## Appendix 11: Information sheet and consent form



**INFORMATION SHEET FOR PARTICIPANTS**

REC Reference Number: **PNM/11/12-35**

**YOU WILL BE GIVEN A COPY OF THIS INFORMATION SHEET**

**Investigating factors linked to trauma reactions and recovery**

We would like to invite you to participate in this original research project that forms part of a doctoral thesis. You should only participate if you want to; choosing not to take part will not disadvantage you in any way. Before you decide whether you want to take part, it is important for you to understand why the research is being done and what your participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information.

**Aims of the research**

People who experience a traumatic event can develop post-traumatic stress disorder (PTSD). One of the main features of this disorder is to have images, thoughts and physiological reactions linked to the event that occur without warning, which can be is incredibly frightening for the individual. This study aims to understand why this happens so that methods may be developed for treating these reactions.

**Who are we asking to take part?**

We are recruiting people over the age of 18 who are fluent in English and not currently experiencing clinically significant mental health problems or a significant history of trauma.

**What will happen if I agree to take part?**

If you agree to participate in this study, we will ask you to complete some questionnaires that we will send to you and ask you to return by email. These questionnaires will ask about symptoms of anxiety, depression and post-traumatic stress disorder and whether you have experienced any traumatic events. Symptoms of PTSD sometimes occur following a catastrophic or highly threatening event and include avoiding reminders of the trauma, having flashbacks and nightmares of the trauma and having poor concentration and feeling irritable. If the screening questionnaires indicate that you do have significant mental health problems then you will be thanked for your time and asked whether you would like to speak further with the researcher but excluded from the main part of the study. Data gathered from the screening stage, both from participants who enter the main study and those who do not, will be scored and the scores will be kept in an anonymised format.

The main study consists of one session and some follow-up questionnaires. The session lasts for about an hour and you will be shown a series of short film clips that contain traumatic material (e.g. humans in distress).Your skin conductance will be measured and you will be asked a few questions about the films. Skin conductance is a way of measuring the changes in electrical conductance of the skin. This is frequently used as a measure of psychological arousal. Skin conductance will be measured using a 4/30 Data acquisition system and by placing two electrodes on each of your wrists, these are harmless and do not hurt.

After the first session, you will be asked to complete a simple diary over the following week and then some questionnaires on-line one week later. The questionnaires should take no more than 15 minutes to complete. Sessions will take place at the Institute of Psychiatry in Denmark Hill.

**Are there any risks in participating in this study?**

The films that we are using do contain scenes of humans and animals in distress and so there is a risk that you may find these upsetting. However, any distress you may experience is likely to be short-lived and very similar studies have been conducted without any adverse consequences. In addition, the content of the clips will be similar to what you may see on a television program or news programs. If you do feel any distress during the session, then we would encourage you to speak to the researcher, Victoria Pile, who is a clinical psychologist in training. You will also be given her contact details to take away with you in case you feel distress in relation to the study later on. If you are still worried or distressed by the videos, then you are able to contact her supervisor, Dr Jennifer Wild who is a consultant clinical psychologist and who specialises in treating trauma reactions.

Your participation is entirely voluntary and so if you decide to take part but later wish to withdraw, you may do so at any time without giving a reason.  All information will be anonymised and kept confidential.

**Are there any benefits to taking part?**

This study hopes to improve understanding of post-traumatic stress disorder and inform psychological interventions for it. In addition, you will receive £10 as compensation for your time. You will also be given the option of being sent a summary of the research findings.

**Arrangements for ensuring confidentiality**

To ensure the confidentiality, you will be randomly allocated a code. This unique code will be used on questionnaires, measures and data analysis so no personally identifiable information will be associated directly with your data. The consent form that you sign, if you choose to take part, will be kept separately from the data in a locked filing cabinet which only the main researcher has access to. After the study has been completed, any information linking you to your code will be destroyed. However, confidentiality will be broken in the unlikely event that you indicate potential harm to yourself or others as it is the researcher’s duty to pass on this information. In this case, the researcher would inform her supervisor who would speak with you and possibly your GP if necessary.

It is up to you to decide whether to take part or not. If you decide to take part you are still free to withdraw at any time and without giving a reason. In addition to withdrawing yourself from the study, you may also withdraw any data/information you have already provided up until March 2013.

If this study has harmed you in any way you can contact King's College London using the details below for further advice and information:

**Name and contact details of the researchers**

**Dr Jennifer Wild**

Institute of Psychiatry (PO77), King's College London
De Crespigny Park
London

SE5 8AF
Telephone: 0207 848 5045 Email: jennifer.wild@kcl.ac.uk

**Victoria Pile**

Institute of Psychiatry, Kings College London

Department of Psychology, 3rd Floor Addiction Sciences Building

4 Windsor Walk, Denmark Hill, London

SE5 8AF
Telephone: 020 7848 0733 Email: victoria.pile@kcl.ac.uk

**CONSENT FORM FOR PARTICIPANTS IN RESEARCH STUDIES**



**Investigating factors linked to trauma reactions and recovery**

**King’s College Research Ethics Committee Ref: PNM/11/12-35**

**Thank you for considering taking part in this research.**

Please complete this form after you have read the Information Sheet and/or listened to an explanation about the research. If you have any questions about this project and what you are being invited to take part in, please ask the researcher before completing this form.

You will be given a copy of this Consent Form to keep and refer to at any time.

**Please tick or initial**

* **I understand that if I decide at any time during the research that I no longer wish to participate in this project, I can notify the researchers involved and withdraw from it immediately without giving any reason. Furthermore, I understand that I will be able to withdraw my data up March 2013*.***
* **I consent to the processing of my personal information for the purposes explained to me. I understand that such information will be handled in accordance with the terms of the Data Protection Act 1998.**

**Participant’s Statement:**

**I ­­­­­­­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_agree that the research project named above has been explained to me to my satisfaction and I agree to take part in the study. I have read both the notes written above and the Information Sheet about the project, and understand what the research study involves.**

**Signed Date**

**Investigator’s Statement:**

**I \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_confirm that I have carefully explained the nature, demands and any foreseeable risks (where applicable) of the proposed research to the participant.**

**Signed Date**