Division of Psychology

Research Ethics Committee

Application Form & Instructions

Version 5. 2013

Instructions

The Psychology Division Research Ethics Committee (DREC) assesses if research proposed by staff or students is ethically suitable and meets the standards of the British Psychological Society, as well as the guidelines set out in the Declaration of Helsinki.

Staff and students are not permitted to approach individual potential participants, collect data, or obtain their consent to participate without first receiving ethical approval from the DREC. For these purposes, research is deemed "unethical" unless it has been officially approved by the DREC.

The DREC meets monthly to discuss and consider all applications that have been made the previous month. Applicants wishing to conduct research involving NHS staff or patients, Armed Services Personnel, or Her Majesty's Prison Service staff or prisoners need to apply to the relevant external research ethics committee.

Applications to the DREC require the applicant to complete this application form AND to attach a copy of the research protocol / proposal. The protocol needs to contain enough detail of background, methodology and procedures involving participants and their data.

Copies of all additional documentation involved in the study need to be included with the application, and this includes:

- Research proposal / protocol
- Introduction letters to participants
- Consent forms
- FAQ sheets
- Questionnaires, Surveys, Psychometric tests
- Posters, Leaflets or Publicity material

Each additional document that is included with the application needs to have a Version number and Date on the document. Examples of such additional documents are included in the appendices of this document.

A checklist is included with the application form that applicants need to complete in order to make sure the application is correct.

Any application that is incomplete, or does not contain enough information to allow the DREC to evaluate the proposed study will be returned to the applicant.

Please submit your application and supporting documents in HARD COPY to:

Professor Craig Jackson
C/O Psychology Division Research Ethics Committee
Division of Psychology Office
Dawson 435

ALL applications must be accompanied by a research proposal / protocol.
Do not email your application

PART A.

Tick one box:

☐ **STAFF project** ☐ **POSTGRADUATE project** ☐ **UNDERGRADUATE project**

Title of Project: _____

_____

Name of Researcher (student): _____

Name of Supervisor (for student research): _____

Date of application: _____

Approx. start date of study: _____ **Approx. end date of study** _____

Email: _____**@mail.bcu.ac.uk**

CHECKLIST

		Yes	No	N/A
1.	Completed DREC Application Form			
2.	Research Proposal / Protocol			
3.	Participant Letter			
4.	Participant Information Sheet / FAQs			
5.	Participant Consent Form			
6.	Validated Questionnaires used			
7.	Non-Validated Questionnaires used			
8.	Advertisement material for research participants, e.g. posters, flyers			

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PART B.

		Yes	No	N/A
1.	Will you describe the main experimental procedures to participants in advance, so that they are informed about what to expect?			
2.	Will you tell participants that their participation is voluntary?			
3.	Will you obtain written consent for participation?			
4.	If the research involves direct observation of behaviour, will you ask participants for their consent to being observed?			
5.	Will you tell participants that they may withdraw from the research at any time, for any reason?			
6.	If participants wish to withdraw from the study, will they be allowed to do so without giving you a reason for their decision?			
7.	With questionnaires, will you give participants the option of omitting questions they do not want to answer?			
8.	Will you tell participants that their data will be treated with full confidentiality and that, if published, it will not be identifiable as theirs?			
9.	Will you debrief participants at the end of their participation (i.e. give them a brief explanation of the study)?			
10.	Will your project involve deliberately misleading participants in any way?			
11.	Is there any realistic risk of any participants experiencing either physical or psychological distress or discomfort? If **yes**, please tick box B below.			
12.	Does your study involve work with animals? If **yes**, please tick box B below.			
13.	Is there any realistic possibility that the researcher may be placed in an unsafe or dangerous situation in the course of this study?			
14.	Has the scientific quality of the research been assessed (by the academic supervisor if a student project)?			
15.	Have the statistical aspects of the research been reviewed (by the academic supervisor if a student project)?			
16.	Will research participants receive any payments, expenses or any other benefits or incentives for taking part in this research?			
17.	Do any of the participants fall into any of the following groups……			
a.	Schoolchildren (pupils / students under 18 years of age)			
b.	People with learning or communication difficulties			
c.	People accessed as Patients or receivers of Healthcare			
d.	People in police custody or within Her Majesty's Prison Service			
e.	People engaged in illegal activities or crime			
f.	People accessed by working as healthcare professionals			
g.	People accessed by working in the armed services			
h.	People accessed by working in Her Majesty's Prison Service			

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PART C.

1. What is the principal research question / objective of the research? *Please put this in language comprehensible to a lay person.*

2. Please give a full summary of your design and methodology. *It should be clear exactly what will happen to the research participant, how many times and in what order.*

3. What is the primary outcome measure for the study?

4. Please list the principal inclusion criteria for participants.

5. Please list the principal exclusion criteria for participants.

6. How long do you expect each participant to be in the study in total?

7. What are the potential risks and burdens for research participants and how will you minimise them?

8. What is the potential for benefit to research participants?

9. What are the potential risks for the researcher(s)?

10. How and by whom will potential participants first be approached?

11. How long will you allow potential participants to decide whether or not to take part?

12. How will you ensure the confidentiality of personal data? *Please provide a general statement of the procedures for ensuring confidentiality, e.g. anonymisation of data.*

13. Who will have access to participants' personal data during the study?

14. What is the sample size for the research? *How many participants/samples/data records do you plan to study in total? If there is more than one group, please give further details below.*

15. Please describe the methods of analysis (statistical or other appropriate methods, e.g. for qualitative research) by which the data will be evaluated to meet the study objectives.

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16. Other key investigators/collaborators (if appropriate) and their contact details. *Please include all grant co−applicants, protocol co−authors and other key members of the research team, including non-doctoral student researchers.*

PART D.

Please tick either Box A or Box B

BOX A *"I consider that this project has **no** significant ethical implications to be brought before the Divisional Ethics Committee."*	**Please tick** ☐
BOX B *"I consider that this project **may** have ethical considerations that should be brought before the Divisional Ethics Committee."*	**Please tick** ☐

I am familiar with the BPS Guidelines for ethical practices in psychological research (and have discussed them with the other researchers / supervisors involved in the project).

Print name: _______________________________ **Date:** _________________

Signed: __________________________________
(Student Researcher if applicable)

Print name: _______________________________ **Date:** _________________

Signed: __________________________________
(Lead Researcher or Academic Supervisor)

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(For Division of Psychology Only)

STATEMENT OF ETHICAL APPROVAL
This project has been considered using agreed Departmental procedures and is now approved.

Print name: _______________________________ **Date:** _________________

Signed: __________________________________
(Chair, Divisional Ethics Committee)

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APPENDIX A. EXAMPLE PATIENT INFORMATION SHEET

Patient Information / FAQ Sheet
03/09/2008
Version 2.0

Improving the interpretation of the flow rate test for earlier identification of men at risk of BPH progression or obstruction of urinary flow.

An observational study.

What is the purpose of this research?
Benign Prostatic Hyperplasia (BPH), or enlargement of the prostate, is a non-cancerous condition, affecting most men from middle age on-wards. Some men have severe symptoms whilst others have very little symptoms. Your Urologist has referred you for a uroflowmetry test (urinary flow rate test) because you may have an enlarged prostate causing you some difficulties, or increased frequency, passing urine. It has been shown to be a simple non-invasive test to measure how well the bladder empties urine, especially in men who may have difficulty due to "prostate trouble".

I am investigating how well this test identifies men who need medical treatment or surgery and to see if improvements can be made in interpreting the test results. All information from you will be completely anonymous. I hope to share the research information with other professionals and perhaps publish the research findings in a medical journal. Nobody will be able to identify that any information is about you.

Why have you been approached?
You may have or do have BPH that is causing problems with your flow of urine. I am interested in studying men who have been referred to the urology department, at Sandwell Hospital, with this condition. Taking part in this research is completely voluntary and you have every right to refuse to participate. You do not need to do anything if you rather not take part. I will not approach you about this, again.

What does taking part involve?
If you decide you would like to take part, information about your prostate symptoms and the results of your flow rate test will be obtained and analysed anonymously. You simply, attend for your flow rate test appointment exactly in the way you have been asked to, in your appointment letter. Your appointment lasts about 30 minutes provided you attend with a full bladder. This is exactly the same way as all other patients who have the same test. The only difference is that you give permission for your information to be used, confidentially, in the study.

How long is the study for?
A number of men (approximately 100) will be studied over a 10 month period. Your participation only requires you to attend for your 30 minute appointment time. **Participation does not require you to attend for any additional visits to the urology clinic**.

What are the risks in taking part?
Some men may not be able to pass urine at all and may need a catheter tube inserted to drain the bladder. This may happen in about 1 in 10 over the age of 70 and can happen anyway. It is not a direct risk of the study itself. The flow rate test requires you to drink plenty of water to fill your bladder in a short time. This challenges your bladder and this may occur, anyway, at anytime because of your prostate.

What are the benefits?
There are no immediate benefits to you but the information studied may help other men, in the future, with prostate problems.

What are the costs to you?
Taking part in the study will not impose further costs on you. **Additional appointments are not required.**

Who else will know you are taking part*?*
I shall send a letter to your consultant urologist to inform him that you are participating in the study. However, your information will be anonymous and only I will know who the original information came from.

What if you change your mind?
You have the right to withdraw at any time. It is completely voluntary and your own decision. You will not receive any different treatment whether you agree to participate or not.

Who should you contact for more information?
Please contact . . . . . .
Tel: . . . . . .

What you should do if you would like to take part.
Please read this information and the consent form carefully, sign it, and then return in the pre-paid envelope provided

Thank you very much for taking the time to read this information.

APPENDIX B. EXAMPLE CONSENT FORM

Daily use of honey applied to hi-fibre bran cereal to increase perceptions of "fullness" after breakfast, for healthy dieters: a comparison study

Participant Consent Form.

VERSION 2 11th June 2008

Please read below and tick the necessary boxes if you wish to participate in the study.

"I confirm that I have read and understood the participant information sheet for this study and have had the opportunity to ask questions which have been answered satisfactorily." ☐

"I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without my legal rights being affected." ☐

"I agree to take part in the above study." ☐

Name of Participant	Date	Signature
Principal Researcher	Date	Signature

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