Privacy & Us

Ethics

Deliverable Number	**D1.6**
Work Package	1
Version	1.0
Deliverable Lead Organisation	KAU
Dissemination Level	Public
Contractual Date of Delivery (release)	2016-06-01
Date of Delivery	2016-05-31
Status	**Final**

Editor

Eva Glavenius (KAU)

Contributors

Simone Fischer-Hübner (KAU)

Reviewers

Harald Zwingelberg (ULD)

This project has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No 675730.

European Commission

Revision table

Version	Date	Author	Change Description
0.1	2016-05-18	Eva Glavenius	Document created
0.2	2016-05-24	Eva Glavenius	Rearranged, added content
0.3	2016-05-26	Eva Glavenius	Added appendix, additions from Simone
04	2016-05-27	Harald Zwingelberg	Review
0.5	2016-05-31	Simone Fischer-Hübner	Review comments addressed

Executive Summary

In this deliverable, D1.6, we address the ethical evaluation process for activities within the Privacy&Us project that may collect and process personal data. The ethical evaluation process differs partially between beneficiaries that already have Ethics Review Boards in their respective organisation, and beneficiaries that do not have Ethics Review Boards in place. This deliverable provides information about the overall ethics evaluation process, as well as information and templates specifically targeted to those beneficiaries that yet do not have an internal process for ethical evaluation in place.

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1 Introduction

In this deliverable, D1.6, we address the ethical evaluation process for activities that may collect or process personal data, such as interviews, surveys and other forms of usability studies, or may raise other kinds of ethical concerns. The ethical evaluation process differs partially between partners that already have Ethics Review Boards in their respective organisation, and partners that do not have Ethics Review Boards in place.
This deliverable D1.6 provides information about the ethics evaluation process, and specifically provides information and templates targeted to those project partners that yet do not have an internal process for ethical evaluation in place.

The ethics review procedure from the expert evaluators set eight ethics requirements to be addressed by the PRIVACY&US project. These eight requirements were already addressed in the Privacy & Us deliverables D8.1 – D8.8, and are therefore not specifically addressed here. We kindly ask to refer to Appendix 1 for a description of the eight ethics requirements set by the expert evaluators. Two of these eight ethics requirements address the ethical evaluation process for activities that may collect personal data (D8.6 and D8.7). Hence, this deliverable, D1.6, can be seen as a complement to D8.6 and D8.7.

2 Abbreviations and acronyms

KAU	KARLSTAD UNIVERSITY
TAU	TEL AVIV UNIVERSITY
UCL	UNIVERSITY COLLEGE LONDON
WU	WIRTSCHAFTSUNIVERSITAT WIEN
GUF	GOETHE UNIVERSITAET FRANKFURT AM MAIN
FAU	FRIEDRICH-ALEXANDER-UNIVERSITY ERLANGEN
UBO	UNIVERSITY OF BONN
UoS	UNIVERSITY OF SALZBURG
REA	RESEARCH EXECUTIVE AGENCY

3 Ethical evaluation process

In this section, we refer to the Ethical evaluation forms that need to be filled in by Privacy & Us researchers before any user studies are conducted that involve or may involve the collection of personal data or may raise other kinds of ethical issues. The process differs dependent on whether partners that have already an Ethics Review Board in place or not.

3.1 Partners with Ethical Review Boards

All plans for usability tests and interviews, and surveys, workshops that may collect personal data or potentially raises any other kind of ethical issues, to be performed at KAU, UCL, and TAU, will be sent for a prior ethical evaluation to the Ethics Review Board at the respective partner organization. In the case of VDS, it will be sent to the Ethics Review Board at UCL, where ESR13 will be enrolled.
The respective Ethical Evaluation Forms to be used by KAU and TAU as well as a sample form by UCL are listed in the Appendices 2-4.

3.2 Partners without Ethical Review Boards

All German and Austrian partner institutions, at which ESRs will be enrolled or at which they will work (i.e., WU, GUF, FAU, UBO, UoS, ULD), do not have Ethics Review Boards in place for non-Medicine departments. These partners will, instead, inform the project officer about their plans for conducting usability tests, interviews, surveys and stakeholder workshops prior to the start of the respective research activity.

Below, we suggest an Ethical Evaluation Form, which the German and Austrian partners may use to inform the project officer about Privacy & Us research activities that may involve the processing of personal data or may raise ethical concerns.

The information to be provided in this Ethical Evaluation Form corresponds to the main information to be filled in ethical evaluation forms By TAU, KAU and UCL (listed in the Appendices 2-4). Besides, we also used the Application form by the Central University Research Ethics Committee (CUREC) by Oxford University[1] as a reference for designing the Privacy & Us form.

[1]See: CUREC 1A check list, https://www.admin.ox.ac.uk/curec/apply/ssh-idrec-process/#d.en.162962

Privacy & Us Ethical Evaluation Form

Contact details:

Principal researcher (supervisor):

PhD student:

Partner organisation:

Address:

Phone number:

Email:

Project description:

Title of the research project:

List of locations where the project will be conducted:

Duration - from (dd/mm/yy) to (dd/mm/yy):

Brief and simple lay description of research, incl. purpose of the study, methodology, how professional guidelines/laws are applied, the use of the results/data:

Test participants:

Describe the nature of research participants and the population from which they will be selected:

Does any of the participants not classify as an adult, healthy volunteer?

Describe the method of recruitment of participants, and criteria for inclusion, and processes for consent to participate (how, where and when consent will be obtained):

Will participants be rewarded for participation, and if so, how?:

Type of data collection:

Describe the type and nature of data that will be collected:

Will your research involve discussing sensitive issues (e.g., related to health, race or ethnic origin, religious beliefs, physical/mental health, trade union membership, sexual life or criminal activities)?:

Risks and Benefits:

Describe any expected risks to the participants (including physical, psychological social, economic or other causes of discomfort) that can be caused by participating in this research. Describe in particular whether the research involves deception of the participants:

Severity of the risks:

Steps taken to minimize the risks or the possible discomfort:

Describe the possible benefits from conducting the research for the participants themselves, the participant population and society:

Explain how the possible benefits exceed the possible risks from the experiments and one can justify the risks:

Data Protection:

Will you ensure that personal data collected directly from participants or via a third party are held and processed in accordance with provisions of European and national data protection legislation?

How will you ensure that any personal or sensitive data are collected, transferred and stored securely? How will information about participants' identity be kept or to what extend will it be anonymized or pseudonymised?
Date: Name: Signature:

While the German and Austrian partners will submit this Ethical Evaluation form for informing the project officer about planned research activities, some of these partners also plan to start in parallel procedures in their institutions to set up their own Ethics Review Boards, which could then in future take over this task of ethical evaluation.

3.3 Submission of process description

All partners will, in addition, notify their data protection official if one exists in their organisations, or otherwise the official data protection agency in charge, for each study if personal data will be collected. Copies of the approval/notification of the process descriptions will be submitted to the project officer (REA).

Pursuant to Art. 19 EU Data Protection Directive 95/46/EC, the content of this notification should at least include:

(a) the name and address of the data controller;
(b) the purposes of the processing;
(c) a description of the categories of data subjects and of data relating to them;
(d) the recipients or categories of recipient to whom the data might be disclosed;
(e) proposed transfers of data to third countries (outside the EU);
(f) a general description allowing a preliminary assessment to be made of the appropriateness of the security measures taken pursuant to Article 17 of the Directive.

In general, we do not plan to process any special categories of personal data. However, if we plan any user studies, for which the possibility of collecting sensitive data cannot be absolutely excluded (e.g., if we plan to interview patients, who could possibly without being asked voluntarily reveal some medical information about themselves in those interviews), we would undergo the process of prior checking (i.e., we would conduct a Privacy Impact Assessment) pursuant in Art. 20 of the EU Directive 95/46/EC.

4 Final Remarks

The Privacy & Us project follows the overall objective to train its innovative early stage researchers (ESRs) to be able to reason, design and develop novel solutions to questions related to the protection of citizens' privacy for facing current and future challenges in the area of privacy and usability.
For achieving this, the project partners agree that it will be of high importance that the ESRs will also learn how to follow privacy and ethical guidelines and rules for protecting personal data and the privacy of research test participants.

The Privacy & Us project comprises leading privacy and security researchers and practitioners, including the data protection agency of the German federal state of Schleswig-Holstein (ULD), and thus does not only have a high competence for respecting and protecting Ethics, Privacy and Data Protection by organisational and technical means but also high awareness of the importance of these values. The project partners will therefore take ethical and data protection rules very serious.

Appendix 1 Ethics requirements from the expert evaluators

The ethics review procedure from the expert evaluators set eight ethics requirements to be addressed by the PRIVACY&US project. These eight requirements have been addressed in the Privacy&Us deliverables D8.1 – D8.8.

Description of the eight ethics requirements as stated in Annex1 Section 1.4 of the Grant Agreement:

Req No	Ethics Issue Category	Ethics Requirement Description	Deliverable number
1	NON-EU COUNTRIES (NEC)	- The applicant must provide details on the material which will be imported to/exported from EU and provide the adequate authorizations if applicable.	D8.3
2	NON-EU COUNTRIES (NEC)	- The applicant must confirm that the ethical standards and guidelines of Horizon2020 will be rigorously applied, regardless of the country in which the research is carried out.	D8.1
3	PROTECTION OF PERSONAL DATA (POPD)	- Detailed information must be provided on the informed consent procedures that will be implemented. Copy of the Informed Consent Forms and Information Sheets templates must be submitted to the REA.	D8.2
4	PROTECTION OF PERSONAL DATA (POPD)	- It is not clear if project involves the collection or processing of sensitive personal data (e.g. ethnicity, political opinion, religious, philosophical conviction or any other) and therefore it has to explicitly stated if not. If yes, it must be justified.	D8.8
5	PROTECTION OF PERSONAL DATA (POPD)	- Copies of approvals/notifications for the collection of personal data by the competent Data Protection Officer / National (or Regional as applicable) Data Protection authority must be submitted to the REA.	D8.7
6	HUMANS (H)	- The applicants must submit ethical approvals obtained for usability test cases and workshops. If, due to national/regional regulations, no ethics approval procedure is available the consortium must inform the REA accordingly prior to the start of the respective research activities.	D8.6
7	HUMANS (H)	- Detailed information must be provided on the informed consent procedures that will be implemented, including copies of templates to be used as information sheets and informed consent. This information must be submitted to the REA prior to the start of any respective research.	D8.5
8	HUMANS (H)	- A summary should be provided on procedures that will be used for the recruitment of participants (including the number of participants) and the type of data/information that will be collected. All this information must be included in the appropriate Working Packages where (a) interviews, (b) surveys and (c) observations of test participants have to be explained.	D8.4

Appendix 2 KAU Ethical Evaluation Form

APPLICATION FOR ETHICAL VETTING

For information concerning the application: *see Appendix and Guidance, (www.epn.se)*

To the Regional Ethical Review Board in:

State the Regional Ethical Review Board to which the entity principally responsible for the research belongs. For a list of boards see *(www.epn.se)*

Date fee paid:

Please note that an application is never complete (and thus able to be processed) until the form is correctly filled in and the fee has been paid.

Project title:

Give a descriptive title in Swedish for laymen, without using confidential information. Where suitable, also state the identity of the project and the number, date, version etc of the project/research plan (protocol or testing plan).

Information to be completed by the Regional Ethical Review Board

Application complete:	Case number:
Request for additional information concerning the application:	Requested
information received: Date of decision:	Date processed:

The application concerns (also applies when an advisory statement is requested):

research in which only one responsible research body participates (5 000 kr)

research in which more than one responsible research body participates (16 000 kr) research in which more than one responsible research body participates,

but in which all the researchers or subjects of research have an immediate link to only one of the responsible research bodies (5 000 kr)

merely processing personal data (5 000 kr)

research involving clinical trials of medicinal products (16 000 kr)

changes to a previously approved application in accordance with section 4 of Statute (2003:615) concerning the Ethical Review of Research Involving Humans (2 000 kr)

If the board decides that the legislation concerning ethical review is not applicable to the study/research project,

is an advisory statement wanted?

Yes: No:

1. Information concerning the entity principally responsible for the research etc.

1:1 The entity principally responsible for the research

The application for ethical vetting of research is to be made by the entity principally responsible for the research. By entity principally responsible for the research is meant a government authority or a physical or legal entity under whose auspices the research is conducted. Research within the state is primarily conducted at the seats of learning, but also at certain other authorities, such as the National Council for Crime Prevention and the National Board of Health and Welfare. Municipalities and county councils can also be those principally responsible for the research, as can legal entitles according to civil private law

Name:

Address:

1:2 Qualified representative for the entity principally responsible for the research

This is a qualified representative of the entity principally responsible for the research (e.g. head of department, head of unit, head of operations). The entities principally responsible for the research are themselves to decide upon by internal consultation, delegation, or by means of power of attorney, the responsible research body which is qualified to act as a representative. A copy of the document in question must be submitted.

Name: Professional title:

Address:

1:3 Researchers who are primarily responsible for the completion of the project (principal contact)

Name: Professional title:

Address: E-mail:

Telephone: Mobile phone:

1:4 Location

The location/s where the project is to be completed (list facility/ies, institution/s, clinic/s etc)

1:5 Other participants

Other persons principally responsible for the research, plus researchers responsible for completing the project locally (principal contacts) are to be listed here or in an annex stating names and addresses (see p. 9, annex 1).

1:6 Applications/notifications to other authorities

Clinical testing of medicinal products

For an application for a permit from the Swedish Medical Products Agency: www.mpa.se

Application submitted (date) Permit granted

EudraCT number:

Cases concerning some kinds of genetic research

If personal data concerning genetic dispositions that have been revealed as a result of a genetic examination is to be dealt with in the study, this must be notified to the Swedish Data Inspection Board in accordance with section 10 of the Personal Data Ordinance (1998:1191). See the Data Inspection Board's home page: www.datainspektionen.se

Notification submitted (date) Will be submitted once approval is granted after ethical vetting

Certain research involving the irradiation of research subjects

The application, in accordance with sections 16 and 22 of the regulations of the Swedish Radiation Safety Authority (SSMFS 2008:35) concerning general obligations with respect to medical and odontological activities involving ionizing radiation, is to be submitted to the Radiation Protection Committee. For more information, contact the relevant local radiation protection committee.

Application submitted (date): Application confirmed

2. Information concerning the project

2:1 Summary of the research project (programme)

The description must be comprehensible to all board members. It is therefore advisable to avoid specialist terminology. State the background and the purpose of the study, together with the scientific question(s) for which answers are being sought. State the most important variables affecting the investigation. State what advances in knowledge can be expected as a result of the project and what the significance of these might be. State if it is a study of records, if the research is an assignment, etc. Detailed information in the research plan, protocol or programme that is intended for specialists must be appended as an annex (see p. 9, annex 2). A more detailed description *that is intended for laymen* concerning the implementation of the study can, if needed, be appended to the obligatory research plan intended for experts.

2:2 What is/are the primary scientific question(s) forming the basis of the design of the project?

If the project can be described as testing a hypothesis, state the primary hypothesis and the secondary hypothesis if there is one. Referral can be made to more detailed information for experts in the form of an appended research plan in accordance with 2:1

2:3 State the results from relevant animal experiments

If animal experiments have not been carried out, the reasons for this must be given.

2:4 Give an overview of the examination procedures used, data collection and the nature of the data.

It should be clear from the description, how it is planned to complete the project. Describe the nature of data that has been collected. Describe how the reliability of the data is ensured (e.g. quality control/monitoring). When questionnaires and interviews are used, the procedure used should be described and, for example, the content of questions and how conclusions are drawn. Questionnaires and rating scales must be appended (see p. 9 annex 5). For medical research should be stated, for example, the types of intervention, the methods of measurement, the number of visits, the time required each time research is carried out and the means used to administer any pharmaceutical preparation and/or isotopes and the amount of blood samples taken (including the accumulated amount when multiple testing takes place). State also if the examination procedure etc differs from routine clinical measures and if so, in what way. State which procedure can be required to administer the prospective treatment after the conclusion of the study. State the procedures used to collect biological material. Account for data sources and procedures when processing personal date. For more detailed information referral can be made to the appended research plan.

2:5 Describe how biological material that has been collected is to be stored in a biobank

By a biobank is meant is meant biological material that has been collected and retained from one or more persons, the origins of which can be traced to the person or persons from which it had originated and is being kept pending further notice or for a certain period of time.
Describe how each sample that is to be retained is to be kept, the coding procedures and what conditions apply when material is released. State who is the person responsible for the biobank. Note that in appropriate cases the biobank is to be notified to the National Swedish Board of Health and Welfare in accordance with the Biobanks in Medical Care Act (2002:297)

2:6 Account for the access to the resources needed during the implementation of the project

State which person or persons are responsible (head of department, head of operations or the equivalent) for the safety of those participating in the research at all the units/clinics where the persons are participating. Affidavits from those responsible *must* be appended (see p. 9 annex 9). It must be clear from the affidavit that all the necessary financial, structural and human resources are available to guarantee the safety of those participating in the research .

2:7 Record-keeping, registering and processing of data

State how the examination procedures and any operations that take place are to be recorded. Account for how the registration and processing of the results will take place. If the material is to be coded, state the procedure: who will be keeping the code list in safe custody and which person or persons have access to them; where they are being kept and for how long and also if the material will be rendered anonymous or destroyed. State if audio and video recordings are to be used. Describe how accessible the data material is, how it is kept and how the requisite confidentiality is attained.

2:8 Describe previous experience (your own and/or others) of the procedure, technique or treatment used.

It is particularly important that the risks of complications are clearly accounted for and that the relevant publications are listed. When patients are to be given a new form of treatment, such as a pharmaceutical product, it should be stated how many patients (with the complaint in question or another one), had previously been given the proposed treatment, dosage of a pharmaceutical product (or a different dosage) and over what period of time the treatment has been studied.

3. Information about the participants in the research

3:1 How are participants in the research chosen?

By participant in the research is meant a living person who is the subject of the research. State the selection criteria (inclusion and exclusion). Give an account of the manner in which the researcher will get in contact with/become aware of suitable participants for the research. State if recruitment will take place from your own studies, the previous studies of others or ongoing studies. If advertising is to take place, the advertising material ***must*** be submitted as an annex (see p. 9 annex 3). If, for example, children or people who, temporarily or permanently, are not capable of themselves giving their informed consent are to participate in the project, this is to be specifically justified. If certain groups (women, children or the elderly, for example) are to be excluded from the project, this is to be specifically justified.

3:2 State the relationship between the researchers/the leader of the research and those people participating in the research

Person administering the treatment (e.g. doctor, psychologist, physiotherapist) - person participating in the research (e.g. patient, client)

Course facilitator (teacher) - student

Employer - employee

Any other relationship that could possibly entail a risk of influence. Describe:

3:3 State the statistical foundation with respect to the size of the population(s) and/or material(s) studied

Give an account of the statistical power, the so-called power-calculation, or give an account of equivalent considerations which clarify the study's ability to answer the questions posed.

3:4 State if participants in the research may be included in several studies, either simultaneously or in another study or other studies closely linked to this one. If so, what kind of research?

3:5 What insurance cover is there for research participants taking part in the project?

It is the responsibility of the entity principally responsible for the research to check that existing insurance policies cover any injuries that may arise.

3:6 What financial remuneration or other benefits are participants in the research entitled to and when is this to be paid? (A more detailed description can be submitted as an annex)

Compensation for discomfort and inconvenience. Sum (before tax):		
Compensation for income from employment	Yes	No
Allowance for travelling expenses	Yes	No
Exemption from costs of pharmaceutical products	Yes	No
Exemption from other costs Which?		
Other benefits Which?		
When is compensation paid?		
Mo compensation to be paid		

4. Information and consent

4:1 The procedure involved and the content of the information that is given when subjects are asked to participate in the research

Describe how and when the information is given and what it contains. Indicate who provides the information. Brief and easily comprehensible written information should normally be given. This written information must be attached to the application (see p. 9 annex 4). If no information or incomplete information is given, detailed reasons for this must be given.

4:2 How is consent to be obtained and from whom?

Describe the procedure, who asks, when this takes place and how the consent is documented. Exhaustive documentation is particularly important, not only when children or people with a diminished ability to make decisions participate in the study of a group or groups such as associations, organisations, companies, church communions, congregations, or school classes.

5. Considerations in the light of research ethics

5:1 Describe the risks that participation might entail and possible complications

This could mean, for example, physical injury, pain, discomfort or other violations of personal integrity that the project entails or can entail. State not only which measures been taken to prevent the risks mentioned above, but also what preparations have been made to deal with these complications. Give an account of the methods that will be used to investigate, register and report undesirable events.

5:2 Describe the predictable benefit for the people participating in the research who are part of the project

5:3 Carry out your own evaluation of the relationship between risk and benefit for participating research subjects

5:4 In a broader perspective, identify and specify which ethical problems, such as risk versus benefit, can arise as a part of or as a result of the project

Here, for example, an account can be given of which groups can be identified or given help as a result of the study.

6 .Presenting the results

6:1 How are both the entity principally responsible for the research and research collaborators guaranteed access to data (to be stated when the research is an assignment) and who is responsible for processing data and writing reports?

6:2 How will the results be made publicly available? Will the study be sent for publishing in a journal or published in some other manner?

State the format in which it is planned to make the results public and indicate the time frame that is applicable.

6:3 In what manner will the right to integrity of those participating in the research be guaranteed when the material is made public or is published?

Will only results at a statistical group level be shown? Describe the procedures or the methods used for concealing identities or ensuring anonymity.

7. Reporting the financial circumstances and dependencies

The purpose of the accounts to be given in points 7:1 - 7:3 is to clarify all direct or indirect circumstances that could possibly affect the researcher's relationship to the persons participating in the research (during the process of information, consent or implementation, for example).

7:1 When the research is an assignment

State who the principal is: for example a company (when there is clinical testing of pharmaceuticals or the testing of other new products, for example) an organisation or an authority.

Name:	Principal contact:
Address:	Telephone/mobile phone:

State the relationship between the entity principally responsible for the research/participating researchers and the principal assigning the research (employee/employer for example).

7:2 Give an account of any financial agreements with a principal or any other financiers (Name, amount)

Where the clinical testing of pharmaceuticals is concerned, reference should be made to agreements entered into with the principal responsible for health care. Similar agreements may occur when other research is commissioned and is to be accounted for in the same way. Separate agreements with the person or persons who are to complete the study are also to be presented. State the amount that is allocated for the study/compensation to the clinic/person completing the research and what the compensation is to cover. Any sums given to persons participating in the research should also be accounted for here (see p. 9, annex 12).

7:3 Give an account of the interests of the entity principally responsible for the research, the principal researcher and of participating researchers

An account is to be given here of, for example, ownership of shares, employment status, consultancy work for companies providing finance and any companies owned by researchers that could benefit financially, directly or indirectly, as a result of the research (see p. 9, annex 12).

8. Signatories

Authorized representative for the entity principally responsible for the research who is the applicant in accordance with p. 1:2.

Place: Date:

Signature: _____

Clarification of signature:

Official title:

The undersigned researcher who is carrying out the project (principal contact) in accordance with p.1:3 hereby certifies that the research will be carried out in accordance with the application.

Place: Date:

Signature: _____

Clarification of signature: Official title:

9. List of annexes

Documents which, in appropriate cases, are to be appended if corresponding information is not on the form, are marked with an x. Mark those annexes that are to be submitted with this application.

Send with application	Annex nr	Description	Clinical testing of pharmaceuticals	Other research
	1	The participating entity principally responsible for the research and collaborating researchers (principal contacts) for research involving the participation of more than one entity principally responsible for the research. For information see p. 1:5	x	x
	2	Research plan intended for specialists. Also an annex intended for laymen, if needed. For information see p. 2:1 and Guidance to the research plan/protocol (programme).	x	x
	3	Advertising material for the recruitment of research participants For information see p. 3:1 and Guidance to the application p. 3:1.	x	x
	4	Written information for those who have been asked. For information see p. 4:1 and Information for research participants.	x	x
	5	Questionnaire. For information see p. 2:4	x	x

	6	Standard EU form (as of 1 May 2004). Also applicable when changes are made	x	
	7	Summary of the protocol in Swedish	x	
	8	User's handbook or product insert/product summary/IB	x	
	9	Testimonial from operations manager or equivalent concerning resources and the safety of those participating in the research. For information see p. 2:6.	x	x
	10	CV of researcher (same as p. 1:3) with primary responsibility for completion (give an account of the competence of the researcher(s) that is of relevance to the study. Information in Guidance to the application p. 1:3.	x	x
	11	Description of remuneration given to research participants. For information see p 3:6 and Guidance to the application p. 3:6	x	x
	12	Agreements with principals/financiers concerning, for example, terms of employment, grants/compensation awarded to the place where the research is conducted, to the principal responsible for health care, to the entity principally responsible for the research or to the researcher. For information see p. 7:2 and 7:3	x	x

Other annexes appended to the application:

Appendix 3 TAU Ethical Evaluation Form

Tel Aviv University
Request for approval by the Ethics Committee for Research with Human Participants

Date:
Researcher:
Phone number: **Email:**

Topic:

Purpose of the study:

Research funding source:

Description of research participants and the population from which they will be selected:

Recruiting of participants, and criteria for inclusion:

Data collection protocol:

Description of expected risks to the participants (including physical, psychological social, economic or other causes of discomfort) that can be caused by participating in this research:

Severity of the risks:

Steps taken to minimize the risks or the possible discomfort:

Description of the possible benefits from conducting the research for the participants themselves, the participant population and society:

Explanation how the possible benefits exceed the possible risks from the experiments and one can justify the risks:

Which steps will be taken to assure the confidentiality of the research participants and to protect the information and data that will be collected?

How will access to the data be protected?

How will information about participants' identity be kept?

Will participants be rewarded for participation, and if so, how and when will the reward be given?

Consent to participating in the research

Who is responsible for obtaining the participants' consent, and how, where and when will consent be obtained?

Signature of the responsible researcher

Appendix 4 UCL sample Ethical Evaluation Form

IMPORTANT: ALL FIELDS MUST BE COMPLETED. THE FORM SHOULD BE COMPLETED IN PLAIN ENGLISH UNDERSTANDABLE TO LAY COMMITTEE MEMBERS.
SEE NOTES IN STATUS BAR FOR ADVICE ON COMPLETING EACH FIELD. YOU SHOULD READ THE ETHICS APPLICATION GUIDELINES AND HAVE THEM AVAILABLE AS YOU COMPLETE THIS FORM.

SECTION A APPLICATION DETAILS

A1 Project Title:

Date of Submission:	Proposed Start Date:
UCL Ethics Project ID Number:	Proposed End Date:

If this is an application for classroom research as distinct from independent study courses, please provide the following additional details:

Course Title:	Course Number:

A2 Principal Researcher
Please note that a student – undergraduate, postgraduate or research postgraduate cannot be the Principal Researcher for Ethics purposes.

Full Name:	Position Held:
Address:	Email:
	Telephone:
	Fax:

Declaration To be Signed by the Principal Researcher

- I have met with and advised the student on the ethical aspects of this project design *(applicable only if the Principal Researcher is not also the Applicant).*
- I understand that it is a UCL requirement for both students & staff researchers to undergo Disclosure and Barring Service (DBS) Checks when working in controlled or regulated activity with children, young people or vulnerable adults. The required DBS Check Disclosure Number(s) is:
- I have obtained approval from the UCL Data Protection Officer stating that the research project is compliant with the Data Protection Act 1998. My Data Protection Registration Number is:
- I am satisfied that the research complies with current professional, departmental and university guidelines including UCL's Risk Assessment Procedures and insurance arrangements.
- I undertake to complete and submit the 'Continuing Review Approval Form' on an annual basis to the UCL Research Ethics Committee.
- I will ensure that changes in approved research protocols are reported promptly and are not initiated without approval by the UCL Research Ethics Committee, except when necessary to eliminate apparent immediate hazards to the participant.
- I will ensure that all adverse or unforeseen problems arising from the research project are reported in a timely fashion to the UCL Research Ethics Committee.
- I will undertake to provide notification when the study is complete and if it fails to start or is abandoned.

SIGNATURE: **DATE:**

A3	**Applicant(s) Details** *(if Applicant is not the Principal Researcher e.g. student details):*	
	Full Name:	
	Position Held:	
	Address:	Email: Telephone: Fax:
	Full Name:	
	Position Held:	
	Address:	Email: Telephone: Fax:

A4 Sponsor/ Other Organisations Involved and Funding

a) Sponsor: ☐ **UCL** ☐ **Other institution**
If your project is sponsored by an institution other than UCL please provide details:

b) Other Organisations: If your study involves another organisation, please provide details. *Evidence that the relevant authority has given permission should be attached or confirmation provided that this will be available upon request.*

c) Funding: What are the sources of funding for this study and will the study result in financial payment or payment in kind to the department or College? *If study is funded solely by UCL this should be stated, the section should not be left blank.*

A5 Signature of Head of Department [or Chair of the Departmental Ethics Committee]
(This must not be the same signature as the Principal Researcher)

A. I have discussed this project with the principal researcher who is suitably qualified to carry out this research and I approve it.

I am satisfied that *[please highlight as appropriate]:*

(1) Data Protection registration:

- **has been satisfactorily completed**
- **has been initiated**
- **is not required**

(2) a risk assessment:

- **has been satisfactorily completed**
- **has been initiated**

(3) appropriate insurance arrangements are in place and appropriate sponsorship [funding] has been approved and is in place to complete the study. ☐ **Yes** ☐ **No**

(4) a Disclosure and Barring Service check(s):

- **has been satisfactorily completed**
- **has been initiated**
- **is not required**

Links to details of UCL's policies on the above can be found at: http://ethics.grad.ucl.ac.uk/procedures.php

****If any of the above checks are not required please clarify why below.**

B. **Having read the 'criteria of minimal risk' as defined on page 3 of our Guidelines at: http://ethics.grad.ucl.ac.uk/forms/guidelines.pdf I recommend that this application should be considered by the Chair of the UCL REC ☐ Yes ☐ No**

PRINT NAME:

SIGNATURE: **DATE:**

SECTION B DETAILS OF THE PROJECT

B1 **Please provide a brief summary of the project in simple prose outlining the intended value of the project, giving necessary scientific background** *(max 500 words)*.

B2 **Briefly characterise in simple prose the research protocol, type of procedure and/or research methodology (e.g. observational, survey research, experimental). Give details of any samples or measurements to be taken** *(max 500 words).*

Attach any questionnaires, psychological tests, etc. (a standardised questionnaire does not need to be attached, but please provide the name and details of the questionnaire together with a published reference to its prior usage).

B3	**Where will the study take place (please provide name of institution/department)?** If the study is to be carried out overseas, what steps have been taken to secure research and ethical permission in the study country? Is the research compliant with Data Protection legislation in the country concerned or is it compliant with the UK Data Protection Act 1998?

B4	**Have collaborating departments whose resources will be needed been informed and agreed to participate?** *Attach any relevant correspondence.*

B5	**How will the results be disseminated, including communication of results with research participants?**

B6	**Please outline any ethical issues that might arise from the proposed study and how they are be addressed.** *Please note that all research projects have some ethical considerations so do not leave this section blank.*

SECTION C DETAILS OF PARTICIPANTS

C1 **Participants to be studied**

C1a. Number of volunteers:	
Upper age limit:	
Lower age limit:	

C1b. Please justify the age range and sample size:

C2	**If you are using data or information held by a third party, please explain how you will obtain this. You should confirm that the information has been obtained in accordance with the UK Data Protection Act 1998.**

C3 **Will the research include children or vulnerable adults such as individuals with a learning disability or cognitive impairment or individuals in a dependent or unequal relationship?** ☐ **Yes** ☐ **No**

How will you ensure that participants in these groups are competent to give consent to take part in this study? *If you have relevant correspondence, please attach it.*

C4 **Will payment or any other incentive, such as gift service or free services, be made to any research participant?**

☐ **Yes** ☐ **No**

If yes, please specify the level of payment to be made and/or the source of the funds/gift/free service to be used.

Please justify the payment/other incentive you intend to offer.

C5 **Recruitment**

(i) Describe how potential participants will be identified:

(ii) Describe how potential participants will be approached:

(iii) Describe how participants will be recruited:

Attach recruitment emails/adverts/webpages. A data protection disclaimer should be included in the text of such literature.

C6 **Will the participants participate on a fully voluntary basis?** ☐ **Yes** ☐ **No**

Will UCL students be involved as participants in the research project? ☐ **Yes** ☐ **No**

If yes, care must be taken to ensure that they are recruited in such a way that they do not feel any obligation to a teacher or member of staff to participate.

Please state how you will bring to the attention of the participants their right to withdraw from the study without penalty?

C7 **CONSENT**

Please describe the process you will use when seeking and obtaining consent.

A copy of the participant information sheet and consent form must be attached to this application. For your convenience proformas are provided in C10 below. These should be filled in and modified as necessary.

In cases where it is not proposed to obtain the participants informed consent, please explain why below.

C8 **Will any form of deception be used that raises ethical issues? If so, please explain.**

C9 **Will you provide a full debriefing at the end of the data collection phase?** ☐ **Yes** ☐ **No**

If 'No', please explain why below.

C10 **Information Sheets And Consent Forms**

A poorly written Information Sheet(s) and Consent Form(s) that lack clarity and simplicity frequently delay ethics approval of research projects. The wording and content of the Information Sheet and Consent Form must be appropriate to the age and educational level of the research participants and clearly state in simple non-technical language what the participant is agreeing to. Use the active voice e.g. "we will book" rather than "bookings will be made". Refer to participants as "you" and yourself as "I" or "we". An appropriate translation of the Forms should be provided where the first language of the participants is not English. If you have different participant groups you should provide Information Sheets and Consent Forms as appropriate (e.g. one for children and one for parents/guardians) using the templates below. Where children are of a reading age, a written Information Sheet should be provided. When participants cannot read or the use of forms would be inappropriate, a description of the verbal information to be provided should be given. Please ensure that you trial the forms on an age-appropriate person before you submit your application.

Information Sheet for in Research Studies

You will be given a copy of this information sheet.

Title of Project:

This study has been approved by the UCL Research Ethics Committee (Project ID Number):

Name

Work Address

Contact Details (*For students, we strongly advise against the use of a personal contact number)

We would like to invite to participate in this research project.

Details of Study:

Please discuss the information above with others if you wish or ask us if there is anything that is not clear or if you would like more information.

It is up to you to decide whether to take part or not; choosing not to take part will not disadvantage you in any way. If you do decide to take part you are still free to withdraw at any time and without giving a reason.

All data will be collected and stored in accordance with the Data Protection Act 1998.

Thank you for reading this information sheet and for considering take part in this research.

When you have completed your Information Sheet, please DELETE the advice section below from your application form before submitting it to the Committee.

Details of Study MUST include the following:

- Aims of the research and possible benefits.
- Who you are recruiting
- What will happen if the participant agrees to take part (when, where, how long etc)
- Any risks (e.g. need for disclosure of information to a third party, possibility for distress)
- Possible benefits (it is good practice to offer participants a copy of the final report)
- Arrangements for ensuring anonymity and confidentiality (see optional statements below for examples). To ensure compliance with the Data Protection Act participants must be informed of what information will be held about them and who will have access to it (this relates to information that is identifiable or could potentially be linked back to an individual.)

Statements which researchers MIGHT also include as appropriate:

- A decision to withdraw at any time, or decision not to take part, will not affect the standard of care/education you receive.
- If you agree to take part you will be asked whether you are happy to be contacted about participation in future studies. Your participation in this study will not be affected should you choose not be re-contacted.
- You may withdraw your data from the project at any time up until it is transcribed for use in the final report (*insert date)*.
- Recorded interviews will be transcribed (written up) and the tape will then be wiped clear.
- If you decide to take part you will be given this information sheet to keep and be asked to sign a consent form.
- Submission of a completed questionnaire implies consent to participate.
- As participation is anonymous it will not be possible for us to withdraw your data once you have returned your questionnaire.
- What if I have further questions, or if something goes wrong? If this study has harmed you in any way or if you wish to make a complaint about the conduct of the study you can contact UCL using the details below for further advice and information:

Student researchers: Insert the name and full UCL contact address and number of your supervisor.

*Staff researchers: Please insert the following: The Chair, *Insert full address details for the UCL Research Ethics Committee, ethics@ucl.ac.uk

Informed Consent Form for in Research Studies

Please complete this form after you have read the Information Sheet and/or listened to an explanation about the research.

Title of Project:

This study has been approved by the UCL Research Ethics Committee (Project ID Number):

Thank you for your interest in taking part in this research. Before you agree to take part, the person organising the research must explain the project to you.

If you have any questions arising from the Information Sheet or explanation already given to you, please ask the researcher before you to decide whether to join in. You will be given a copy of this Consent Form to keep and refer to at any time.

Participant's Statement

I

- have read the notes written above and the Information Sheet, and understand what the study involves.
- understand that if I decide at any time that I no longer wish to take part in this project, I can notify the researchers involved and withdraw immediately.
- consent to the processing of my personal information for the purposes of this research study.
- understand that such information will be treated as strictly confidential and handled in accordance with the provisions of the Data Protection Act 1998.
- agree that the research project named above has been explained to me to my satisfaction and I agree to take part in this study.
- Agree that my data, after it has been fully anonymised, can be shared with other researchers *[to satisfy Research Council funded projects as Research Councils have changed their guidance regarding data sharing]*

Signed: Date:

When you have completed your Informed Consent Form, please DELETE the advice section below from your application form before submitting it to the Committee.

Statements which researchers MIGHT include as appropriate:

- I understand that my participation will be taped/video recorded and I consent to use of this material as part of the project.
- I understand that I must not take part if
- I agree to be contacted in the future by UCL researchers who would like to invite me to participate in follow-up studies.
- I understand that the information I have submitted will be published as a report and I will be sent a copy. Confidentiality and anonymity will be maintained and it will not be possible to identify me from any publications.
- I understand that I am being paid for my assistance in this research and that some of my personal details will be passed to UCL Finance for administration purposes.
- I agree that my non-personal research data may be used by others for future research. I am assured that the confidentiality of my personal data will be upheld through the removal of identifiers.

This is not an exhaustive list and you should consider whether you need to amend any of these statements or design different ones that are more applicable to your research.

D1	**Have UCL's Risk Assessment Procedures been followed?** ☐ **Yes** ☐ **No** If **No**, please explain.

D2	**Does UCL's insurer need to be notified about your project before insurance cover can be provided?** ☐ **Yes** ☐ **No** *The insurance for all UCL studies is provided by a commercial insurer. For the majority of studies the cover is automatic. However, for a minority of studies, in certain categories, the insurer requires prior notification of the project before cover can be provided.* If **Yes**, please provide confirmation that the appropriate insurance cover has been agreed. *Please attach your UCL insurance registration form and any related correspondence.*

D3	**Please state briefly any precautions being taken to protect the health and safety of researchers and others associated with the project (as distinct from the research participants).**

D4	**Will these participants participate in any activities that may be potentially stressful or harmful in connection with this research?** ☐ **Yes** ☐ **No** If **Yes**, please describe the nature of the risk or stress and how you will minimise and monitor it.

D5	**Will group or individual interviews/questionnaires raise any topics or issues that might be sensitive, embarrassing or upsetting for participants?** If **Yes,** please explain how you will deal with this.

D6	**Please describe any expected benefits to the participant.**

D7	**Specify whether the following procedures are involved:** **Any invasive procedure(s)** ☐ **Yes** ☐ **No** **Physical contact** ☐ **Yes** ☐ **No** **Any procedure(s) that may cause mental distress** ☐ **Yes** ☐ **No** Please state briefly any precautions being taken to protect the health and safety of the research participants.

D8	**Does the research involve the use of drugs?** ☐ **Yes** ☐ **No** If **Yes**, please name the drug/product and its intended use in the research and then complete Appendix I **Does the project involve the use of genetically modified materials?** ☐ **Yes** ☐ **No** If **Yes**, has approval from the Genetic Modification Safety Committee been obtained for work? ☐ Yes ☐ No If **Yes**, please quote the Genetic Modification Reference Number:

D9	**Will any non-ionising radiation be used on the research participant(s)?** ☐ **Yes** ☐ **No** If **Yes**, please complete Appendix II.
D10	**Are you using a medical device in the UK that is CE-marked and is being used within its product indication?** ☐ **Yes** ☐ **No** If **Yes**, please complete Appendix III.

CHECKLIST

Please submit ether 12 copies (1 original + 11 double sided photocopies) of your completed application form for full committee review or 3 copies (1 original + 2 double sided copies) for chair's action, together with the appropriate supporting documentation from the list below to the UCL Research Ethics Committee Administrator. You should also submit your application form electronically to the Administrator at: ethics@ucl.ac.uk

Documents to be Attached to Application Form (if applicable)	Ticked if attached	Tick if not relevant
Section B: Details of the Project		
• Questionnaire(s) / Psychological Tests	☐	☐
• Relevant correspondence relating to involvement of collaborating department/s and agreed participation in the research.	☐	☐
Section C: Details of Participants	☐	☐
• Parental/guardian consent form for research involving participants under 18	☐	☐
• Participant/s information sheet	☐	☐
• Participant/s consent form/s	☐	☐
• Advertisement		
Section D: Details of Risks and Benefits to the Researcher and the Researched	☐	☐
• Insurance registration form and related correspondence		
Appendix I: Research Involving the Use of Drugs	☐	☐
• Relevant correspondence relating to agreed arrangements for dispensing with the pharmacy	☐	☐
• Written confirmation from the manufacturer that the drug/substance has has been manufactured to GMP	☐	☐
• Proposed volunteer contract	☐	☐
• Full declaration of financial or direct interest	☐	☐
• Copies of certificates: CTA etc…		
Appendix II: Use of Non-Ionising Radiation		
Appendix III: Use Medical Devices		

Please note that correspondence regarding the application will normally be sent to the Principal Researcher and copied to other named individuals.