

20 September 2019



Barbara Medea
School Psychology

Faculty of Medical Sciences
Newcastle University
Medical School
Framlington Place
Newcastle upon Tyne
NE2 4HH

FACULTY OF MEDICAL SCIENCES: ETHICS COMMITTEE

Dear Barbara

Title: Psychological construct underpinning Body-Focused Repetitive Behaviours Disorders
Application No: 1800/14292/2019
Start date to end date: 02/08/2019 to 02/09/2019

On behalf of the Faculty of Medical Sciences Ethics Committee, I am writing to confirm that the ethical aspects of your proposal have been considered and your study has been given ethical approval.

The approval is limited to this project: **1800/14292/2019**. If you wish for a further approval to extend this project, please submit a re-application to the FMS Ethics Committee and this will be considered.

During the course of your research project you may find it necessary to revise your protocol. Substantial changes in methodology, or changes that impact on the interface between the researcher and the participants must be considered by the FMS Ethics Committee, prior to implementation.*

At the close of your research project, please report any adverse events that have occurred and the actions that were taken to the FMS Ethics Committee.*

Best wishes,

Yours sincerely

A handwritten signature in black ink, appearing to read "M. Holbrough".

Marjorie Holbrough
On behalf of Faculty Ethics Committee

cc.
Professor Daniel Nettle, Chair of FMS Ethics Committee
Mrs Kay Howes, Research Manager

*Please refer to the latest guidance available on the internal Newcastle web-site.

Faculty of Medical Sciences

FMS Ethics Committee

Note of Guidance on Amendments to Ethical Approval

Amendments to Ethical Approval include an extension to the period of approval and an amendment to the research protocol.

1) To extend the period of approval

The period of approval ends with the close of the original project. If there is to be an additional research question to answer or a follow-up study then a further period of ethical approval needs to be applied for. Please submit a reasoned request and further application to the FMS Ethics Committee.

In your reasoned request and application please give your Ethics Approval code (given on the approval letter) together with the details of the proposed work and a new expected end date.

This should be sent to: fmsethics@ncl.ac.uk.

2) To extend approval to accommodate a change in protocol

During the course of carrying out your research it may be necessary to make substantial changes to the methodology or the way in which you interface with participants. For example you may need to include a different test or use a different piece of testing equipment, or significantly alter the number of tests a participant undertakes, or extend your recruitment of participants to include additional sources, or include additional pieces of information from participants in your consent form. These examples are not exhaustive.

Any changes must be considered. If you are in any doubt about what would constitute a change, please seek advice from the FMS Research Office, please contact fmsethics@ncl.ac.uk.

If you need to get your ethical approval extended to cover a changed protocol, please submit a request to the FMS Committee and this will be considered. Your request should be sent to: fmsethics@ncl.ac.uk.

In your request please give your Ethics Approval code (given in your approval letter) together with all of the details of the changes that you have decided are necessary. From experience, the easiest way to demonstrate changes would be to amend the original application using "track changes" so that the new details and removal of old details is clearly shown. (Where the changes are limited to the consent form and information sheets it is just these, with the changes clearly shown, that need to be submitted.) This will save time in the process of considering the changes you require and facilitate a quicker response to you and minimise the delay to your work.

Faculty of Medical Sciences

FMS Ethics Committee

Note of Guidance on Reporting Adverse Events

At the close of your project, please ensure that any adverse events have been reported to the FMS Ethics Committee.

An adverse event is where a participant might have suffered negative experiences as a result of participating in your study. Adverse events might include expected and unexpected outcomes where researchers felt the need to help participants to deal with their negative experiences.

While adverse events may not be common, they may occur. If this is the case, then a brief summary of each event and the actions that were taken must be reported.

Your report must include your Ethics Approval code (given in your approval letter) and should be sent to: fmsethics@ncl.ac.uk.