**Participant Information Sheet Template – Guidance Notes**

**N.B. the template follows this guidance**

**Who should use this template?**

This template is for the use of anyone who intends to conduct a study where a record of information is required, either in the form of research data, and/or to ensure that suitably informed consent has been obtained (often required under data protection legislation). ‘Research’ should be interpreted to include knowledge transfer and innovation projects where these include ethical issues.

**When should a written participant information sheet be used?**

Information regarding research/innovation activities must be provided wherever possible, and a record that it has been given should be kept. It is not always necessary to use a separate information sheet, and it is possible and perfectly acceptable to use other media for the provision of information.

Potential participants should have the opportunity to consider information without any pressure from the research team and in a convenient location. For instance, many researchers opt to allow potential participants at least 24 hours to consider study related information before seeking their consent to participate, but this is only guideline. In general the complexity and risk involved in a study will dictate the length of time participants will need to consider their involvement.

In the case of simple studies involving no significant ethical issues, oral information can be adequate; it is nevertheless essential that the researcher keeps a record of having imparted the information. Formal written information must always be provided for participation in studies that pose risks extending beyond those experienced in day to day life. It should also be provided if personal or special category data are to be obtained and stored. It is also essential if the researcher intends to retain participant contact details with the intention of inviting them to particpate in other studies, retain data to be used in further research, or pass data on to others outside of the research team.

It is best practice to test a draft information sheet, ideally with a member of the intended research population. Public and participant engagement in research design is always desirable, and indeed often mandatory for projects being submitted to NHS ethics committees. The aim is to ensure readability and clarity.

**Who is the template designed for?**

The template is aimed at potential research participants who have the capacity to understand, weigh and retain the information and communicate any questions or concerns regarding it. Researchers should make judgments about the target reading age of any document. If it is to be used for the general population a reading age of 8-10 years is desirable. A higher reading age would be acceptable for any document to be read by University students and staff. It is not lawful for any person to provide proxy consent unless the participant is a minor – normally understood as being under 16 years of age. In this case a person or appropriate body (e.g. Social Services in the case of a looked after child) with parental responsibility, can provide consent. Any associated information sheet should include references to ‘your child’ or similar. If a minor, under the age of 16 years has the capacity to understand necessary information (in a medium suited to optimise that understanding) and consent to particpate in the study in question, they can consent for themselves. It is generally agreed that it would be wrong to deny a competent minor the opportunity to consent for themselves (often referred to in terms of “Gillick competence”). It is a matter of debate (simply because the matter has never been addressed through the Courts) whether parental consent, to participate in research, is required ***in addition*** to that of the minor, but it is wise to seek it. If both the consent of the minor and their parent(s) is sought then it is normal to provide separate information sheets. In the case of minors who lack sufficient capacity to consent it is good practice to provide a simplified version of an information sheet, often using illustrations and/or cartoons, to enable the young person to be sufficiently informed to register their assent – to be understood as basic agreement reflected by willingness to cooperate with study procedures.

If there are good reasons for recruiting adults (16 years of age or older) lacking capacity, the study has to be reviewed by an NHS Ethics Committee or the Social Care Ethics Committee. In this case the information sheet and consent form have to be adjusted so that they permit a declaration provided by a consultee. The consultee is required to declare that they believe that the incapacitated adult would have consented to each of the clauses within the consent form had they the capacity to do so. The information sheet should be addressed to the consultee and refer to ‘your relative / friend / patient etc.’. Research involving adults lacking capacity is legally and ethically complex – further advice should be sought at the design stage of the study.

**What must be included in a written participant information sheet?**

The following elements are essential:

* Departmental headed paper identifying the researcher(s) and, if relevant, the supervisor(s).
* Study title – which must be consistent with any other references to the title in other documents – unless the study involves deception and the ethics committee gives a favourable opinion of the use of a different title. Titles should ideally include the following elements (as appropriate):
	+ Any study intervention
	+ The study population
	+ The research outcomes
	+ The use of any comparator

For example, ‘An observational study comparing the parenting skills of mothers with autism with those of non-autistic mothers, with the aim of detecting key differences with regard to attachment’

* Document date and version number – normally in a footer. This is essential for tracking and identifying which document has been ethically reviewed.
* Reference to any associated consent form identifying its date and version number.
* An invitation paragraph. This should include an introduction to the researcher and, if relevant, the research team. If the lead researcher is a student their status should be made clear and information about the main supervisor included, in addition to that relating to the student.
* A concise summary of the study including:
	+ Why? What research question is being addressed and what is its relevance to participants, the public and the academic community?
	+ What? What is being studied and what will the participant be expected to do? How long will any involvement be? When does the study start and end?
	+ Who? Who is eligible to participate?
	+ Where? Where will the research be conducted?

Do not go into too much detail at this point but try to ensure that potential participants can get a clear but concise picture of the research you are asking them to take part in.

* Further detail about what is involved in participating in the study:
	+ The main topic of the research (in a little more detail) – what precisely is being investigated?
	+ Why the potential participant has been invited. How they have been identified. Who else will be participating?
	+ What, if any, are the main interventions or observations? What will happen to participants in the course of the study? What, if anything, will happen once the study has been completed?
	+ What information will be collected and how will it be managed. Will it be sensitive or have the potential to cause distress? Will there be any photography or audio / video recording? Will verbatim quotes be used in any publications or presentations? What provisions are to be made for confidentiality and /or anonymity? Who, other than the researcher, will have access to data? Will those data be fully anonymised, linked anonymised or identify the participant, either by name or a combination of other data? Are there any plans to retain data, tissue, DNA etc., including personal data, for further research or for the purposes of compiling a bank or registry? (Data sharing is usually a good thing but this must be explained to potential participants) Where will the data be stored – this is especially relevant if the data might be stored abroad in countries that have weaker data protection legislation.
	+ Are there any special requirments which must be met in order to participate? Are there any particular inclusion and exclusion criteria? Will there be any restrictions on participants’ life styles? Are there any particular inconveniences or restrictions entailed in participating?
	+ What, if any, are the advantages of participating? (It is perfectly acceptable to state that there are none beyond supporting the academic advancement of the researcher(s)).
	+ What, if any are the risks, burdens or disadvantages of participating? Will participation have any impact on issues such as health insurance? Could the research lead to incidental findings that might be relevant to the health or well-being of the participant?
	+ Will there be any rewards (it is acceptable to make reasonable payments to participants, reflecting the time and effort required)? Will travel and any other out of pocket expenses be reimbursed? Are there any tax implications?
	+ Are there any particular responsibilities that the participant should be aware of?
* Further, supporting information.
	+ What will happen in the event of something going wrong? Relevant insurance details should be provided.
	+ How should the participant withdraw from the study if they wish? This might include restrictions such as retention and use of any data collected up to the point of withdrawal.
	+ Who is funding the research? If there are any commercial interests they should be made clear.
	+ Who has reviewed the research? The name of the Ethics Committee should be stated.
	+ To whom should a complaint be made? The normal sequence is to the researcher or their supervisor initially, if not satisfied then the head of department, finally the University Complaints Officer.
	+ Further information and contact details
* A final paragraph thanking the potential participant for reading the document and considering participation.

**What are the principles underpinning the need to provide information when seeking consent ?**

The key ethical principle relates to respect for persons. This may be expressed in a variety of ways depending on the ethical framework adopted by differing ethicists. Sometimes it is expressed as respect for autonomy, in other contexts it is seen as a duty. The overriding requirement is that a person’s liberty should not be compromised without their explicit permission. Nothing should be done to a person, nor should their privacy be invaded without that person’s clear permission. It is recognised that any permission granted must be voluntary and based on **sufficient and necessary information** – hence the normal expectation that any consent form will be accompanied by relevant information, often in the form of a participant information sheet. In some studies deception is necessary; information, including the title of the study, might defensibly be incomplete or misleading. The ethics committee will decide whether deception is necessary to meet the scientifically determined objectives of the study and, if appropriate, agree to its use. It will always be necessary to debrief participants after they have been exposed to deception and remind them of their right to withdraw any data –effectively re-confirming consent. Whether deception is involved or not, voluntary participation must always be acknowledged by offering opportunities to withdraw, in person and / or a right to withdraw data. In many studies there will be a time limit after which it will not be possible to withdraw data – participants must be made aware of such a limit.

 When considering informed consent, researchers must consult key laws, policies, procedures, codes and declarations. It is helpful to refer to these in the application to the ethics committee. The following comprise the main sources – some are for guidance purposes, others state mandatory obligations. The majority of University policies can be accessed using:

<https://www.port.ac.uk/about-us/structure-and-governance/policies-and-standards>

* The University of Portsmouth Ethics Policy
* The University Research Data Management Policy, associated retention schedules and [practical guidance on storing and managing research data](https://library.port.ac.uk/researchdata.html).
* The UUK [Concordat to Support Research Integrity](https://www.universitiesuk.ac.uk/policy-and-analysis/reports/Documents/2019/the-concordat-to-support-research-integrity.pdf)- the University has signed up to the commitments expressed in the Concordat – researchers are required to respect these commitments
* The [UKRI Policy and Guidelines on Governance of Good Research Conduct](https://www.ukri.org/our-work/supporting-healthy-research-and-innovation-culture/research-integrity/) – this document is useful regardless of funding matters.
* The [UKRIO Code of Practice for Research](http://ukrio.org/publications/code-of-practice-for-research/) – the University has adopted this Code as its own. Any breach of the Code could invoke the University Procedure for the Investigation of Alleged Misconduct in Research
* Discipline specific guidance – most subject disciplines publish guidance on the ethical conduct of research
* As of 25th May 2018 the EU General Data Protection Regulation (GDPR) caused the UK to replace its 1998 Data Protection Act with the 2018 Data Protection Act. General guidance for University of Portsmouth staff and students can be found on: https://www.port.ac.uk/about-us/structure-and-governance/legal/data-protection

**How should completed study information sheets be stored?**

Storage must reflect compliance with the University [Research Data Management Policy](http://policies.docstore.port.ac.uk/policy-167.pdf), associated retention schedules and [practical guidance on storing and managing research data](https://library.port.ac.uk/researchdata.html).

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**PLEASE DO NOT SUBMIT THE UNEDITED TEMPLATE TO AN ETHICS COMMITTEE**

**THIS FORM MUST BE ON DEPARTMENTAL HEADED PAPER INCLUDING RELEVANT CONTACT DETAILS. ANY GUIDANCE NOTES PROVIDED IN BLUE MUST BE DELETED. THE FORM MUST HAVE A DATE AND VERSION NUMBER.**

**PARTICIPANT INFORMATION SHEET**

Title of Project: (please see guidance, above)

Name and Contact Details of Researcher(s):

Name and Contact Details of Supervisor (if relevant):

Ethics Committee Reference Number: (this may not be available at the time the form is submitted for review)

**1. Invitation**

I/ We would like to invite you to take part in my/our research study. Joining the study is entirely up to you, before you decide I/we would like you to understand why the research is being done and what it would involve for you. I/ one of our team, will go through this information sheet with you, to help you decide whether or not you would like to take part and answer any questions you may have. I/ We would suggest this should take about XX minutes. Please feel free to talk to others about the study if you wish.Do ask if anything is unclear.

I am / we are ………….. (Please add any information designed to introduce the researcher(s) in person including their status and role(s) as a researcher)

**2. Study Summary**

This study is concerned with…………………which is important because…………….. We are seeking participants who should be……………………… Participation in the research would require you to attend…………….and take approximately X hours of your time.

*Please insert a description of the type of participants you are seeking e.g. healthy males and females, aged between 18 and 39. Also give any inclusion or exclusion criteria, which may be physical characteristics (e.g. volunteers must be used to maximal exercise, or must not be cold-water habituated etc.)* or employment / experiential characteristics (*e.g.* must be students, retail shop assistants, managers, marketers, professionals etc.). Give some indication of time involved and any travel implications.

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

*Please insert here a description of the reason for the study, the techniques being used, and the practical details of the study as far as concerns the participants. It is entirely reasonable for projects to be primarily educational- so feel free to state that it is to help you gain a degree if this is a prime purpose of the study.*

**4. Why have I been invited?**

*You should explain how the potential participant was identified, including any reference to a gatekeeper. You should explain briefly why you need to recruit the reader and other similar potential participants (e.g. healthy volunteer, client of X service, professional qualified as X, customer of X service, student, person with condition X, person with abilities such as fit males, trained cyclists, women runners etc.). You should give an indication of the total number of participants. You should make it clear whether you are inviting the participant in a personal capacity or as a member of an organisation (e.g. you might be inviting a company representative for an interview with the intention of learning more about the company from his professional perspective; on the other hand you might be seeking his personal view as a person with particular expertise reflected in his status as an employee).*

**5. Do I have to take part?**

No, taking part in this research is entirely voluntary. It is up to you to decide if you want to volunteer for the study. We will describe the study in this information sheet. If you agree to take part, we will then ask you to sign the attached consent form, dated xxx, version number, xxx.

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

*To answer this question, try to put yourself in the participant’s shoes. This section should include: how long the participant will be involved in the research (e.g. an interview lasting approximately 1 hour, an experiment lasting for xxx, a series of experiments lasting 3 hours per day for 4 days, completion of questionnaires which should take approximately xxx), the total duration of the research (e.g. 1 week, 2 months etc.); what generally will happen (e.g. answering a series of questions, talking freely on a subject, viewing a video recording followed by xxx, participating as an audience member and xxx, donating a sample of xxx, or, more specifically, a two-hour stepping exercise in a hot chamber, 1 hour swimming session in cold (15 °C) water etc.) You should inform the participant if your study will involve video/audio-taping or photography. You should also make it clear whether you intend to publish information which might identify the participant e.g. verbatim comments extracted from an interview transcript or completed questionnaire; the use of verbatim comments is often optional. Specific consent will be needed if published material identifies, or has the potential to identify, the participant. You should set out simply the research methods you intend to use. Sometimes a table or flowchart is helpful.*

**7. Expenses and payments**

*Please explain whether you intend to pay participants for their time and any burdens associated with the research or whether there will be some small token of monetary or other value (e.g. research participation credits used in Psychology) or any other gifts, as a thank-you,. You should make it clear whether you intend to reimburse travel and other out of pocket expenses (if funding does not permit reimbursement you should explain that this is the case and make potential participants aware of the situation.*

**8. Anything else I will have to do?**

*Please insert here a clear explanation of any restrictions which will be placed on participants, or any instructions for them (e.g. that they should not drink alcohol within the 24 hours prior to each experiment, and should be free of the after-effects of alcohol exposure at the time of testing or that they will not be able to drive or operate heavy machinery for the 24 hours following each experiment, they should bring sports kit to the laboratory etc.).*

**9. What data will be collected and / or measurements taken?**

*Explain here what data will be collected and / or what measurements will be taken. If any specialised equipment is to be used it should be described – particularly if it is attached to, worn by, or inserted in participants. This can include photographs of equipment / sensors on their own, or whilst attached to, or being used by participants where appropriate. Any safety implications should be identified and steps taken to mitigate risks explained. Details of any personal or sensitive data to be collected should also be provided here; participants should be made aware of any data collection that might be emotionally distressing or intrusive.*

*If any study procedures are likely to reveal incidental findings which might have significance for the health or wellbeing of the participant, the situation must be explained. It is often the case that research procedures are of little diagnostic value but, if they are then interventions such as informing the participant’s GP should be explained.*

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

*Here you should include details of any possible disadvantages or risks of participation (e.g. you may be tired following the experiment, emotional distress, accidental disclosure of personal or sensitive data, mild pain or discomfort, etc.). You should also explain how the risks are minimised (e.g. safety procedures, risk assessments, medical screening and any first-aid / medical provision). In the case of potential to cause distress it is helpful to identify statutory and voluntary agencies which might be accessed for help.*

*If the study requires an Independent medical officer (IMO) (likely to be Department of Sports and Exercise Science only), please insert the following statement, otherwise delete:* An independent medical officer / paramedic [*delete as appropriate*] will be [*insert here the availability during the trial, e.g. `in attendance throughout’, `on call from within the building’, or ‘available by telephone for consultation’.*] Their sole function is to act independently of the study team to ensure your safety and well-being. You may consult with them if you wish.

*If the study does not require a medical officer or paramedic but nevertheless involves risks to health and safety, please describe the level of first-aid cover provided during the study (e.g. first-aider in attendance or in the building. If the experiment does not require first-aid cover, there is no need to describe this in the participant information sheet.*

**11. What are the possible advantages or benefits of taking part?**

*Direct benefits can be as simple as a training session (for exercise studies), or payment for participation. However often there is no direct benefit to the participant but you might want to suggest outcomes such as an improved service or better understanding of something. You must not exaggerate the possible benefits. If there are no direct benefits to the participant then please state as much e.g. ‘You will not receive any direct personal benefits from participating but society (or a sub-group of society) may benefit from the results of this work by……’*

**12. Will my data be kept confidential?**

*Confidentiality is not always necessary or desirable – e.g. the research topic might be concerned with recovering ‘lost voices’, in which case it would be unethical to treat data in confidence. In some cases participants wish to be identified and acknowledged. Please make sure that, whatever arrangements are explained and offered here, consent is sought, as appropriate, and recorded in the consent form.*

*Anonymisation might be offered as a strategy to ensure confidentiality. Again, anonymity is not ethically required for all participants, in all studies; if it is to be provided, further explanation will be required and should be summarised here. Will data be fully anonymised or linked anonymised? Will anonymity ensure that the participant cannot be identified – sometimes it is possible to identify a participant using a combination of available data. Clear explanation of any anonymisation strategies should be given here and any risks of the participant being identified must be clearly stated.*

*Any limitations regarding confidentiality must be clearly stated. Limits might relate to the safeguarding of the participant or others. They might also relate to matters such as the action a researcher might make in the event of the participant disclosing an unprosecuted criminal offence or, in the case of a professional practitioner, misconduct.*

*Normally the following phrase is included:*

The raw data, which identifies you, will be kept securely by the researcher and / or their supervisor. (*Secure storage arrangements should be explained e.g. ‘on a password protected research folder on the university system’)*

*You should tell the participant how their confidentiality will be safeguarded during and after the study. You must tell the participants how your procedures for handling, processing, storage and destruction of their data will be managed. The participant must be told:*

*- what data will be collected (ideally in bullet points)*

*- how their data will be collected (e.g. paper records, electronic data acquisition systems, video or audio recording, photography etc.);*

 *- that it will be stored securely, and detailing who will have access to the data;*

*- what it will be used for in the study and, if relevant, after the study e.g. shared with other researchers, used for further research, retained for the purposes of constructing a data base or registry etc.*

*- whether the data will be stored abroad*

*Similar considerations apply to any collection of tissue or DNA*

Typical statements include:

“The data, when made anonymous, may be presented to others at academic conferences, or published as a project report, academic dissertation or in academic journals or book. It could also be made available to any commissioner or funder of the research.”

“Anonymous data**, which does not identify you**, will be publicly shared at the end of the project and made open access. A CC-BY licence will be applied to this publicly shared data. This will allow anyone else (including researchers, businesses, governments, charities, and the general public) to use the anonymised data for any purpose that they wish, providing they credit the University and research team as the original creators. No restrictions will be placed on this shared anonymised data limiting its reuse to only non-commercial ventures.”

“The raw data, which would identify you, will not be passed to anyone outside the study team without your express written permission. The exception to this will be any regulatory authority which has the legal right to access the data for the purposes of conducting an audit or enquiry, in exceptional cases. These agencies treat your personal data in confidence.”

“The raw data will be retained for a minimum of 10 years. When it is no longer required, the data will be disposed of securely (*e.g.* electronic media and paper records / images) destroyed.” *Note the policy for retention of research data requires retention for between 10 to 30 years and can be accessed from section 7, (and subsections) at the following link:*

*https://www.port.ac.uk/about-us/structure-and-governance/legal/retention-schedules*

*While the University policy requires a minimum of 10 years retention period, if your research is externally funded then your funder may have a longer retention period which takes precedence.*

*Note that in some cases sensitive raw data may be destroyed soon after collection when the data for analysis have been extracted e.g. video images or sound recordings. Make this clear to the participants if this is the case, and what data will be retained.*

*When writing this section, you should consult the following sections of the Research Data Management web page:*

[*Storing personal research data*](https://library.port.ac.uk/researchdata.html#Managing_personal_data)

[*Storing data while your project is taking place*](https://library.port.ac.uk/researchdata.html#Data_storage_and_security_WHILE_my_research_project_is_taking_place)

[*Managing (including sharing) research data after your project has finished*](https://library.port.ac.uk/researchdata.html#Openly_sharing_and_preservation_of_research_data_AFTER_my_research_project_has_finished)

[*Licencing*](https://library.port.ac.uk/researchdata.html#Intellectual_Property_Rights_Copyright_and_Licensing)

GDPR compliance

In 2018 the EU’s General Data Protection Regulations came into force along with the UK’s Data Protection Act 2018. THESE DO NOT APPLY TO ANONYMOUS DATA. If you are intending to collect identifiable personal or special category data you must first consider the legal basis you will use for handling this. Normally this legal basis will be consent, although it should be noted that organisations such as the Health Research Authority recommend alternatives in some cases. There is more advice available on wording for alternative legal bases on <https://www.port.ac.uk/research/research-culture/research-ethics> If you intend to use consent as your legal basis the following text must be added (although please proof-read your document to make sure you are not duplicating statements):

The [enter name of department /school /project team etc] of the University of Portsmouth wishes to process your personal data (that is, collect, use, store and destroy data that identifies you) as part of the [enter name of the project / survey / reason for requiring the data]. If you have any queries about this [project / survey / other reason for processing] please contact [enter contact details of someone in the dept / school or project team etc] or if you have any general queries about how your data will be processed, please contact the University’s Data Protection Officer, Samantha Hill, using any of the following contact details:

Samantha Hill, 023 9284 3642 or information-matters@port.ac.uk
University House, Winston Churchill Avenue, Portsmouth, Hampshire, PO1 2UP, UK

We ask for your consent to process the data we ask for in the [project / survey / other reason for processing], so that we can conduct the research as described in the participant information sheet. We will only share your personalised data with [enter here anyone with whom we might share the data outside of the University if relevant].

Your personal data will be held securely on [University servers / held on paper in cabinets] (we [will/will not] store your data outside the EU) for [how long do we keep the data in a way that can identify anyone?], and securely destroyed after that date. [If we might keep the information anonymously after this date it is best to explain that here and why we might do this].

Although you have the right to request a copy of the personal data we hold about you, to restrict the use of your personal data, to be forgotten, to data portability, and to withdraw your consent for the use of your data, it is possible that we may not be able to fully comply with those rights where your data has been used for the research and / or has been anonymised. For more information on your rights in general, please see the information on the following links:

https://www.port.ac.uk/about-us/structure-and-governance/legal/data-protection-and-gdpr/requesting-your-data

You also have the right to lodge a complaint about the use of your personal data to initially the University (email information-matters@port.ac.uk) and then, if you are unhappy with our response, to the Information Commissioner’s Office (ICO) – for more information please see <https://ico.org.uk/your-data-matters/raising-concerns/> .

**13. What will happen if I don’t want to carry on with the study?**

As a volunteer you can stop any participation (add detail here – test / experiment / interview etc.) at any time, or withdraw from the study at any time before (specify date), without giving a reason if you do not wish to. If you do withdraw from a study after some data have been collected you will be asked if you are content for the data collected thus far to be retained and included in the study. If you prefer, the data collected can be destroyed and not included in the study. Once the research has been completed, and the data analysed, it will not be possible for you to withdraw your data from the study.

**14. What if there is a problem?**

If you have a query, concern or complaint about any aspect of this study, in the first instance you should contact the researcher(s) if appropriate. If the researcher is a student, there will also be an academic member of staff listed as the supervisor whom you can contact. If there is a complaint and there is a supervisor listed, please contact the Supervisor with details of the complaint. The contact details for both the researcher and any supervisor are detailed on page 1.

If your concern or complaint is not resolved by the researcher or their supervisor, you should contact the Head of Department:

The Head of Department xxx xxx

Department / School of….. 023 9284 xxxx

University of Portsmouth xxxx.xxxx@port.ac.uk

xxxx

xxxxx

Portsmouth

PO1 XXX

If the complaint remains unresolved, please contact:

 The University Complaints Officer

023 9284 3642 complaintsadvice@port.ac.uk

(If the data collection is being undertaken outside of the UK, phone numbers should specify UK access codes and addresses should include the fact that Portsmouth is in the UK.)

**15. Who is funding the research?**

This research is being funded by [*give details of the funding agency e.g. The University of Portsmouth, The Ministry of Defence, Company Name etc. or joint funding details.*] None of the researchers or study staff will receive any financial reward by conducting this study, other than their normal salary / bursary as an employee / student of the University (or alternative if this is not the case *i.e.* paid consultancy work).

**16. Who has reviewed the study?**

Research involving human participants is reviewed by an ethics committee to ensure that the dignity and well-being of participants is respected. This study has been reviewed by the xxxxx Faculty Ethics Committee and been given favourable ethical opinion.

**Thank you**

 Thank you for taking time to read this information sheet and for considering volunteering for this research.