the decision you recorded and the number of days remaining are displayed in the top right hand section of the screen.

Receipting further information/modification

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.
2. Select the appropriate decision and click **Save Decision**. Enter the date on the final SSA decision letter that is provided to the site principal 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 compete.



- Always 'check-in' responses to requests for further information/modifications on the **Checklist** tab to automatically restart the clock.
- Only validate the SSA application once.



- Use the HREC approval date as the date you start the SSA clock.