



Standard Operating Procedure for ACREC Review of Ethical Applications

The ACREC operates, in accordance with University policies and in conjunction with the guidelines and processes implemented by the HPRA, to ethically review proposed activities that involve animals for scientific purposes conducted at the University of Galway.

Application process for ethical review

- Applications should be submitted at least three months prior to the intended start date of the project.
- Applications must be completed on the official ACREC approved Application form(s), in line with the guidelines and checklists.
- ACREC Application forms, guidelines, checklists and deadlines for receipt of applications to ensure consideration at the next meeting will be posted on the ACREC SharePoint (<https://nuigalwayie.sharepoint.com/sites/ACRECforNUIG>)
- ACREC approval is required for all projects which include animal procedures, and will subsequently require HPRA approval (Project authorisation). In this instance, approval should be requested using the ACREC-HPRA Project Authorisation Form
- ACREC approval is required for the use of laboratory animals for the provision of organs and tissues for scientific purposes. In this instance, approval should be requested using the Tissue Harvesting Application Form.
- ACREC approval is also required for all amendments and deviations to ACREC and/or HPRA approved projects. In these instances, approval should be requested by completing and submitting the relevant amendment forms
- Completed applications should be emailed to ACREC@universityofgalway.ie before the relevant deadline.

Ethical review and approval process

- On receipt, each new application will be assigned a unique filing identification code (Filing ID).
- Revised and amended applications will retain the Filing ID of the original application.
- Each new, revised and amended application will be pre-screened to ensure it is complete and eligible for review. If incomplete the applicant will be requested to resubmit a completed application.
- All new, revised and amended applications will be confidentially shared for review with the full ACREC membership a minimum of 14 days prior to the review meeting.
- Each new, revised and amended application will be assigned a lead reviewer a minimum of 1 week before the review meeting.
- The committee Statistician will review each application for issues related to statistical power and analysis.

- ACREC members may choose to communicate directly with applicant researchers before or after committee review of new, revised or amended applications if they believe that this will improve the quality or efficiency of the review process but they are not obliged to do-so.
- Comments submitted in advance by the primary reviewer and statistician or other ACREC members, will be entered into a preliminary review report by the ACREC administrator and made available to all members at the meeting.
- Each new, revised and amended application will be discussed in detail at the review meeting with conflicted members abstaining. The discussion will be led by the primary reviewer but will involve all members present. Following the discussion, the committee will reach a decision either by consensus or by majority. The Chairperson will make a record of the members present for the discussion and the decision reached and whether it was reached by consensus or majority.
- OPTIONS FOR COMMITTEE DECISION ON A NEW OR AMENDED APPLICATION WILL BE:
 - REJECT: Application is rejected. A new application can be submitted if it addresses the concerns leading to rejection.
 - DEFER: Application is neither accepted nor rejected. A resubmission to address major concerns or insufficient content is required and will undergo full committee review. Resubmissions must be submitted by the ACREC deadline for receipt of applications to ensure consideration at the next meeting.
 - PROVISIONALLY APPROVE: Application must be revised to address minor committee concerns then returned for re-review by the primary reviewer and statistician. A decision will be communicated to the applicant within 15 working days after receipt who may recommend provisional approval (further minor changes), approval or full committee review.
 - APPROVE: Application is approved without further revision.
- Within 5 working days of the review meeting the primary reviewer will complete a final report on the application summarising the major and minor comments from all committee members who participated in the discussion. This report will be forwarded to the ACREC administrator who will incorporate it into a decision letter.
- The decision letter, including the final committee report and decision, clear explanations of the decision and, if necessary, instructions on how to respond will be sent to the applicant within 8 working days of the review meeting.
- The decision letter will also make clear that:
 - The applicant must adhere fully to the approval decision and to any conditions or contingency specified by the ACREC.
 - The applicant must ensure that the research is not extended, modified, or altered in any way without obtaining prior approval for any proposed extensions, modifications, or alterations from the ACREC.
 - ACREC approval does not constitute permission to proceed with the research project prior to AWB review and issuing of a project authorization by the HPRA where required.
 - The final project authorisation and protocol approved by the HPRA must be submitted to the ACREC, highlighting any discrepancies between this and ACREC approval.
 - It is the sole responsibility of the applicant to comply with all the Irish and European law relating to research. If any legally required licences or project or

individual authorisations are necessary, the researcher has the sole responsibility of ensuring that such licences/authorisations are in place before any research commences

- Neither the University nor the ACREC or its individual members accept legal liability for any advice or assistance offered to the applicant or to any third party in the processing of the application or the carrying out of the research.
 - The approved experiments and procedures will be subject to periodic review by the University of Galway Animal Welfare Body (AWB) and ethical approval may be suspended or withdrawn if significant deviations from the approved protocol or severity of animal pain and distress in excess of that expected are observed.
 - ACREC will, in keeping with Regulation 63(1) and 63(3) of S.I. No. 543 of 2012, report to the AWB any deviations it becomes aware of which negatively impact on animal health or welfare and which vary from the terms and conditions of a project authorisation within 3 weeks of it coming to the Committee's attention.
 - Applicants are requested to use the tissue sharing system/calendar at the University of Galway. This is a condition of ACREC approval.
 - Please note that for the purpose of improving ACREC review processes, a retrospective comparison of the ACREC-approved application and the final HPRA-approved version may be undertaken.
 - The authorisation holder shall ensure that unexpected adverse events and escalation in the expected severity of a procedure are immediately communicated to the designated veterinarian and the establishment's AWB.
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- Provisional Approval is granted for a period of 6 months. If an applicant has not replied to ACREC comments within this period, a new application must be submitted and will undergo full ACREC review.
 - If an application is rejected, the applicant may request to meet with members of the committee to discuss the application and may appeal the decision. An appeal should be addressed in writing by the applicant to the ACREC Chairperson via the ACREC administrator. Upon receiving an appeal, the ACREC Chairperson will communicate further with the applicant as necessary and will formally present the appeal to the full ACREC membership at the earliest scheduled meeting. The option of soliciting an opinion from an external expert will be considered during the discussion of an appeal. Following discussion of the appeal, with or without opinion from an external expert, the committee will reach a decision either by consensus or by majority. Options for committee decision on an appeal will be: APPEAL REJECTED – the original decision is upheld. APPEAL ACCEPTED – the original decision is changed to an alternative decision (Defer, Approve with Revision or Approve).
 - Once a new, revised or amended application receives full approval, ACREC will issue an approval certificate with a start date of the date of approval and an end date of the proposed end date of the project or 5 years after the start date (whichever is sooner).
 - In the case of amended applications, the date of amendment will be reflected in a revised certificate of approval.
 - All ACREC approved HPRA project authorisation or amendment applications must undergo review by the AWB, after which they are submitted to the HPRA for review and approval. No research can commence prior to full approval by the HPRA.
 - Tissue harvesting applications that receive full ACREC approval but be submitted to the AWB for review/discussion prior to commencing the project.

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- The minutes of all meetings will be prepared by the ACREC administrator, in consultation with the Chairperson.
- The ACREC will retain a permanent, secure record of all application reviews, decisions and applicant communications.
- All researcher communications regarding applications will be made via the ACREC administrator.