

Recording of dates for multi-stage HREC review

1. Where a sub-committee meets to consider applications before they proceed to a full HREC meeting, the closing date for submissions for the sub-committee meeting should be entered as the start date for the HREC application in AU RED.
2. Any pre-HREC sub-committee meeting should be created in AU RED as meeting type '*Scientific Sub Committee*'. No decision can be recorded for this committee type, which is appropriate as it is the role of the sub-committee to make recommendations to the HREC, not to make decisions in its own right.
3. The outcomes of a sub-committee meeting should be recorded in AU RED as follows:
 - 3.1. Scenario 1: Sub-committee determines that the HREC application is scientifically sound
 - a) The application proceeds to the HREC meeting with a positive recommendation.
 - b) The HREC reviews the application and makes a decision.
 - c) The clock is stopped on the date that the investigator is notified of the HREC decision.
 - 3.2. Scenario 2: Sub-committee determines that further information is needed. A request for further information is sent to the investigator prior to the HREC meeting.
 - a) The application is placed on the agenda for the HREC meeting; the clock is still running.
 - b) The requested information is received prior to the HREC meeting.
 - c) The HREC reviews the application and the additional information and makes a decision.
 - d) If the HREC determines that further information is required, a decision of 'Further information/modification requested' is recorded in AU RED.
 - e) The clock is stopped on the date that the investigator is notified of the HREC decision.
 - 3.3. Scenario 3: Sub-committee determines that further information is needed but the requested information is not received in time for the HREC meeting
 - a) A request for further information is sent to the investigator prior to the HREC meeting.
 - b) The application is placed on the agenda for the HREC meeting; the clock is still running.
 - c) The requested information is not received prior to the HREC meeting.
 - d) The HREC cannot make a determination; a decision of 'Further information/modification requested' is recorded in AU RED.
 - e) The date of the HREC meeting is deemed to be the date that further information was sought by the sub-committee i.e. the clock is stopped on the HREC meeting date. It is possible that the HREC may identify additional information that needs to be sought. In either case, the date of the HREC meeting is deemed to be the date that the initial request for further information was sent to the investigator.
 - 3.4. Scenario 4: Sub-committee determines the HREC application is not scientifically sound
 - a) The application proceeds to the HREC meeting with a recommendation that it is not approved.
 - b) The HREC endorses the recommendation; a decision of 'Not approved' is recorded in AU RED.
 - c) The clock is stopped on the date that the investigator is notified of the HREC decision.
4. The clock should never be stopped before the HREC application goes to the first HREC meeting. Only the HREC can make the initial decision.