**Psychology Specific Guidance for Ethics Applications**

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# Ethical approval subject specific guidance notes – psychology

# Guidance notes - preparing an ethical application form

The easiest way to complete your application is to write a research protocol and copy and paste details from this into the form. The following headings correspond to the application form and can be used when writing your protocol. Your protocol should be written succinctly, stating clearly what you intend to do and why, typically it shouldn’t be longer than 1500 words in total. In some instances (e.g. for large scale, multi-component studies) this may not provide sufficient space to adequately describe your study. In these cases, we will accept longer forms up to a limit of 3000 words.

It is acknowledged that different and competing research paradigms exist around research and that some studies may develop underpinned by a more social science/humanities perspective. Such studies may be better served by an alternative protocol structure to that proposed here and such researchers are free to develop their protocols as they see fit. Forms adopting such approaches will be reviewed with these distinctions in mind. However, clarity around the rationale, approach, procedures and ethical issues inherent in such studies will still be deemed essential and need to be included in the ethical application form.

Internet-mediated research (IMR) is becoming more widely utilised, however IMR can raise particular, sometimes non-obvious challenges in adhering to existing ethics principles. These issues include: the public-private domain distinction online; confidentiality and security of online data; procedures for obtaining valid consent; procedures for ensuring withdrawal rights and debriefing; levels of researcher control; and implications for scientific value and potential harm.

When developing a protocol it is essential that researchers make themselves aware of specific study design and ethical issues inherent in: (i) research with particular vulnerable groups (e.g. children, people with impaired capacity, survivors/offenders etc.); (ii) studies that involve gathering sensitive secondary data (e.g. abuse and neglect information); and (iii) research in particular organisational settings (e.g. hospitals, prisons, social services etc.). Guidance should be available from your supervisor if your research is part of a course of study.

The sections below provide guidance on preparing a study protocol and completing the question in the ethical application form.

# Key points to note from BPS guidance on Internet Mediated Research (IMR)

* Consideration of Privacy – what is legitimately public or private?
* Consideration of informed consent - how can a researcher ensure procedures are robust to get informed consent?
* Are materials used protected by copyright?
* Can participants withdraw their data and by what mechanism?
* If a participant misses debriefing information, does this impact on any potential critical debrief (e.g. where deception has been used)?
* Is there any need for control which may not be feasible within an online forum (e.g. require a certain individual to do the whole task)?
* Could there be any social disruption through the recruitment of participants within internet forums based on certain communities?
* You need to be mindful that compromising anonymity/confidentiality of a social structure is potentially harmful.
* If a study is particularly high risk, consider its suitability for IMR
* Clarity is imperative. Inform participants of the potentially unsecure nature of online information transfer
* Verbatim quotes can be traced back to the original discussion/poster simply using Google.
* Anonymity cannot be guaranteed – IP addresses can be traced to an individual
* When offering incentives, you may consider using a separate survey for email address collection. Ensure that survey responses are kept separate to identifiable information.
* In many cases, personal data leakage risk is low, but it is imperative to take steps to assess and reduce risks and informing participants of these.
* Do not conflate information sheet and consent forms.

The information above has been summarised from The BPS Ethics Guidelines for Internet-Mediated Research. Original document can be found [here](https://www.bps.org.uk/sites/www.bps.org.uk/files/Policy/Policy%20-%20Files/Ethics%20Guidelines%20for%20Internet-mediated%20Research%20%282017%29.pdf).

British Psychological Society (2017). Ethics Guidelines for Internet-mediated Research. INF206/04.2017. Leicester: Author. Available from: <https://www.bps.org.uk/sites/www.bps.org.uk/files/Policy/Policy%20-%20Files/Ethics%20Guidelines%20for%20Internet-mediated%20Research%20%282017%29.pdf>

#

# Application form specific guidance

# Section One – Name, email, project supervisor/director of studies/investigator, contact number, funding information, ethical category, service user involvement.

These questions ask for background information about the applicant, contact information and the principle investigator/supervisor/director of studies. Information will also be required regarding funding (internally/externally/neither) and the ethical category your project falls in (categories are outlined in the [handbook](https://www.wlv.ac.uk/media/departments/research/documents/Handbook-for-Ethical-Approval-%26-Practice-Procedures.pdf)). You will also need to give details of service user involvement in the development and/or completion of the research. Your application should be submitted by the 1st of each month to fehwethics@wlv.ac.uk and applications will be reviewed and a response given by 30/31st of the same month unless otherwise notified. However, if your application is urgent for any reason please indicate the specific date when the decision is needed and explain that the review is needed urgently in the submissions email.

# Section Two – Title, research question(s)/hypothesis, outline, study method, vulnerable participants, analysis, external agency approval, ethical considerations.

## 2.1 – Project title

Every research protocol and subsequent project requires a title. This should be thought out and presented carefully and accurately as your study protocol will become known by its title, and the ethics committee use the title to address correspondence to you and others involved with the research. Typically, these are no more than 20 words.

## 2.2. – Research questions/hypothesis

This section requires you to provide a succinct and accurate account of the rationale for the research summarising the main arguments from the background literature. This should be followed by a statement relating to the question the research proposes to answer which can be stated as one of the following: (i) research question(s); (ii) research aims / objectives; or (iii) research hypotheses. These can be listed or numbered and must reflect the title of the research and study design.

## 2.3 – Brief outline of project, state rationale, aims and expected outcomes (300 words)

This section should include about a paragraph, which summarises the literature (taken from your literature review) and therefore provides a theoretical background and justification for your particular study. This is an important section for students seeking ethical approval because it constitutes the scientific background underpinning the proposed study. It is deemed important in demonstrating that the study is worthwhile conducting. Recency and accuracy of reference material used to support your justification is essential.

## 2.4 – How will your research be conducted (750 words max)

**Omit details of analysis here, this will be asked in a separate question**

In this section describe the study method so that it can be easily understood. Please ensure you clearly explain any acronyms and subject specific terminology. You can use the following subheadings if you wish. Focus on giving a brief account of your method, whilst giving more detail about any issues and procedures that are ethically sensitive or contentious also providing an account of measures taken to protect the wellbeing of participants.

### *Research Design/Approach.*

Explain briefly what type of design/approach is being proposed. It is important to back up your selected design with appropriate methodological references. The following is an example:

*'This cross-sectional study will employ a quantitative survey as this method is typically used to seek the opinions of a large sample of respondents. The study is primarily confirmatory, aiming to replicate and confirm the findings from previous studies, but it also contains descriptive and exploratory components. The quantitative survey has been described by Coolican (2009) as …’*

### *Recruitment, Sampling & Study Participants.*

Explain first, the *population* that you wish to target. You will also need to describe the inclusion and exclusion criteria you will be employing. Once you have identified the population, state *how* you will recruit a sample from this population. You will also need to decide on a sampling strategy and describe this. The following are examples:

*The target population of the study is District Nurses in the West Midlands of which there are currently ... in practice. From this population, a random sample has been selected from a database held by a single Trust. A random sample is a probability sample (Clifford, 1997) thereby ensuring generalisability to the target population. It is estimated that there are currently 150 district nurses practising in the Trust.*

*A purposive non-probability sample of adults who are received cognitive behaviour therapy to help them with a personal bereavement will be recruited into this study. Services offering this therapy will be approached and asked to circulate an advertisement (See Appendix 2) for potential participants. It is hoped that 15 participants will be recruited into this qualitative investigation and that from this saturation of themes will be achieved, if not then the sample size will be extended until saturation of themes has been achieved.*

In qualitative research, you will not need to generalise your findings to the target population, but nevertheless you need to demonstrate that you have given thought to how to select your sample. Sampling strategies should once again be detailed.

In quantitative research you should have a good idea (and preferably you should be certain) of the *number* of respondents in the sample.

### *Materials/Data Collection Method(s)*

You must clearly state the materials and data collection methods you are intending to utilize in order to gather the data to achieve your research goal. Any tools to be used for data collection will need to be included as an appendix. These must be referenced into your protocol. The following accounts are examples:

*A self-complete questionnaire (see Appendix 1) has been designed to ascertain participants’ opinions of the effectiveness of the different types of therapeutic interventions currently being used in….*

*The sf-36 health questionnaire (Turner-Bowker et al., 2002) will be used as a measure of the participants’ physical and mental wellbeing. This assessment has been found to have excellent reliability and validity and has been used previously as a measure of wellbeing.*

*The study will also involve a documentary analysis. This will involve an analysis of participant records, for the purposes of recording the type and frequency of pain relief given, the tool devised to conduct the documentary analysis is shown in Appendix 2.*

*Semi-structured telephone interviews will be employed to gather the data. The interview schedule/topic guide can be found in Appendix 1, and covers …. Open-ended questions were developed in conjunction with experts in the field and have been piloted with two social workers who offered comments to enhance clarity of questions 3 and 5. This interview approach was adopted because…*

### *Data Collection Procedure*

Here describe details of where data collection will occur and the process or steps you will take to gather your data. This should be sufficiently detailed so that the ethics committee understands what will happen to participants within your study.

You must consider any safety and risks inherent in your data collection. This is particularly important if you will be the lone researcher conducting surveys or interviews in participants’ homes.

### *Pilot study*

A pilot study is not always necessary. If you are intending to conduct a pilot study you need to state how this will be conducted, on how many and why. If you decide not to carry out a pilot study, you must justify this decision. Information on pilot studies can be found in any good research text.

### *References*

References used within the protocol should be listed in accordance with your subject group (e.g. for Psychology students APA referencing style should be employed, for Social work students Harvard referencing style is the norm).

Clifford, C. (1997). *Nursing and Health Care Research: A skills-based introduction*. Prentice Hall. London.

Coolican, H., (2009). *Research methods and statistics in Psychology* (5th Edition). London : Routledge

Braun, V. & Clarke, V. (2006) Using thematic analysis in psychology. *Qualitative Research in* Psychology, 3, 77-101.

Turner-Bowker, D.M., Bartley, P.J. & Ware, J.E., Jr. (2002). *SF-36® Health Survey & “SF” Bibliography: Third Edition (1988-2000)*. Lincoln, RI: QualityMetric Incorporated.

## 2.5a – Does your research involve children under 18 years of age?

Occasionally research will involve children under 18 years of age, this must be declared here as there are additional ethical implications and procedures required for research with this population.

## 2.5b – If yes, do you have an Enhanced Disclosure Certificate from the Criminal Records Bureau/Disclosure Barring Service

It is imperative that you obtain a DBS certificate. If it is the case that your application has been submitted and is being processed it is recommended to select no but mention this in the email when sending your ethics application.

## 2.6 – Are participants in your study going to be recruited from a potentially vulnerable group? See RPU website [here](https://www.wlv.ac.uk/research/research-policies-procedures--guidelines/ethics-guidance/)

If you answer yes here, you must describe the groups and what measures you will take to respect their rights and safeguard them. Groups include those who, within the context of the study to be undertaken, may be considered to be vulnerable, such as children, people with learning or communication difficulties, patients/clients (including people with diagnosed psychological or health conditions), people in custody or offenders, other vulnerable groups (e.g. crime victims/survivors, homeless people, substance misusers etc.).

## 2.7 – How will your data be analysed?

You need to give some thought to how you intend to analyse your data. External Research Ethics Committees have been known to reject ethics forms because this has not been addressed. Explain what will happen to the data you have collected along with the analytic procedures that will be used.

If you will be using a particular analytic package or approach, this information should also be included (e.g. SPSS; NVIVO). Some examples are as follows:

*The interviews will be analysed by using thematic analysis following the steps proposed by Braun & Clarke (2006). The steps are as follows…*

Or, if you are conducting a quantitative study the following could apply.

*Data will be entered into SPPS (v.20, 2013) and screened to check it meets the requirements of parametric data. If it meets these requirements, as two groups of 30 subjects are being compared, the unrelated t-test will be used. If the screening reveals that the data does not meet the requirements of parametric data then, the non-parametric equivalent, the Mann Whitney ‘U’ test will be used.*

English is the language that must be used for reporting data. It is the responsibility of the researcher or project team to provide sufficient evidence, where the collecting and recording is in another language, of accurate translation of data collection materials.

## 2.8 – Is ethical approval required by an external agency? (e.g. NHS, other university, outside organisation)

Indicate here if any additional approvals are needed or have already been sought. If approval has been attained, you will also need to enter contact details of an individual who can verify this is necessary.

## 2,9 – What, in your view are the ethical considerations involved in this project? (e.g. confidentiality, consent, risk, physical or psychological harm, etc.) Please explain in full sentences. Do not simply list the issues. Please make it clear how you are going to deal with issues with regard to your own welfare and safety.

Here you must detail the ethical considerations involved in this project individually (e.g. risks to you, gaining consent, coercion, deception etc.). There may well be additional ethical issues you need to consider depending on the specific nature of your proposed research methods. It is essential these are documented comprehensively, and any supporting documents will need to be placed in appendices. Please explain in full sentences. Do not simply list the issues.

**Note:** It is imperative that psychologists and psychology students undertaking research to follow the BPS Code of Human Research Ethics. This code will help orient you to the ethical issues you need to be mindful of when designing a research investigation. The code can be found here:

<http://www.bps.org.uk/sites/default/files/documents/code_of_human_research_ethics.pdf>

Other disciplines will have their own codes that they need to adhere to (e.g. HCPC, College of Social work, Royal College of Nursing).

There is a requirement to give details of all aspects of permission and approval to conduct the study you are proposing.

## 2.10 – Have participants been/will be fully informed of the risks and benefits of participating and of their right to refuse participation or withdraw from the research at any time?

Here you need to detail how the participants will be informed about the risks and benefits inherent in the study and about their right to withdraw from the study. Typically, this occurs via an information sheet so you can refer to the appended information sheet here.

It is important that you are clear about potential harms and do not overstate potential benefits. You need to explain how you intend to protect the participants from harm.

Consider if there is any possibility of either physical or psychological distress. If so, you need to include details of how this will be managed (e.g. by providing details of free support services, for example victim support). If there are no direct benefits to the participant but the study may provide benefit in the future and enhance knowledge, then this is the information you should provide to participants.

Also consider the limits of withdrawal. Typically, studies should allow participants to withdraw at any time, however in practice this may not be possible. For instance, if data is collected anonymously with no identifying information it will be impossible to remove this afterwards or if you have begun your qualitative analysis or submitted you research for a course or for publication it will be very difficult to remove individual participant data at that point. Thus, the actual limits of withdrawal should be made clear to participants.

## 2.11 & 2.12 – Anonymity and confidentiality

These questions refer specifically to the ethical issues around anonymising data and keeping data and participant information confidential.

It is not sufficient to state that 'confidentiality and anonymity will be maintained'. You need to state *how* you intend to achieve this. Equally, you need to consider *how* you will anonymise the data and the steps you will take to *protect* the data once it is collected. Here is an example:

*Confidentiality will be maintained in this study by not divulging information to other personnel, except for those directly involved in the study, such as research supervisors and examiners. Such personnel will be unable to link the data to participants, as the data will be anonymised by using codes on the questionnaires and interview transcripts. Any quotes used in the research will use a pseudonym rather than the participant’s name. Place names and any other identifiable information will also be changed to preserve anonymity.*

In some situations, it may not be possible or ethical to guarantee full confidentiality, e.g. if safeguarding becomes an issue. If anything is raised during the interview that indicates that either your participant or someone else is at risk of harm, then these concerns will have to be considered further, or discussed with your research supervisor if you are a student, and may require the information to be shared with another agency. It is also important to state what you will do if a safeguarding issues becomes apparent while collecting data (typically this would involve ceasing data collection and informing the participant that they have raised a safeguarding issue and that this needs to be shared with the relevant bodies).

Another common situation in which full confidentiality and anonymity cannot be attained is when conducted internet-based research (see above for internet-mediated research guidance). Due to the inherent nature of the internet there is always a possibility that information can be intercepted or potentially stolen. It would be wise to include a statement in your information sheet of online questionnaires explaining that: “while XYZ measures will be taken to protect your right to anonymity and confidentiality it must be understood that given the fact that this questionnaire/study/server takes place on the internet that there is a very small risk of data interception.

See RPU website (www.wlv.ac.uk/rpu) and follow link to Ethical Guidance pages for guidance on anonymity)

See RPU website (www.wlv.ac.uk/rpu) and follow link to Ethical Guidance pages for definition of confidentiality).

## 2.13 – How will you store your data during and after the project?

This question refers specifically to the ethical issues around secure data storage. You need to state how and how long you will store the data for and how it will be kept secure. An example is provided below:

*Data will be protected by keeping questionnaires, transcripts and interview recordings in a secure facility in a locked filing cabinet, accessibly only to the research team. The data from the study will be stored for 2 years and then destroyed confidentially.*

In most cases the University standard for storing data is 2 years to enable full dissemination of the data and any project auditing required. However, you may store data for as long as you feel you need to as long as you justify this.

See RPU website (www.wlv.ac.uk/rpu) and follow link to Ethical Guidance pages for definition of and guidance on data protection and storage)

# Section Three

This section pertains to research that involves the acquisition or analysis of data sets from “potentially illicit origin” and information pertaining to whether the research is potentially security-sensitive such as military commissions or concerning extremist or terrorist groups.

## 3.1 – Is this data set of potentially illicit origin?

Some research studies may indeed involve data acquired from sources in which it is impossible to obtain the consent of the original data owners or data subjects – in any application in which this is the case.

## 3.2 – Does your research fit into any of the following security-sensitive categories?

See RPU website [here](https://www.wlv.ac.uk/research/research-policies-procedures--guidelines/ethics-guidance/) for clarification on whether your research may fit into any of these categories.

If you answer no to question 3.1 & 3.2 you will not have to complete questions 3.3 – 3.8.

## 3.3 & 3.4 & 3.5 – Pertains to whether research will involve the storage or transmission of items that can be interpreted as promoting or endorsing terrorist acts, and whether these items will be securely stored and traced.

You will have to note here simply yes or no. However, if you do not agree to store sensitive items on a secure university file store you will need a comprehensive explanation as to why and the steps you will take to ensure security.

## 3.6 – Do you agree NOT to transmit electronically to any third party, documents in the secure university document store?

## 3.7 – Will your research involve visits to websites that might be associated with extreme or terrorist organisations?

If you select yes you will have to list which websites and why you deem this necessary.

## 3.8 - You are advised that visits to websites that might be associated with extreme or terrorist organisations may be subject to surveillance by the police. Accessing those sites from University IP addresses might lead to police enquiries. Do you understand this risk?

This section is for you to acknowledge the risk associated with visiting websites associated with extreme or terrorist organisation and that the visiting of such websites may result in Police Surveillance. It must also be understood by yourself that if research of this calibre is undertaken on personal devices then the monitoring would extend to monitoring of your personal devices also. **Given the drastic changes imposed on us by COVID-19 this risk is hugely increased for researchers as researching from home naturally means that the IP address will be yours. Be aware of this.**

See comment

# Section Four

##

## 4.1 - Appendices

This is relevant and required for all studies. Please list the items that you are submitting with this document. (These will need to be submitted to fehwethics@wlv.ac.uk ) You may want to include additional information that will help the panel with their decision such as your proposal. You need to provide examples of research instruments, recruitment posters and leaflets, information sheets (age appropriate) assent forms (for children), consent forms, risk assessment if research is carried out abroad.

These are generic samples included as guidance, if you use these as templates, yours should be adapted to fit your own study. You may wish to develop your materials differently to these but please ensure you cover all the relevant information in each component. These are typically presented in the Appendices of your Protocol and should be appended to your ethical application form.

1. Sample letter to study site/organisation - Letter for Access and Approval from management/organisation
2. Sample letter to participants
3. General consent form and right to withdraw
4. Consent form involving access to medical/patient/client records
5. Participant Information Sheet
6. Risk Assessment

### *Appendix 1: Sample letter to Study site/Organisation.*

###

Name, title/position and address of receiver

(Note: University rather than personal contact details should be included)

Dear

As part of my … course at the University of Wolverhampton, I am proposing to

conduct a research project into… To do this I require your support/help with… If you agree to take part this will involve … The potential benefits of this research include …

I am therefore writing to seek your permission to conduct this study in … (state where) with … (state whom) and enclose a copy of the research protocol for your information.

I look forward to hearing from you.

Yours sincerely

Researcher’s signature

### *Appendix 2: Sample Letter to participants.*

**Note:** Local Research Ethics Committees have varying expectations regarding the letter to participants. Some require students to state that they are so, so that participants/clients can decide whether to involve themselves in such a project. Other Local Research Ethics Committees have expressed the view that participants might feel a sense of obligation to help the student with the project. We believe it is most important to respect participants’ right to refuse and that regardless of the aims of the project, especially as many research participants participate for reasons of charity and kindness to the researcher. The letter overleaf is an example of the ‘tone’ you should use in your letter.



Dear ……….

I am writing to invite you to participate in a research project, which I am conducting as part of a … course in … at the University of Wolverhampton. I enclose an information sheet, which explains the title and aims of the project and what taking part will involve.

Some examples…

**If you are willing to be interviewed, the interview would take between 45 and 60 minutes. Anything you say would be totally confidential and any notes made as a result of the interview would be destroyed afterwards. The interview would take place … (State location) at a time that is convenient to yourself. A report will be written of the findings and numbers will replace all names so that you cannot be identified.**

If you feel that you would like to be interviewed, please indicate on the attached sheet and hand the letter to the district nurse next time she visits you. If you would prefer not to be involved, please destroy/ignore this letter. If you decide not to be involved, I would like to assure you that your care will not be affected in any way.

Yours sincerely,

Signed

### *Appendix 3: General consent form and right to withdraw*

Below we provide examples of consent forms. You may wish to develop your own. The examples can be used as templates but must be adapted so they are appropriate for your study. **Note** - Some organisations and external approval bodies (e.g. NHS ethics committees, for example Staffordshire) require you to ask permission to use quotations in your work/ publications. If so, please include this on the consent form if you will be using quotations. Please ensure you find out if this is relevant.

****

**CONSENT FORM**

**Title of Project:**

**Name of Researcher:**

**Please initial boxes**

1. I confirm that I have read and understand the information sheet dated ………………. (version 1, 2 etc.) for the above study and have had

the opportunity to ask questions.

1. I understand that my participation is voluntary and that I am free

to withdraw at any time/up until commencement of data analysis[[1]](#footnote-1),

without giving any reason.

1. I understand that my data will be stored securely and confidentially[[2]](#footnote-2)
and that I will not be identifiable in any report or publication
2. I understand that the researcher may wish to publish this study

and any results found, for which I give my permission

1. I agree for my interview to be tape recorded and for the data to be

used for the purpose of this study.

1. I agree to take part in the above study.

……………………….. …………………….. …………………………

Name Date Signature

……………………….. …………………….. …………………………

Name of person taking Date Signature

consent (if different from researcher, state position)

…………………………. ……………………. …………………………

Researcher Date Signature

### *Appendix 4: Consent Form Involving Access to Medical or Client Records*



**Title of Project:**

**Name of Researcher:**

**Please initial boxes**

1. I confirm that I have read and understand the information sheet

dated …………. (version 1, 2, etc.) 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/up until commencement of data analysis,

without giving any reason, without my medical care or legal rights

being affected.

3. I understand that sections of any of my (medical/case) 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 data will be stored securely and confidentially
and that I will not be identifiable in any report or publication

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

……………………….. …………………….. …………………………

Name Date Signature

……………………….. …………………….. …………………………

Name of person taking Date Signature

consent (if different from researcher, state position)

…………………………. ……………………. …………………………

Researcher Date Signature

### *Appendix 5: Participant information sheet*

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 can take many forms though one of the most user friendly is the question and answer format which is described below. The information sheet should contain information that answers each question and tells participants about the study and what it involves. The questions set out below aim to cover the things participants would typically need to know, but you may wish to change them to better suit your study, or to use an alternative approach to the question and answer format.

The information sheet should be written in simple, non-technical terms (avoiding jargon and abbreviations) 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. If you are preparing your information sheet for younger or older people or people with cognitive impairments or health issues you will need to ensure that it is comprehensible and not confusing or off-putting to these groups.

Use the University logo at the top. You may also need to add the logos used by any partner organizations involved in or supporting the research. University rather than personal contact details should be used in documentation.

Try to be clear but brief, participants are unlikely to want to read an information sheet that is longer than a couple of pages. If your information sheet is very long you may need to revise your data collection methods incorporating more detail about the procedure you will use to go through the information sheet with participants.

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Participant Information Sheet

**Study title**

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

**Invitation paragraph (Optional)**

This should explain that the participant is being asked to voluntarily 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 friends, / relatives. 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”.*

**What is the purpose of the study?**

A brief lay summary of the background and aim of the study should be given here. What is the area being studied? Why are you investigating it? What question do you aim to answer? Also mention the duration of the study.

**Why have I been chosen?**

You should explain how the participant was identified, why they have been chosen and how many other participants will be studied.

**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[[3]](#footnote-3) and without giving a reason.”*

For studies where participants may be in receipt of healthcare, services or therapeutic interventions it is important to also state that withdrawing from the study will not affect the standard of care they receive.

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

You should say how long the participant will be involved in the research, how long the research will last (if this is different). You will need to explain what exactly will happen e.g. you will be asked to take part in an interview where you will be asked questions about.... If the methodology is complex you may wish to draw a simple flowchart or plan indicating what will happen. What are the participant’s responsibilities? Set down clearly what you expect of them.

You should set out simply the data collection methods you intend to use.

**What are the potential benefits and risks of taking part?**

Where there is no intended benefit to the participant from taking part in the study this should be stated clearly. Instead you should focus on the wider benefits of the study findings in terms of future benefits to understanding, practice or care. It is important not to exaggerate the possible benefits to the particular participant during the course of the study, e.g. by saying they will be given extra attention. This could be seen as coercive.

You should also explain any potential risks for participants that may occur if they decide to take part. If there is a serious risk of harm you will need to justify why this risk is necessary in terms of the importance of the research. An example of this section is below.

*“Though there are no direct benefits for you if you take part, by taking part you will help us to find out about… and this may improve … in the future.*

*There are no risks to you in taking part outside of those you would experience in everyday life. However, by taking part, you may remember things that you may find upsetting. If this occurs, the researcher will ask you if you want to continue to participate in the interview. Any decision you make will be respected.”*

**Will my taking part in the study be kept confidential?**

The answer here should typically be yes. It is important here to explain how the data your participants provide will be stored and how their data will be presented in your write up. Here discussion on anonymity, confidentiality, security of storage and removal of identifying information are the main considerations. An example is below.

*“Yes. All the information about your participation in this study will be kept confidential. The transcription of the interview you participate in/the surveys you completed will be stored on a password protected computer in a locked office. Only the researchers working on the project will have access to the information. You will not be identifiable in any publication or report as the data will be grouped together and all identifying information will be removed.”*

If you cannot guarantee full confidentiality (e.g. due to potential safeguarding issues) you need to make this clear to potential participants here. You should explain that if anything is raised during the interview that indicates that either the participant or someone else is at risk of harm, then these concerns will have to be taken further. Explain where they will be taken too and whom the information will potentially be shared with.

**What will happen at the end of the research study?**

You should also tell the participants how the findings will be disseminated. When and where are the results likely to be published? Will you provide a lay summary of your findings to participants? Where can they obtain a copy of the published results or access the lay summary?

**What if I have a problem or concern?**

Here you should give details of who the person (For student projects typically the supervisor) can contact if they have any questions or complaints about the method, conduct of the research. It is also good practice to include the details of the Dean of Research Silke Machold, email: s.machold@wlv.ac.uk

*“If you have a concern about any aspect of this study, you should ask to speak with the researchers who will do their best to answer your questions”*

**Who has reviewed the study?**

You may wish to give the name of the Research Ethics Committee(s) which reviewed the study (you do not however have to list the members of the Committee).

**Contact for further information**

You should give the participant a contact point for further information. University rather than personal contact details should be used in documentation.

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

**Additional information:**

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

Typically, the Participant Information Sheet should state that the participant will be given a copy of the information sheet and a signed consent form to keep. Though we acknowledge that this may not be possible for online survey-based research.

**Note: Appendix 6 contains Guidelines for Ethics approval for overseas research projects and for students undertaking research outside the United Kingdom ONLY.**

### *Appendix 6: Risk Assessment*

**Over-riding principles**

The following are the principles that supervisors, project designers and School Ethics Committees must consider when designing and approving student and staff research projects, which are to be undertaken outside the United Kingdom:

1. The **health and safety** of the person or persons undertaking the project and of the subjects of the research project should be a primary consideration.
2. Any **legal liabilities and responsibilities** that could arise out of the research project by reason of the local legal jurisdiction in which the project is to be conducted.
3. Researchers and Project teams must take account of **cultural sensitivities** and cultural differences and the extent to which these may impact on the research and its viability and validity.
4. Issues relating to the **access** to data sources must also be carefully considered. This is especially important for research projects that require access to children and vulnerable adults but must be considered in all situations where the data sources are human subjects. The issues to be considered by project teams include the circumstances in which data subjects might be **coerced** into participating in the project. Researchers and Project teams must also consider the question of **informed consent** and the way in which this is obtained from the data subject in jurisdictions, which, because of cultural differences, approach the matter of informed consent differently from the approach taken in the United Kingdom.
5. **Language issues** especially in relation to the collection, recording and reporting of data. It is important to emphasise that English is the language that must be used for reporting data. It is the responsibility of the researcher or project team to provide sufficient evidence, where the collecting and recording is in another language, of accurate translation. This may, for example, involve independent translation into English of consent forms, data collection instruments or other documentation used in the research. Ultimately it is essential for quality assurance purposes that the research supervisor and external examiners are able to verify all aspects of the research.
6. All **data** collected in relation to the research project must be secured at all times to ensure confidentiality. This is especially important during periods when the data or the media on which the data is stored is in transit.

It is recommended, that any research study incorporating research work outside the United Kingdom, that involves human subjects, should be treated by the School Ethics Committee as Category B research. A document that contains a **Risk Analysis** **and Assessment** must accompany all research protocols that entail research outside of the United Kingdom.

The analysis must contain a statement in relation to each of the issues detailed in 1 – 6 above as follows:

* 1. Health and Safety risks
	2. Legal risks
	3. Cultural issues
	4. Access to data including issues relating to the dangers of coercion and also informed consent on the part of the data subjects
	5. Language
	6. Protection of data

**Example of a student’s Risk Assessment:**

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**(See:** [**http://www2.wlv.ac.uk/webteam/curr\_sdts/sharpen/ss-HowtoAvoidAM.doc**](http://www2.wlv.ac.uk/webteam/curr_sdts/sharpen/ss-HowtoAvoidAM.doc)**)**

### *Risk Analysis and Assessment*

***a. Health and Safety***

The study will be conducted with strict regards to health and safety of the participants and researcher. The research approach is not associated with potential health or safety risks that can negatively impact on participants’ state of health. However, a safety protocol would be followed to ensure safety of researcher and participants.

A safety protocol for researcher is intended to detail policies and procedures for prevention, intervention and follow-up of harmful incidents during a study. Harmful events can include physical and or verbal aggression in which the physical or psychological safety of the researcher is jeopardised.

The degree of risk associated with a specific research project is largely determined by the nature of the research participants, the nature of the research topic, and the nature of the environment in which the research occurs.

The researcher is well familiar with the settings and interview will be conducted in a public place during the daytime, in a well- lit room. A designated person will be informed of the time, date, venue, start and end of the interview. Attention will be paid to any possible violation of the researcher safety zones during data collection. The researcher would carry mobile phones and a safety alarm to deter would-be attacker in or around the settings. Security department of the ……. will be alerted to offer personal consultation, assistance and advice. Researchers will not volunteer any personal information that would lead another person to the researcher’s home (e.g., home address, home telephone number).

***b. Legal Risks***.

Full ethical clearance will be obtained from …………. prior to commencement of the study. No legal liabilities or responsibility is envisaged as a result of carrying out the study. There is dearth of study that has examined the research topic from the patients’ perspectives.

***c. Cultural Issues*.**

The location of the setting of data collection is significant in conducting safe research.

The study will be conducted in……. a state with people of diverse cultural and ethnic groups. The researcher is well familiar with the cultural norms of people in the study setting and actually grew up in the environment. As a result, there will be no cultural sensitivities and differences affecting the viability and validity of data.

***d. Access to data including issues relating to the dangers of coercion and also informed consent on the part of the data subjects.***

A written consent will be obtained from the participants before the study. This would be done through introductory letters and information sheets to enable them to decide whether they wish to be research participants without coercion or deception and that participation is entirely voluntary. Their confidentiality will be maintained by sharing the information among only those that are involved in the study such as research supervisor and examiners. The principle of informed consent in……is not influenced by cultural difference.

***e. Language.***

In ……… English Language is the official language and is widely used in communication in both private and public places. As 90% of the people in……. communicate in basic English Language fluently, the interview will be conducted in English. English will be the medium for all data collection, recordings and reporting. Consent will be obtained from participants in English Language.

***f. Protection of data.***

Participants’ privacy would be maintained throughout the study. Anonymity will be maintained by using pseudonyms in place of participants’ personal names. Data will be protected by keeping tape recordings and interview transcripts in secure safe with lock after the interview, during transit and when not in use; and destroy 2 years after the study.

1. For some studies it may be difficult to withdraw an individual participant’s data (e.g. following interviews and conducting qualitative thematic analysis). In such circumstances it is important that you make it clear that participants can only withdraw their data up until the commencement of the data analysis. Also, if you collect data anonymously you may not be able to identify the data to subsequently remove it. This limitation on withdrawal from the study must also be made clear. [↑](#footnote-ref-1)
2. Ensure participants understand that if safeguarding issues are raised the information may not be kept fully confidential and may be shared with relevant organisations. [↑](#footnote-ref-2)
3. For some studies it may be difficult to withdraw an individual participant’s data (e.g. following interviews and conducting qualitative thematic analysis). In such circumstances it is important that you make it clear that participants can only withdraw their data up until the commencement of the data analysis. Also, if you collect data anonymously you may not be able to identify the data to subsequently remove it. This limitation on withdrawal from the study must also be made clear. [↑](#footnote-ref-3)