ETHICAL PROCEDURES FOR THE CONDUCT OF RESEARCH INVOLVING HUMAN PARTICIPANTS

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1. INTRODUCTION

The adoption of an ethical position in respect of research requires that researchers observe and protect the rights of participants/potential participants and act systematically to ensure that participants are able to exercise those rights. These procedures are designed to ensure that this occurs in all research involving human participants undertaken by all members of the University. This means that members of staff and postgraduate students who wish to undertake research involving human participants in any way, including participation in surveys, interviews or experimental approaches, must consider ethical issues at the earliest possible stage in the planning and preparation of their research proposal. There are two reasons for this. Firstly, consideration of ethical principles is relevant to and may influence, central aspects of the research design, methodology and sampling. Secondly, they must allow for consultation and Peer Review and for the Ethics Review process.

Researchers should refer to *An Introduction to Ethics Issues and Principles in Research Involving Human Participants* (CCCU, 2006) and *Ethics Policy for Research Involving Human Participants* (CCCU, 2006) to ensure that they are aware of all the issues that must be taken into account in preparing their work; all research incorporates ethical dimensions. This means that the justification for a piece of research is crucial; how, when, where and by whom research is conducted, how it is funded and its wider value are integral to its undertaking. Furthermore, it can never be guaranteed that research with human participants will not cause harm in its most general interpretation. Many projects involve only minimal risk while others carry more substantial possibilities. An appropriate ethical framework seeks to minimise risk and permit both researchers and participants to balance risk against harm in an open, informed and independent way. The intention is to ensure that the level of ethical review undertaken is proportionate to the level of risk involved.

2. OVERVIEW

2.1 These procedures are designed to provide guidance for staff and postgraduate students and their research supervisors who wish to undertake research that will involve human participants or data derived from them; they do not refer to work involving animals.

2.2 These procedures draw attention to some of the ethical issues that must be addressed in such research including participants in surveys, interviews and experimental methods and whether communicating face-to-face or through the use of telephone, post or email and which may subject them to any possibility of social, psychological, physical or professional harm.

2.3 They also refer to research in which the usual forms of consent may be bypassed and/or that which calls for the secondary use of existing human specimens or data.

2.4 These procedures assume that researchers will choose to comply with the ethics policy through a desire to ensure that participants and other researchers are treated ethically and appropriately during the conduct of their work.

3. SCOPE AND REMIT

3.1 All research involving human participants undertaken as part of formal University activity is subject to these procedures. This includes:

- Candidates undertaking postgraduate or research degrees.
- Supervisors of research undertaken by postgraduate or research degree students.
- Staff involved in personal research, collaborative research with other colleagues (internally or externally), contract research projects and those working with any external body or consultancy employed by the University.

- Members of staff who undertake research with students and/or other members of staff.

3.2 The scope is wide and offers a framework in which ethical principles can be considered at all stages of the research process.

3.3 The objective is to document the procedures for ethical approval which must be obtained before the start of any research.

4. REQUIREMENTS FOR APPROVAL

4.1 All research that involves human participants in any way, including those participating in interviews, surveys or experiments, must comply with these procedures and with any additional codes of ethics that apply in specific areas or organisations within which research is to be undertaken (e.g. NHS procedures, codes within Local Authorities, Research Councils' Research Ethics Frameworks).

4.2 No research that involves human participants must commence in the absence of ethical approval.

4.3 No application for ethical approval can be made until a successful Peer Review has been undertaken.

4.4 Any research which involves patients, data derived from patients, staff or resources within in the NHS must be submitted to, and receive approval from, an NHS Research Ethics Committee. Such approval is accepted by the University as equivalent to approval from the relevant internal committee, but notification of submissions and outcomes must still be submitted to the University Research Ethics and Governance Committee because it has responsibility for monitoring all research undertaken within CCCU. Further information on when and how to apply to NHS Research Ethics Committees can be found in the Faculty of Health and Social Care variant of these Procedures.

5. ETHICAL ISSUES THAT MUST BE ADDRESSED IN A RESEARCH PROPOSAL

If a proposal requires ethical approval it is necessary to comment on the ways that the following issues have been addressed in the design of the research and the selected methodology.

5.1 Rationale and statement of value of the research. The contribution that it is expected that the research will make and the way in which the selected design/methodology addresses this.

5.2 A clear description of the research design which, where appropriate, justifies the composition and size of the sample.

Consent must be gained for the use of tape recordings, videos or other material data provided; details of the way that the anonymity of the data will be assured must be provided.

5.3 Informed consent. This necessitates:

- Clear identification of who will be carrying out the research and contact details
- A statement that the participant has been given written information about the research, that they understand the nature of the work and what is expected of them
- Written acknowledgement by the participants that they have understood:
  - ◊ The procedures to be undertaken
  - ◊ Any risks associated therewith

- ◊ Any discomfort, inconvenience or longer term effects that may be entailed
- ◊ The measures to be taken should adverse effects arise
- ◊ Their right to withdraw at any time and
- ◊ Their satisfaction that their confidentiality will be safeguarded.

- Identification of the steps to be taken to ensure that participants do not feel pressurised to participate (coercion). This should include:
  - ◊ Ensuring that participants are aware of their right to withdraw at any time without giving a reason and without putting their care, treatment or education in jeopardy
  - ◊ Offering opportunities to renegotiate consent throughout the life of the project
- Where research participants are under 16 years of age the requirements of the Children Act (1989) must be followed.
- Where consent is required from the very young or the very ill, the mentally vulnerable or impaired and those whose native language in not that in which the research is being carried out (usually English) special care is needed; a translation of the informed consent procedures may be needed and, at times, it will be necessary to use a proxy to collect the data
- Lastly, considerable care may be needed where participants are to be approached through a 'gatekeeper' when consent must be obtained from the subjects directly without denying the gatekeeper's interests.

5.4 Openness and honesty. It is expected that the majority of research undertaken within the University will be open and honest with participants about the research, its purpose and its application. In the exceptional circumstance that information must be withheld from participants, ethics approval will only be given if:

- Withholding of information is absolutely essential to the integrity of the research and that the research is shown to be valuable and worthwhile
- Potential harm arising from the withholding of information can be managed by effective debriefing procedures once the work has been completed
- Withholding information about the specific purpose of methods of the study at the outset may be acceptable provided all the other information listed above is available to research participants.

Covert observational techniques in the absence of informed consent should only be adopted in exceptional circumstances and if no other methodological approach is possible. Consent should be sought from all participants once data collection is complete.

6. APPLICATION PROCESS: Approval, notification and documentation

This section identifies the procedures that **must** be followed when seeking approval for all research involving human participants whether this is undertaken by staff or students in the University.

- All research must be approved through both peer review and the relevant Research Ethics Committee (internal or external).
- No research may be started without evidence of compliance with these procedures
- Notification includes completing the relevant documentation as set out below and including it with the formal record of the research study concerned; copies should also be sent to the relevant Head of Department and the Faculty Director of

Research

- Formal approval can be obtained in one of two ways depending upon the position/status of the person concerned (see Appendix 1)

6.1 Assessing the need for ethical review

6.1.1 Self-Assessment Checklist

To determine the need for ethical review, principal researchers must complete a Research Ethics Review Checklist for all projects that involve human participants. A copy of the latest version of this Checklist and detailed notes on its use is available at at http://www.canterbury.ac.uk/research/governance/checklist.asp on the Research website. The intention is to ensure that the level of ethical review undertaken is proportionate to the level of risk involved. The Checklist will determine whether formal ethical review will be required and, if so, by which reviewing body.

6.2 Research undertaken by taught Masters students

6.2.1 If the Research Ethics Review Checklist determines the need for a formal Ethical Review, the required documentation should be submitted to the research supervisor. For such applications peer review by the supervisor will be sufficient provided that the appropriate documentation is completed prior to application for approval to the appropriate Research Ethics Committee.

6.2.2 Such documentation should be scrutinised by the Programme Director or Pathway Leader before the work is submitted to the appropriate Research Ethics Committee.

6.2.3 No student should be expected to attend an NHS or other external Research Ethics Committee unless accompanied by an appropriate member of staff, usually the Research Supervisor.

6.2.4 No student should be permitted to commence their research until and unless the appropriate documentation has been completed and appended to the student's records.

6.3 Research undertaken by all other members of the University, whether this is part of a higher degree or an independent research project

6.3.1 If the Research Ethics Review Checklist determines the need for a formal Ethical Review, the completed documentation must be submitted to the relevant Faculty Director of Research who will arrange for both independent peer review and submission for approval by the appropriate Research Ethics Committee.

6.3.2. Once satisfactory reviews have been obtained, confirmation should be appended to the appropriate research records and copies sent to the research supervisor (where appropriate); copies should also be sent to the relevant Head of Department and Faculty Director of Research.

6.3.3 Researchers intending to involve NHS facilities, patients or staff – or data derived from them – must then seek agreement from the relevant Consultant, Director etc of the NHS Trust in which their research is to take place prior to making an application for NHS approval. Similar agreements may be required for other external Research Ethics Committees (e.g. Local Authority Social Services).

6.3.4 Researchers may then seek approval through the relevant NHS or other external authorities.

7. MAKING AN APPLICATION FOR ETHICAL REVIEW

Any work submitted for ethical review either internally or externally must include:

- A completed application form
- A satisfactory peer review
- A full proposal including any questionnaires, interview schedules or other materials to be used in the collection of data
- Completed participant information sheet(s) (see Appendix 2)
- Participant consent form

For internal review by Faculty Research Ethics Committees, this completed documentation must be submitted as instructed at the top of the Application Form by all applicants.

For external review, the instructions for applicants and any guidance notes should be read carefully and fully complied with.

Failure to submit all the necessary material or follow instructions will inevitably result in a delay in the processing of applications.

8. REFERENCES

Canterbury Christ Church University 2006, *An Introduction to Ethics Issues and Principles in Research Involving Human Participants*, CCCU.

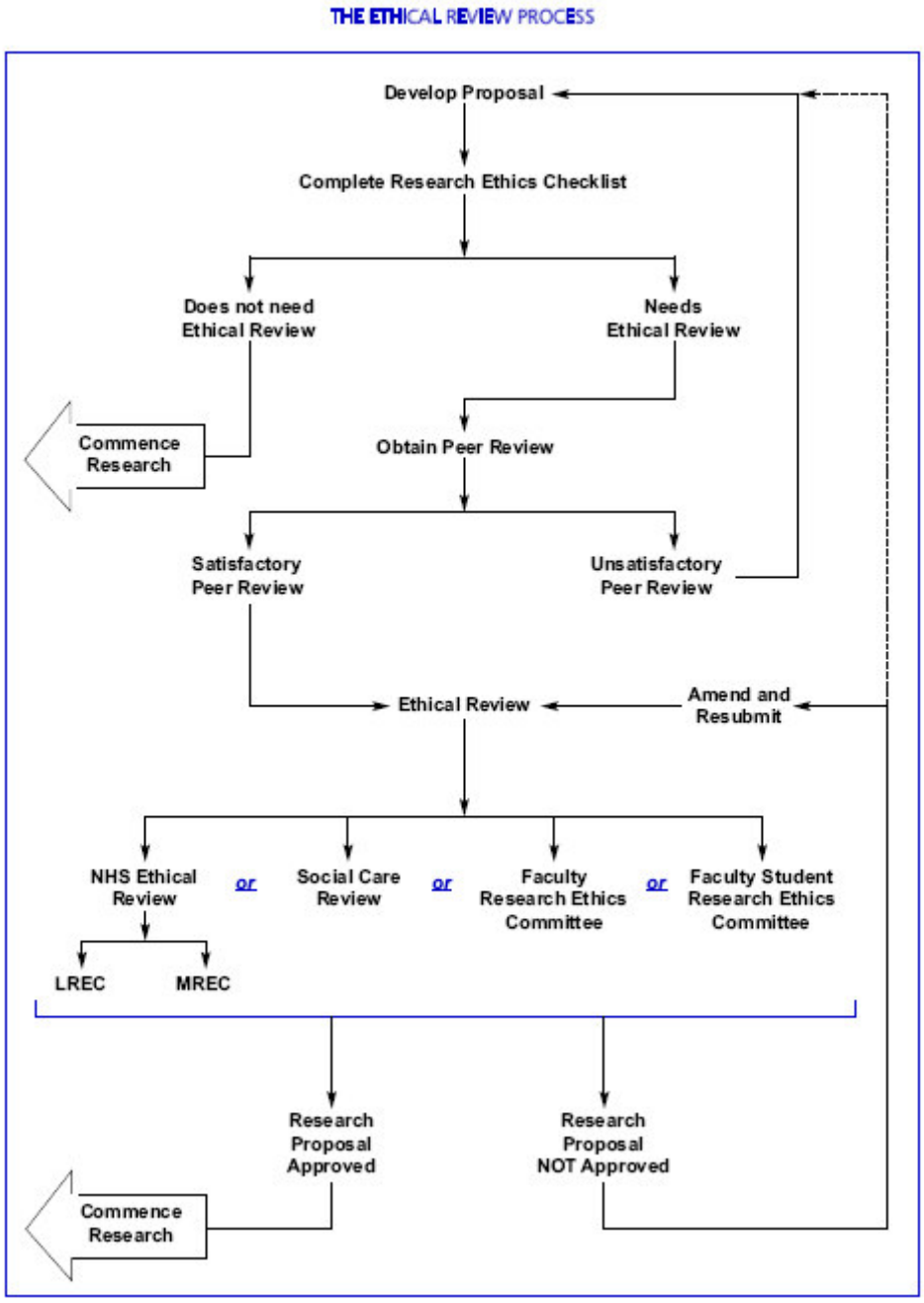
Canterbury Christ Church University 2006, *Ethics Policy for the Conduct of Research involving Human Participants*, CCCU.

The Children Act 1989, The Stationery Office, London

APPENDIX 1

FLOW DIAGRAM OF THE ETHICAL REVIEW PROCESS

Figure 1



A separate pdf version of this page is available at:

http://www.canterbury.ac.uk/research/governance/index.asp

APPENDIX 2

CHECKLIST: SUMMARY OF INFORMATION TO BE GIVEN TO PARTICIPANTS

- Duration, aims and nature of the research
- Who is funding it
- The University department, principal investigator and project team who will carry it out
- Contact addresses and telephone numbers of one of the above
- The amount of time involved for the participant
- Statement on the right to withdraw at any time without penalty
- Description of any procedures to be undertaken
- Description of any discomfort or inconvenience likely to be involved
- Description of any risks that may be entailed, including long-term effects
- Description of procedures to be followed by participant should adverse effects arise
- Procedures to protect them from harm during the research
- Procedures to assure confidentiality and anonymity
- Information about storage of data (i.e. security measures, length of time etc)
- How the results will be disseminated
- Who to contact in the event of a complaint

NB Only if it is absolutely necessary should the methods that will be used be fully described in the participant information sheet.