ETHICS COMMITTEE FORM

NAME OF PROPOSER:	Pascal Belin
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POSITION HELD:	Professor in Psychology
DEPARTMENT/ GROUP/CENTRE:	Centre for Cognitive Neuroimaging (CCNi) & Department of Psychology
NAME OF SUPERVISOR:	N/A

PROJECT TITLE: **Standard Functional Magnetic Resonance Imaging (fMRI) Studies of Cognitive Mechanisms in Normal Adult Volunteers**

1. DESCRIBE THE BASIC PURPOSES OF THE PROPOSED RESEARCH:

This proposal describes "standard fMRI studies" as we propose to conduct them in CCNi.

The term "standard fMRI studies" used throughout this document refers to studies conducted in normal adult volunteers, for which brain scans are acquired while the volunteer performs cognitive/motor tasks.

Each new study falling into the "standard fMRI studies" category will require its own ethics approval, but the proposal will refer to the present document to ease the submission and review the process.

Studies not falling into the "standard fMRI studies" category, for example, because they involve children, clinical patients or stimulation of a deceitful or painful nature, will require submission to the Ethics Board with full details.

2. INDICATE WHO IS FUNDING THE RESEARCH (IF COMMERCIALLY FUNDED, ENSURE THAT PARTICIPANTS ARE INFORMED)

The experiments carried out in the MRI suite of the CCNi will be funded by various research councils and funding bodies.

3. DESCRIBE THE DESIGN OF YOUR EXPERIMENT (E.G. CONDITIONS, NUMBER OF SUBJECTS, PROCEDURE AND EQUIPMENT WHERE APPROPRIATE) (BPS Section 2&8):

A "standard fMRI study" unfolds as follows:

Potential volunteers are contacted by an investigator prior to the date of the scanning, so they have time to read the Study Information Sheet (cf. attached example), understand the research and what their participation involves, and ask questions if necessary.

At the time of the experiment, the investigator meets the volunteer and answers potential questions before asking the volunteers to give their written informed consent by filling and signing the Study Consent Form (cf. attached example).

The volunteer is then interviewed by the MR radiographer, or an "authorized scanning staff member" (cf. attached document "DUTIES AND RESPONSIBILITIES OF THE AUTHORISED MR SCANNING STAFF MEMBERS AT THE CCNi") to ensure that the volunteer presents no contra-indication to an MR examination. This is performed by going through a list of questions with the volunteer, detailed in the MRI screening form (cf. attached form). A 'new' screening form is required to be completed for each scanning session, even if the volunteer has already been scanned.

Once the Study Consent Form is signed and the MRI screening form completed without having revealed any contra-indication to the MR examination, the volunteer is prepared for the experiment. This includes asking the volunteer to change from his/her clothes into an MR-safe garment (thus minimising the risk of introducing metal into the MRI suite), explaining the instructions of the particular study (e.g., cognitive or motor task).

The volunteer is then installed on the bed of the MR scanner and equipped with the necessary stimulation (e.g., goggles for visual stimulation, headphones for auditory stimulation) and/or recording equipment (e.g., respiration, skin conductance). An emergency call button is also given to the volunteer so he/she can alert the experimenters during scanning if necessary. Once the volunteer is equipped, the scanner bed is entered into the magnet bore and the examination starts.

Throughout the examination, visual (through the glass panel of the examination room) and auditory contact (through a microphone in the scanner bore) is kept with the volunteer to ensure normal unfolding of the experimental session. The brain scans are acquired while the volunteer executes the cognitive/motor task as per the instructions.

Once the scan acquisition is finished, the volunteer is taken out of the scanner and asked for feedback. The time during which the volunteer is inside the scanner does not exceed 90 minutes (typically 60 minutes) during a "standard fMRI study".

The number of subjects depends on the particular study; it may vary from a single participant to several hundreds for large-scale studies.

All volunteers will be informed that they may discontinue participating in the experiment at any time.

4. DESCRIBE HOW THE PROCEDURES AFFECT THE PARTICIPANTS:

There is no documented side effect to being scanned by MRI.

However, because of the strong magnetic field produced by the machine, volunteers with medical implants known to contain ferromagnetic metal (Aneurysm Clip, Heart/Vascular Clip, Prosthetic Valve, Metal Prosthesis), pacemakers, metal fragments in body, history of epilepsy, claustrophobia, and/or pregnancy can't be included in the study **(**cf. MRI screening form, attached**)**. Volunteers are also asked to change into an MR-safe attire to minimise the risk of ferromagnetic objects being introduced in the MRI suite and transformed into a potentially lethal missile. (cf. section 2 and document "DUTIES AND RESPONSIBILITIES OF THE AUTHORISED MR SCANNING STAFF MEMBERS AT THE CCNi").

In addition, the MRI machine generates a loud banging noise during scanning. Volunteers will be given earplugs to be protected against this noise. For studies involving auditory stimulation, the protection against the scanning noise will be provided by the stimulation headphones.

5. STATE WHAT IN YOUR OPINION ARE THE ETHICAL ISSUES INVOLVED IN THE PROPOSAL (BPS All Sections):

One issue is to ensure that participants are aware of the contra-indications. This is done by a detailed information form. In addition with a qualified person, each volunteer reads through and signs a safety questionnaire.

Another potentially problematic issue is the issue of incidental findings.

Brain scans will NOT be routinely examined for abnormalities by a trained neuro-radiologist. However, it is possible that an abnormality is detected in the scan of a normal volunteer by the radiographer or one of the investigators.

Should this situation occur, the volunteer's GP will be directly contacted. The Study Consent Form (cf. attached example) contains a section that explains the issue of incidental findings to the volunteer. The volunteer is asked in this section to provide contact details for his/her GP and to state whether he/she accepts that the GP will be directly contacted in the case of such findings. If the volunteer does not accept his/her GP to be directly contacted, he/she will be excluded from the study.

6. SPECIFY WHETHER THE RESEARCH WILL INVOLVE CHILDREN OR THOSE WITH MENTAL DISABILITY OR HANDICAP (BPS Section 3):

No, fMRI studies involving these populations will submit a full ethics proposal.

7. STATE IF PAYMENT WILL BE MADE TO SUBJECTS:

A standard payment of £6 per hour will be made to subjects.

8. DESCRIBE PROCEDURES FOR OBTAINING CONSENT FROM SUBJECTS (BPS Section 3):

Participants will be recruited by adverts detailing the purpose and duration of the experiment. Written informed consent will be obtained from participants prior to the study.

9. STATE WHETHER THE PROPOSAL IS IN ACCORD WITH THE B.P.S. CODE OF CONDUCT (BPS All Sections):

"Standard fMRI studies" are in accord with the BPS code of conduct.

10. DESCRIBE HOW THE SUBJECTS' ANONYMITY AND CONFIDENTIALITY WILL BE MAINTAINED (BPS Section 7):

Participants' anonymity will be assured by only referring to a subject number during analysis. Records of personal details will only be kept if subjects agree (for example to contact them for other studies).

11. DATE ON WHICH PROJECT WILL BEGIN:

fMRI scanning will start at CCNi after February 1st, 2008.

12. LOCATION AT WHICH THE PROJECT WILL BE CARRIED OUT:

"Standard fMRI studies" will all be performed in the fMRI suite of CCNi, which is at the back of the Psychology Department building.

13. DESCRIBE HOW SUBJECTS WILL BE DEBRIEFED AT THE END OF THE EXPERIMENT. (THIS MUST INCLUDE THE OPPORTUNITY TO CONTACT THE EXPERIMENTER (OR SUPERVISOR) FOR FEEDBACK ON THE GENERAL OUTCOME OF THE EXPERIMENT) (BPS Section 5&10):

After the experiment participants will be briefed about the purpose of the research. They are given contact details of the investigator on the Study Consent Form (attached) for further questions and concerns. If they are interested, they will be given a more detailed description of the experiment and its aims.

14. TEXT OF SUBJECT CONSENT AND INFORMATION FORM (BPS Section 3&6):

Cf. attached documents.