METANOIA INSTITUTE

METANOIA STAFF RESEARCH APPLICATION FORM

SECTION 1: PERSONAL DETAILS *Please complete the header with your name and Department*	
Name, work title and Faculty (lead):	
Other investigators:	
Correspondence address:	
Telephone no:	
Email:*(All correspondence will be sent by email unless otherwise requested.)*	

SECTION 2: PROJECT DETAILS	
Title of project:	
Proposed start date: *(Please note that approval can take some time. Please submit applications in a timely manner. Reasons should be given for late or retrospective submissions in order to secure approval.)*	
Duration:	
Purpose of the proposed investigation. Please attach a protocol outlining the rationale for the project, research questions, method, participants and procedure.	
Is the protocol attached: YES ☐ NO ☐	
SECTION 3: ETHICAL ISSUES AND RISK:	
Please highlight ethical issues and risk and ways of mitigating them within the project:	

SECTION 4: PARTICIPANTS

- You should use the Participant Consent Form template and amend it as necessary
- You should also attach any other information to be given to participants
- You should consider carefully what information you provide to participants, e.g. scope of study, number of participants, duration of study, risks/benefits of the project. It is recommended that the participant has two copies of the consent form so they can retain one for information.
- If images or anything else which might allow the identification of participants is to be publicly accessible (e.g. on the web), further written consent must be secured. A separate section regarding this should be included on the participant consent form.

Give details of the method of recruitment, and potential benefits or incentives to participants if any (include any financial benefits where appropriate).
(NB: Please remember that written permission – or in some cases, ethics approval – will have to be sought from any organisations where recruitment is carried out or posters placed (e.g. if you recruit in GP's surgeries you might require NHS approval)

Will you be involving participants who are aged under 18?

YES ☐ NO ☐

Will you be involving participants who might be considered to be vulnerable (please give details if not addressed elsewhere on this form)?

YES ☐ NO ☐

If you have answered highlight the particular issues raised by working with these participants and how these issues have been addressed.

Details of DBS check (date and disclosure number)
Please note: if you are unsure whether this is required, please check with Douglas Bertram (The Executive Officer) and advise us accordingly

SECTION 5: HEALTH AND SAFETY
Have you completed the Risk Assessment Form and attached it to the application?

YES ☐ NO ☐

SECTION 6: PUBLICATION OF RESULTS
How will you disseminate your findings? (e.g. publication)
How will you ensure the anonymity of your participants? (If your participants do not wish to remain anonymous you must obtain their written consent.)

SECTION 7: STORAGE AND RETENTION OF DATA
Please refer to Codes of Practice for Research http://www.metanoia.ac.uk/media/1979/mrec-code-of-research-ethics-v2-2015-1.pdf
Describe how and where the data will be stored and how they will be kept secure:
Research materials:
Documents containing personal details of any participants:

SECTION 8: EXTERNAL GUIDELINES, APPROVAL & FUNDING
Are there any relevant subject-specific ethics guidelines (e.g. from a professional society)? If so how will these inform your research process?
Has/will the project be submitted for approval to the ethics committee of any other organisation, e.g. NHS ethics approval?
What is the outcome of this?

Is your project externally funded?
(Please note: you do not need to submit an ethics application or gain ethics approval for a project when applying for funding – this can be done when you receive confirmation that the application for funding has been successful)

YES ☐ NO ☐

Please state the name of the funding organisation/ company below and provide any other relevant information:

Has your research been approved by your line manager and the Faculty Head?

YES ☐ NO ☐

SECTION 9: APPLICANT'S CONFIRMATION

I confirm that the information supplied on this form is correct and confirm that the above checklist has been fully completed.

Applicant's signature:	*Please use an electronic signature or type your name*
Date:	

The Application Form does **not** need to be printed out. The form and attachments should be sent by email to the MREC Servicing Officer, Duncan Steed (duncan.steed@metanoia.ac.uk).

- Ethics Application Form
- Participant Information Sheet
- Participant Consent Form
- Risk Assessment Form
- Any other information
  (e.g. information sheet, advertising material, questionnaires, debriefing letter)

METANOIA INSTITUTE & MIDDLESEX UNIVERSITY

GUIDELINES AND TEMPLATES FOR A
PARTICIPANT INFORMATION SHEET (PIS) AND CONSENT FORM

Potential recruits to your research study must be given sufficient information to allow them to decide whether or not they want to take part. An Information Sheet should contain information under the headings given below **where appropriate**, and in the order specified. It should be written in simple, non-technical terms and be easily understood by a lay person. Use short words, sentences and paragraphs. 'The readability' of any text can be roughly estimated by the application of standard formulae. Checks on readability are provided in most word processing packages. Use a minimum of size 12 Arial font.

1. Study title

Is the title self-explanatory to a lay person? If not, a simplified title should be included.

2. Invitation paragraph

This should explain that the participant is being asked to take part in a research study. The following is a suitable example:

'You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it 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. Take time to decide whether or not you wish to take part.

Thank you for reading this.'

3. What is the purpose of the study?

The background and aim of the study should be given here. Also mention the duration of the study.

4. Why have I been chosen?

You should explain how and why the participant was chosen and how many other participants will be studied.

5. Do I have to take part?

You should explain that taking part in the research is entirely voluntary. You could use the following paragraph:-

'It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason.

A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive (include this section only if applicable).

6. What will happen to me if I take part?

You should say how long the person will be involved in the research, how long the research will last (if this is different), how often they will need to visit a clinic (if this is appropriate) and how long these visits will be. What exactly will happen e.g. tests, interviews, etc.? What are the participant's responsibilities? Set down clearly what you expect of them.

You should set out simply the research methods you intend to use – For example:-

Survey:

In a survey we aim to collect information to answer the research question through the use of questionnaires, interviews, and sometimes though observation.

Randomised Trial:

Sometimes because we do not know which way of treating participants is best, we need to make comparisons. People will be put into groups and then compared. The groups are selected by a computer which has no information about the individual – i.e. by chance. Participants in each group then have a different treatment and these are compared.

You should tell the participants what chance they have of getting the study drug/treatment e.g. a one in four chances.

Please note that in order to ensure quality assurance and equity this project may be selected for audit by a designated member of the committee. This means that the designated member can request to see signed consent forms. However, if this is the case your signed consent form will only be accessed by the designated auditor or member of the audit team.

7. What do I have to do?

What does taking part actually entail? For example, a questionnaire, a semi-structured interview, focus groups etc. You should also give an indication of the length of time that the research will require if the participant consents to take part. In addition, you should inform the participants of any lifestyle restrictions e.g. dietary or physical exercise and what happens if the participant becomes pregnant.

8. What are the alternatives for diagnosis or treatment?

For therapeutic research the participant should be told what other treatments are available.

9. What are the side effects of any intervention received when taking part?

For any new procedure you should explain the possible side effects. If they suffer these or any other symptoms they should report them next time you meet. You should also give them a contact name and number to phone if they become in any way concerned. The name and number of the person to contact in the event of an emergency (if that is different) should also be given.

10. What are the possible disadvantages and risks of taking part?

For studies where there could be harm to an unborn child if the participant were pregnant or became pregnant during the study, the following (or similar) should be said:

'It is possible that if the treatment is given to a pregnant woman it will harm the unborn child. Pregnant women must not therefore take part in this study; neither should women who plan to become pregnant during the study. Women who are at risk of pregnancy may be asked to have a pregnancy test before taking part to exclude the possibility of pregnancy. Women who could become pregnant must use an effective contraceptive during the course of this study. Any woman who finds that she has become pregnant while taking part in the study should immediately tell the researcher and her medical practitioner.

Use the pregnancy statement carefully. In certain circumstances (e.g. terminal illness) it would be inappropriate and insensitive to bring up pregnancy.

There should also be an appropriate warning and advice for men if the treatment could damage sperm which might therefore lead to a risk of a damaged foetus.

If future insurance status e.g. for life insurance or private medical insurance, could be affected by taking part this should be stated (if e.g. high blood pressure is detected.) If the participants have private medical insurance you should ask them to check with the company before agreeing to take part in the trial. They will need to do this to ensure that their participation will not affect their medical insurance.

You should state what happens if you find a condition of which the person was unaware. Is it treatable? What are you going to do with this information? What might be uncovered?

If there are no possible disadvantages or risks were none, it would be advisable to state that there is no known risk in participating in this project.

11. What are the possible benefits of taking part?

Where there is no intended benefit to the participant from taking part in the study this should be stated clearly.

It is important not to exaggerate the possible benefits to the particular person during the course of the study, e.g. by saying they will be given extra attention. This could be seen as coercive. It would be reasonable to say something similar to:

'We hope that participating in the study will help you. However, this cannot be guaranteed. The information we get from this study may help us to treat future participants with (name of condition) better.'

12. Will my taking part in this study be kept confidential?

You should explain that all information collected about them will be kept strictly confidential. A suggested form of words is:

'All information that is collected about you during the course of the research will be kept strictly confidential. Any information about you which is used will have your name and address removed so that you cannot be recognised from it.'

You should always bear in mind that you, as the researcher, are responsible for ensuring that when collecting or using data, you are not contravening the legal or regulatory requirements in any part of the UK.

Please include a statement that all data will be stored, analysed and reported in compliance with the Data Protection legislation of the relevant country where the study is being conducted.

13. What will happen to the results of the research study?

You should be able to tell the participants what will happen to the results of the research. Please state if this research will be published as part of a postgraduate dissertation. When are the results likely to be published? Where can they obtain a copy of the published results? You might add that they will not be identified in any report/publication.

14. Who has reviewed the study?

You **must** give the full name of the Research Ethics Committee(s), which reviewed the study (you do not however have to list the members of the Committee). This committee is the Metanoia Research Ethics Committee.

15. Contact for further information

You should give the participant a contact point for further information. This **must** be yours and your supervisor's name, work/university address, work/university telephone number and e-mail address. (Please do not disclose personal home and mobile telephone numbers)

Remember to thank your participant for taking part in this study!

The participant information sheet should be dated and given a version number.

The Participant Information Sheet should state that the participant would be given a copy of the information sheet and a signed consent form to keep.

METANOIA INSTITUTE

CONSENT FORM

Title of Project:

Name of Researcher:

Please initial box

1. I confirm that I have read and understand the information sheet dated .....……for the above study and have had the opportunity to ask questions. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason. If I choose to withdraw, I can decide what happens to any data I have provided. ☐

3. **Delete 3 and/or 4 if not applicable:**
I understand that sections of any of my medical notes may be looked at by responsible individuals from [company name] or from regulatory authorities where it is relevant to my taking part in research. I give permission for these individuals to have access to my records. ☐

4. I understand that my interview will be taped and subsequently transcribed. ☐

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

6. I agree that this form that bears my name and signature may be seen by a designated auditor. ☐

_____	_____	_____
Name of participant	Date	Signature
_____	_____	_____
Name of person taking consent	Date	Signature (if different from researcher)
_____	_____	_____
Researcher	Date	Signature

2 copies for participant; 1 copy for researcher

INDEPENDENT FIELD/LOCATION WORK RISK ASSESSMENT

This proforma must be completed as part of the research ethics submission for all field/location work. It is to be completed by the person carrying out the field/location work (which in most cases is the candidate) in conjunction with the research supervisor.

FIELD/LOCATION WORK DETAILS

Name of person carrying out field/location work
(usually the candidate).....

Telephone numbers and name of next of kin who may be contacted in the event of an accident	**FIELD/LOCATION WORK NEXT OF KIN** **Name** …… **Phone** ……..
Physical or psychological limitations to carrying out the proposed/location work	……..……..……..……..……. ……..……..……..……..…….. ……..……..……..……..…….. ……..……..……..……..…….
Any health problems (full details) which may be relevant to proposed field/location work activity in case of emergencies.	……..……..……..……. ……..……..……..……..……. ……..……..……..……. ……..……..……..…….
Locality (Country and Region)	…….. ……..……..……..…….
Travel arrangements	……. ……..……..……..…… ……..……..……..……
NB: Comprehensive travel and health insurance must always be obtained for independent overseas field/location work.	……..……..……..…….
Dates of travel and field/location work	……..……..……..…… ……..……..……..……

Hazard Identification and Risk Assessment PLEASE READ VERY CAREFULLY

List the localities to be visited or specify routes to be followed **(Col. 1).** For each locality, enter the potential hazards that may be identified beyond those accepted in everyday life. Add details giving cause for concern **(Col. 2).**

Examples of Potential Hazards :

Lone working: difficult to summon help, alone or in isolation, lone interviews.
Dealing with the public: personal attack, causing offence/intrusion, misinterpreted, political, ethnic, cultural, socio- economic differences/problems. Known or suspected criminal offenders.
Safety Standards (other work organisations, transport, hotels, etc), working at night, areas of high crime.
Ill health: personal considerations or vulnerabilities, pre-determined medical conditions (asthma, allergies, fitting) general fitness, disabilities, persons suited to task.

If no hazard can be identified beyond those of everyday life, enter 'NONE'.

1. LOCALITY/ROUTE	2. POTENTIAL HAZARDS

Risk Minimisation/Control Measures **PLEASE READ VERY CAREFULLY**

For each hazard identified **(Col 2),** list the precautions/control measures in place or that will be taken **(Col 3)** to **"reduce the risk to acceptable levels",** and the safety equipment **(Col 5)** that will be employed.

Assuming the safety precautions/control methods that will be adopted **(Col. 3),** categorise the fieldwork/location work risk for each location/route as negligible, low, moderate or high **(Col. 4). Risk increases with both the increasing likelihood of an accident and the increasing severity of the consequences of an accident.**

An acceptable level of risk is: a risk which can be safely controlled by person taking part in the activity using the precautions and control measures noted including the necessary instructions, information and training relevant to that risk. The resultant risk should not be significantly higher than that encountered in everyday life.

Examples of control measures/precautions:
Establish emergency procedures (means of raising an alarm, back up arrangements). Working with colleagues (pairs). **Lone working is not permitted where the risk of physical or verbal violence is a realistic possibility.** Training in interview techniques and avoiding /defusing conflict, following advice from local organisations, wearing of clothing unlikely to cause offence or unwanted attention. Interviews in neutral locations.

Checks on Health and Safety standards & welfare facilities of travel, accommodation and outside organisations. Seek information on social/cultural/political status of fieldwork/location area.

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3. PRECAUTIONS/CONTROL MEASURES	**4. RISK ASSESSMENT** (low, moderate, high)	**5. SAFETY**

DECLARATION: The undersigned have assessed the activity and the associated risks and declare that there is no significant risk or that the risk will be controlled by the method(s) listed above/over. Those participating in the work have read the assessment and will put in place precautions/control measures identified.

NB: Risk should be constantly reassessed during the fieldwork/location work period and additional precautions taken or fieldwork/location work discontinued if the risk is seen to be unacceptable.

Signature of the fieldworker(Staff member) ……..……..…….……..... **Date** ……..……

FIELD/LOCATIONWORK CHECK LIST

1. Ensure that **all members** of the field party/location party possess the following attributes (where relevant) at a level appropriate to the proposed activity and likely field/location conditions:

- ☐ Safety knowledge and training?
- ☐ Awareness of cultural, social and political differences?

2. Have all the necessary arrangements been made and information/instruction gained, and have the relevant authorities been consulted or informed with regard to:

- ☐ Legal access to sites and/or persons?
- ☐ Political sensitivity of the proposed topic, its method or location?
- ☐ Weather conditions, tide times and ranges?
- ☐ Crime risk? Emergency procedures?
- ☐ Travel and accommodation arrangement?