3.1.8 What happens if changes are made to the project after ethics approval has been obtained?

In this situation, the researcher must consider whether the proposed amendment constitutes a significant change that could have a potential impact on the dignity, rights, safety and wellbeing of the participants. A 'significant change' refers to a new research approach or method that, had it been planned at the time, would have been mentioned on the original research ethics approval application. Examples of this include:

- engagement with a different group of participants;
- a different method for recruiting participants;
- a different approach to obtaining consent, such as major changes in the information given to participants or in the consent form;
- a different method of data gathering; or
- a different venue for data collection.

This list is indicative, rather than exhaustive. In such cases, or if there is any other doubt about whether a proposed change is significant, the researcher should complete an Ethics Amendment form [here] which will be forwarded to the lead reviewer who originally reviewed the project. The reviewer will then consider the changes and liaise with the Ethics Administrator to advise the researcher on the appropriate course of action. This could involve re-applying for full ethics approval, if the changes are particularly significant; alternatively, the reviewer may be happy to approve the changes immediately. The Ethics Administrator will make a record of the proposed changes and the actions that were undertaken as a result, and upload a copy of this to the original approved application in the online Ethics Application System.

The requirements of this section do not apply to the routine, everyday adjustments to data gathering plans and activities that researchers must often make in response to the contingencies of research. Nor does it apply to minor corrections in the written information given to participants, such as remedying spelling errors or typos. Discretion, responsibility and common sense are necessary in interpreting this section: researchers are required to reflect upon what they are doing, its relationship to their original ethics approval application, and whether any ongoing adjustments are significant, in the terms outlined above.