

Amendment Guidance for Research Ethics Application Management System (REAMS).

If you have an approved ethics application and would like to make changes to your protocol or your research group, you need to file an amendment. An **amendment application supersedes the earlier version** which will become void, only the latest amendment is valid.

There are two different kinds of amendments: **Minor Amendments** and **Substantial Amendments** and the procedure varies depending on if your ethics approval was processed in REAMS or before the system was launched. **Please read and follow this guide.**

1. Minor amendments

The amendments listed below can be considered as minor without the need for ethical review. However, **all minor amendments** to your ethics application **must be submitted** to the relevant **University's Faculty Research Ethics Committee** in order for them to have a record of the most recent version of your application for audit purposes.

The following changes are considered to be 'minor amendments':

- a) A change of project title only: with the caveat that the project remains the same and only the title is amended.
- b) A change to the project end date up to *two* years (maximum) after the original *end* date.
- c) Extending the team with additional member(s) and changes to individual members, e.g., replacing one post doc with another will not require ethical review if the protocol has not changed. However, a change of **principal investigator/supervisor** will require a substantial amendment to be submitted. Special care needs to be taken if a student is added. If a student is added to the application in a supporting role a substantial amendment needs to be filed and if the student is becoming the new PI for a project this will require a full new application via REAMS.
- d) Change in emergency contact phone number for the PI and or applicant
- e) Change in department but not in Faculty
- f) Inclusion of new *research* sites with the caveat that:
 - nothing else will change, e.g., the same protocol will be followed and already approved documents will be used **and**
 - new sites are similar to existing sites.If different kinds of sites will be used, (e.g. adding schools to university sites), this will require a substantial amendment to be submitted.
- g) Any combination of the above changes.

There are two different routes to submit a minor amendment to an already approved ethics application:

1.1 Minor amendments to projects that were originally approved in REAMS:

- Open your **approved application** in REAMS, then click “+ Create Sub Form” and choose “Minor Amendment Form.” Start your amendment by clicking “Click here to begin your amendment” and then follow through the form, signing it at the end.
- The new information that you add in this special minor amendment form will be incorporated into your application and will be visible if you ask for further amendments or if you print your form as pdf. If you need to make another minor amendment, click the line “Research Ethics Application Form” of your application to mark it grey, then use “+ Create Sub Form” again and follow the same procedure as above.
- Multiple Amendments can be filed and should be named consecutively (MA-1, MA-2, MA-3, MA-4, etc. for minor and substantial amendments, respectively).

1.2 Minor amendments to projects that were approved prior to the launch of REAMS:

- These are not processed in REAMS. You should **highlight** the minor change on the version of your ethics application which was previously approved (word or pdf file).
- Submit it attached to an E-mail to your Faculty Research Ethics Officer stating that you are sending a minor amendment.
- In your E-mail confirm which minor amendment(s) (a-g above) apply and state that there are no other changes than those listed in a-e above.
- Your Research Ethics Officer will save the updated application and record the minor change(s) for their Committee(s) records and reports.

2. Substantial Amendments

Substantial Amendments are amendments other than those listed above (under ‘Minor Amendments’ items a-g). **All Substantial Amendment must be submitted in REAMS and reviewed and approved** by one of the Faculty Research Ethics Committees before the amendment is implemented.

2.1 Substantial Amendments to ethics applications which were originally approved in REAMS:

Open your **approved application** in REAMS, click “+ create Sub Form” and choose “Substantial Amendment Form.” You can then work through your most recent REAMS form for the application and make all the changes you need. The system will ask for your amendment number and as mentioned above please add the numbers consecutively irrespective of it being a substantial or minor amendment (SA-1, SA-2, SA-3, SA-4 etc). If you are introducing changes in your supporting documents, please delete the old file and upload the new files. Once you submit your amendment it will be reviewed and approved by the Chair of your Faculty’s Ethics Committee.

2.2 Substantial Amendments to projects which were originally approved before REAMS was launched:

1. Take your previously approved version of your application. That is either your first application, or your latest amendment that you filed before REAMS started.
2. Amend all the documents in which you need to make changes and **highlight** all changes and additions in yellow and delete old parts by “strike through”, so that it is possible to see what was there previously.
3. Find the E-mail with your approval letter, or any other E-mail indicating the Application ID number (e.g., FST19127, FHMREC20007, FL18597).
4. When you have this information, access REAMS, “create project” and begin your new application. Follow through the questions of the form.
5. When you reach the question: “Is this an amendment to a project previously approved pre-REAMS by Lancaster University,” tick “Yes.” Then answer the next set of questions.

6. When you reach the question: "Which system was the previous application approved on?" select "I confirm this is an amendment to a paper-based application." You will then need to provide the previous application ID number and answer questions regarding your amendment.
7. Thereafter, the program will direct you on how to upload the files of your amended application. Please upload **all** files that are part of your application, that means those files where you did changes (amended) as well as those files that were kept unchanged. This is necessary as your application has not previously been added into REAMS. When uploading the file in the respective fields, please indicate in the field version number if the file has been amended (write: "amended") or if the file is still identical to your old application (write: "original").
8. Accept all declarations and sign the form, it will then be automatically sent to the Research Ethics Officer, or if applicable to your supervisor.