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| RNCM Ethics Approval Form for NON-PRACTICE-BASED research involving human participation (from January 2018) |

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| Type of project *(delete as necessary)* | | | | STAFF | POSTGRADUATE | | UNDERGRADUATE |
| Title of project: | |  | | | | | |
| Name of researcher(s): | | |  | | | | |
| Name of supervisor(s) *(for student research)*, line manager or  head of department *(staff research)*: | | | | | |  | |
| Date: |  | | | | | | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | *Mark with* ✓ *in box* | YES | NO | N/A |
| 1 | Will you tell participants the purpose of your research at the outset, explain what you will ask them to do (e.g. take part in interviews or experiments, take tests or be observed) and tell them how long it will take, so that they know what to expect? **If you are undertaking questionnaire research, please complete the RNCM Ethics Approval Form for questionnaire research with adults only.** |  |  |  |
| 2 | Will you tell participants that their participation is voluntary? |  |  |  |
| 3 | Will you obtain participants’ written consent to take part in your research? |  |  |  |
| 4 | If the research is observational, will you ask participants to give their consent to being observed? |  |  |  |
| 5 | Will you tell participants that they may withdraw from the research at any time without giving any reason? |  |  |  |
| 6 | If participants are required to complete questionnaires as part of the research, will you tell them they have the option of omitting certain questions if they do not want to answer them? |  |  |  |
| 7 | Will you tell participants that their data will be treated with full confidentiality and that, if published, it will not be identifiable as theirs? |  |  |  |
| 8 | Will you debrief participants at the end of their participation (i.e. give them a brief explanation of the study)? |  |  |  |
| 9 | If the research involves interviews, will you obtain participants’ consent to have their interviews audio- or video-recorded, and tell them that you will not record them if they refuse to give consent? |  |  |  |
| 10 | If you make audio- or video-recordings, will you obtain participants’ consent for you to play excerpts from the recordings in the course of disseminating your research (e.g. in presentations)? |  |  |  |

If you have replied **No** to any of Q1-10, but have **completed Box A** on the next page, please give an explanation on a continuation sheet. (Note: N/A = not applicable).

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | *Mark with* ✓ *in box* | YES | NO | N/A |
| 11 | Will your project involve deliberately misleading participants in any way? |  |  |  |
| 12 | Is there any realistic risk of any participants experiencing either physical or psychological distress or discomfort? If **Yes**, give details on a continuation sheet and state what you will tell them to do if they should experience any problems (e.g. who they can contact for help). |  |  |  |
| 13 | Will any conflicts of interest arise from your research? |  |  |  |

If you have replied **Yes** to Q11, Q12 or Q13 you should normally **complete Box B** on the next page; if not, please give a full explanation on a continuation sheet.

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|  | *Mark with* ✓ *in box* | | YES | NO | N/A |
| 14 | Does your project involve work with animals? If yes, please **mark Box B** on the next page. | |  |  |  |
| 15 | Are respondents likely to be members of any of these vulnerable groups? If so, please refer to the BERA Ethical Guidelines or the BPS Code of Human Research Ethics, and **complete Box B** on the next page.  **You should ensure that you have DBS (Disclosure and Barring Service) clearance (normally arranged by RNCM).** | Infants and children under the age of 18 |  |  |  |
| People with physiological and/or psychological impairments and/or learning disorders |  |  |  |
| People dependent on the protection or under the control of others |  |  |  |
| Patients |  |  |  |
| Parents of sick children |  |  |  |
| People with limited knowledge of the English language |  |  |  |
| People engaged in illegal activities (such as drug-taking). |  |  |  |

PLEASE COMPLETE **EITHER** BOX A **OR** BOX B BELOW AND **PROVIDE** **THE DETAILS REQUIRED** IN SUPPORT OF YOUR APPLICATION, THEN SIGN THE FORM (print, sign and scan, or provide electronic signatures).

*Mark with* ✓

|  |  |
| --- | --- |
| **A.** I consider that this project raises **no** important ethical issues that need be considered by the RNCM Research Ethics Committee. |  |
| **Give a brief description of the purpose of the research, methodological approach** (e.g. quantitative, qualitative, mixed methods) **and specific methods**: design, participants (recruitment methods, number, age, sex, exclusion/inclusion criteria), materials/apparatus, procedure, proposed analyses *(maximum 200 words)*. **If your research involves interviews, please provide the interview schedule on a continuation sheet.** |  |

**OR**

*Mark with* ✓

|  |  |
| --- | --- |
| **B.** I consider that this project **may** raise ethical issues that should be considered by the RNCM Research Ethics Committee, and/or it will be carried out with children or other vulnerable groups. |  |
| **Please provide all the information listed below on a continuation sheet headed Ethical Considerations.**   1. Title of project 2. Purpose of project and its academic rationale 3. The methodological approach (e.g. quantitative, qualitative, mixed methods) and specific methods you are using: design, participants (recruitment methods, number, age, sex, exclusion/inclusion criteria), materials/apparatus, procedure, proposed analyses 4. A clear and concise statement of the ethical considerations raised by the project and how you intend to deal with them 5. How you will obtain informed consent and provide debriefing 6. Estimated start date and duration of project |  |

**Please sign below** to confirm that you have read and are familiar with *EITHER* the [BERA ethical guidelines (4th edition)](https://www.bera.ac.uk/wp-content/uploads/2018/06/BERA-Ethical-Guidelines-for-Educational-Research_4thEdn_2018.pdf) *OR* the BPS Code of Human Research Ethics and (if appropriate) have discussed them with the other researchers involved in the project / your supervisor / line manager / head of department.

|  |  |  |
| --- | --- | --- |
| **Signed: …………………………………….....**  *(Researcher)* | **Print Name: …………………………………..** | **Date: ……………….** |
| **Signed: …………………………………….….**  *(Supervisor, line manager or head of department)* | **Print Name: …………………………………..** | **Date: ……………….** |

This form, any continuation sheets you wish to include, the participant information sheet and sample consent form (see templates that follow) should be combined in a single document labelled with your name and the title of the project, and submitted electronically to Dr Michelle Phillips, Chair of the RNCM Research Ethics Committee.

Guidance on producing participant information sheets for non-practice-based research involving human participation

The purpose of a participant information sheet (PIS) is to help potential participants make an informed choice as to whether they want to take part in your research project. You need to give them enough, accurate information as to what will be expected of them, so that they can decide. You must tell them that if they do take part, they are free to withdraw from the project at any time, either by physically leaving and/or by withdrawing consent for you to use whatever contribution they have already made to your research. You need to make sure that everyone who takes part in your project knows why they have been asked to participate, what they will have to do, how you will use their contribution in your research, with whom you will be sharing it and in what form (e.g. in a conference presentation, master’s or PhD thesis, report, journal article or book).

Please use the template below, including all the headings. You should be able to print the final document on no more than two sides of A4 paper.

**Title**

The title of your research project should be self-explanatory. If it isn’t, please provide a simplified title.

**Date:**

**Invitation**

You should start by inviting the reader to take part in your research having chosen to do so on the basis of what they are about to read. You could use or adapt the following paragraph in your PIS:

You are being invited to take part in my research project. 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 me/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. You will be given this information sheet to keep. Thank you for reading this.

**Project**

Next, you must tell them what the aim of the project is. You should outline the broad methodological approach you are taking and specify the research methods you are using. If you intend to audio- or video-record participants, say so here, and tell the reader that they can refuse consent to be recorded, and/or for the recordings to be played when you come to report the research.

**Characteristics of participants**

You must say why you have asked this reader, in particular, to take part in your project, and how many other participants will be involved.

**Voluntary participation**

You must say that participation in your project is entirely voluntary and that if the reader does not want to take part or changes their mind having agreed to do so, they won’t be penalized in any way. You could use or adapt the following paragraph in your PIS:

It is up to you to decide if you want to take part in my project or not. If you don’t want to take part, or you change your mind about taking part, having agreed to do so, you won’t be penalized in any way. 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, without giving any reason. You can withdraw either by physically leaving and/or by withdrawing consent for me to use whatever contribution you have already made to the research. Again, you won’t be penalized in any way.

**Nature of participation**

You must say how long the project is going to last, how often participants will be required and for how long each time. You must say what you will ask them to do on each occasion. Please be as specific as possible – give dates, times and places where possible.

**Lifestyle restrictions**

You must say if participants are likely to experience any restrictions to their lifestyle as a result of taking part in your project and what these will be. Or, if they are *not* likely to experience any lifestyle restrictions, please include a sentence to say so here.

**Potential risks to participants**

You must say if participants are at any risk of being offended, shocked or harmed by your research. If unforeseen risks arise during the course of your project, remember that you will need to bring these to the attention of participants and ensure that you have their informed consent to continue taking part. If there are no foreseeable risks, please include a sentence to say so here.

**Potential benefits to participants**

You must tell the reader if they can reasonably expect to experience any benefits associated with taking part in the project, but without exaggeration, since this could be seen as coercive. If no benefit to participants is intended, however, please say so. You could use and complete the following sentence in your PIS:

While people taking part in my project are unlikely to experience any personal benefits as a result, I hope my research will.…

**Possible termination of research**

You must say that if your project has to be terminated for any reason and participants and/or the contribution they have made are no longer required for the research they will be told, and told why.

**Confidentiality and anonymity**

You are responsible for ensuring that you are not contravening the legal or regulatory requirements in any part of the UK when you collect, store and disseminate data about or from participants. You must tell the reader that if they agree to take part in your project you will ask them to sign a form giving their informed consent to do so, which they will be given to keep. This will give you permission for you to collect information about them and provided by them, **for the purposes of the present research project only**. Information about participants will be kept strictly confidential. Information from participants will only be attributed to them by name with their explicit permission. You could include the following sentences in your PIS:

Information that is collected about you, for the purposes of the research, will be kept strictly confidential. Information you provide will only be attributed to you by name with your explicit permission.

However, if there are any circumstances in which you are not be able to offer full confidentiality, for example if a disclosure in the research could lead to a safeguarding concern, you should make clear to participants the process that would be followed.

**Storing personal data and information**

You are responsible for storing participants’ personal data and any information they provide securely and destroying it after a specified period. You could include the following sentences in your PIS:

Your personal data and any information that you provide for the purposes of the research will be stored securely as follows: ……………… for ……………. years. If I wish to re-use it within this time period I will seek your permission to do so. At the end of the period it will be destroyed.

**Outputs**

You must say how you will use the contribution that participants make to your project, with whom you will share it, and in what form (e.g. in a conference presentation, master’s or PhD thesis, report, journal article or book).

**Debriefing**

You must say when and how you will debrief the participant, i.e. tell them about the findings of your research, and how they can obtain a copy of the report if/when it is published or presented.

**Ethical approval**

You should tell the reader that the RNCM Research Ethics Committee (REC) has reviewed your project and granted ethical approval for it to be carried out.

**Contact details**

Please provide your contact details (name, institutional affiliation, email address, telephone number) and those of your supervisor, line manager or head of department, as appropriate. *Do not disclose personal email addresses.*

**Thank you**

Please thank the reader for reading to the end of the PIS.

Guidance on producing consent forms for non-practice-based research involving human participation

You are encouraged to use or adapt the following template:

|  |  |  |
| --- | --- | --- |
| **Title of project:** | | |
| **Name of researcher:** | | |
| **Participant identification code for this project:**   |  |  |  | | --- | --- | --- | | 1. | I confirm that I have read and understood the participant information sheet dated [insert date] for research project in which I have been asked to take part 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. |  | |  |  |  | | 3. | I give the researcher(s) permission to collect information about me and from me for the purposes of the research project provided all information about me will be kept confidential, stored securely and destroyed after ………… years. |  | |  |  |  | | 4. | I DO/ DO NOT [delete as appropriate] give permission for information from me to be attributed to me by name. |  | |  |  |  | | 5. | I DO/ DO NOT [delete as appropriate] give permission for audio- or video-recordings of me to be played in the course of reporting the research. |  | |  |  |  | | 6. | I agree to take part in the above-named project. |  | | | |
| **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Name of participant** | **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Date Signature** |
| **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Name of person taking consent**  *(if different from lead researcher)* | **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Date Signature** |
| **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Researcher** | **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Date Signature** |

**Copies**

One copy for the participant, and one copy for the researcher / supervisor.

**Summary:** Your application should consist of

1. Your signed Ethics Approval Form and any further information you have been asked to provide (e.g. continuation sheets, interview schedule)

2. The participant information sheet and sample consent form.

Please combine all documents into a single file (.doc or .pdf) and send it to the Chair of the RNCM Research Ethics Committee ([michelle.phillips@rncm.ac.uk](mailto:michelle.phillips@rncm.ac.uk)).