

Guidelines for Amendments to approved Biosafety and Radiation Safety proposals.

All amendments whether they are minor or major, must be approved by the Biosafety and Radiation Safety Committee (BRSC) **before they can commence**. Amendments can include a change to a procedure, a change in the host-vector system used or a change of micro-organism or biological material used, the addition of staff members or students, the absence or change of the principal investigator, an extension of time and linking an existing approval to a new source of funding. It is the responsibility of the principal investigator and/or co-investigator to seek approval from the BRSC for any amendment prior to commencement. Failure to do so will mean non-compliance with the approved protocol. Where changes are not clearly part of an existing, approved proposal, a new application to the BRSC must be submitted for review and approval. Amendments are approved at BRSC meetings. They must be submitted in writing and include the required number of copies.

Note: Where the project involves a change in the radio-isotope used, a new application must be submitted to the Committee.

- 1. Change to a procedure:** The request for a change in procedure must include the applicant's relevant experience with the proposed techniques and the risk assessment and management of the proposed procedure. Where a change has the potential to impact significantly on risk management and where the procedure has not been previously approved by the BRSC in any project, then the change is not considered to be an amendment and should be submitted as a new project. A change from one approved procedure to another approved procedure could be considered as an amendment.
- 2. Change of micro-organism or biological material:** Where the project involves a change in the micro-organism or biological material used, provided that the procedure remains the same, then it will be considered an amendment. **Where this change is to a non-approved host-vector system or to a higher risk group organism, a new application must be submitted.**
- 3. Addition of staff members/ students:** When there is a change in staff listed on an approved project, the BRSC must be notified in writing of all personnel to be added. The request must include the relevant experience with the techniques used in the project, if any training is required and who will give that training. Where inexperience or previous experience is absent, training in specific techniques is mandatory.
- 4. Absence or change in Principal Investigator:** In the event of the Principal investigator being absent or on leave for a period greater than six weeks or when a temporary supervisor is appointed, the BRSC must be formally notified in writing and approve the temporary person responsible for the project, who will ensure adequate supervision of the project.
- 5. Extension of time:** Normally research or teaching proposals are approved for a period of three years with the submission of a progress report annually. Where the duration of a project is for a shorter period, provided that the procedures remain the same, an extension may be granted by the BRSC.

6. Linking an existing BRSC approval to a new source of research funding:

Researchers can link a new funding source granted to an existing BRSC approval by providing the Committee with the following:

- Confirming the project described in the new funding application is identical to and fully covered by the research protocol that was described in the application submitted to and approved by the BRSC;
- Requesting an extension of approval along with the duration noting the maximum permitted approval period is 3 years;
- Completing the first three pages of the BRSC application form (Section A) with the title as it appears on the funding application, new funding source identified and new personnel added to the project identified.

This is submitted under the Chief investigator's signature.

Where the funding application is in the name of the co-investigator on the BRSC approved application, the Chief investigator for the BRSC project needs to be a named investigator on the funding application.

Where there are minor variations between the research plan described in the funding application and the project approved by the BRSC, it may be possible to address these following the guidelines above under dot point 2.

Note: BRSC approval cannot be granted to new grants/scholarship/fellowship applications or awards without confirmation of approval.