COMMITTEE ON THE USE OF HUMAN SUBJECTS IN RESEARCH - CUHSR

APPLICATION FORM FOR ETHICAL REVIEW

ESADE
RAMON LLULL UNIVERSITY

The Committee on the Use of Human Subjects in Research (CUHSR) has set in place procedures to ensure that is meeting its obligations as a responsible institution, in terms of the knowledge, expertise, and integrity of its members and their ability to conduct research to high standards of scholarship and ethics.

Please complete this form electronically and email it, together with your supporting documents to the CUHSR. (give email address). **Only emailed applications will be accepted.**

WHICH APPLICATION LEVEL DO I NEED?		
The checklist below will direct you to which level application is needed. The **CUHSR level 1 application** is designed largely for research where ethical issues are relatively few and straightforward. This includes interviews, fieldwork and oral history. The **CUHSR level 2 application** is only required where there are more complex sets of ethical issues due to the type of participants or procedures involved.		
Contact details and project description (NB: must be typed not handwritten)		
1. **Principal researcher/**supervisor (title and name) (if student research):		
2. Name of student (if student research):		
3. Degree programme, e.g. BBA, MRes, PhD (if student research):		
4. Department or Institute name:		
5. Address for correspondence (if different from 4 above):		
6. University e-mail (**not** private email) and telephone contact:		
7. Name and status of others taking part in the project, e.g. third year undergraduate; postdoctoral research assistant:		
8. Title of research project:		
9. List of location(s) where project will be conducted:		
10. Anticipated duration of research project overall:	months or years (maximum 5)	
11. Anticipated start and end dates of the research project involving human participants:	From: (dd/mm/yy) To: (dd/mm/yy) Please note that you will need ethics approval **before** you start your research. It may take up to 30 days to process.	
12. Have you, or do you intend to, apply for external funding for this project/study?	Yes	No
If YES, please give the name of the funding body, call details, etc.		

13. Title and very brief and simple lay description of research (about 150 words), plus description (about 200 words) of the nature of participants.

WHAT THIS CHECKLIST WILL NOT ASSESS
This checklist does not cover research governance, satisfactory methodology, or compliance with the requirements of publishers when administering their tests or questionnaires. As principal researcher, it is your responsibility to ensure that requirements in these areas are met.

SECTION A: INITIAL CHECKLIST

This section determines whether your study is Low Risk or High Risk.

(Please mark 'X' in the Yes/No column as appropriate to indicate your response to ALL questions.)

1. Will your study involve participants who are particularly vulnerable or unable to give informed consent or in a dependant position (e.g. people under 18, people with learning difficulties, over-researched groups or people in care facilities)?	Yes	No
2. Will participants be required to take part in the study without their consent or knowledge at the time (e.g. covert observation of people in non-public places) and / or will deception of any sort be used?	Yes	No
3. Will it be possible to link identities or information back to individual participants in any way?	Yes	No
4. Might the study induce psychological stress or anxiety, or produce humiliation or cause harm or negative consequences beyond the risks encountered in the everyday life of the participants?	Yes	No
5. Will the study involve discussion of sensitive topics (e.g. sexual activity, drug use, ethnicity, political behaviour, potential illegal activities)?	Yes	No
6. Will any drugs, placebos or other sensitive substances (such as food substances or vitamins) be administered as part of this study and will any invasive or potentially harmful procedures of any kind be used?	Yes	No
7. Will your study involve working with any substances and / or equipment which may be considered hazardous?	Yes	No
8. Will financial inducements (other than reasonable expenses, compensation for time) be offered to participants?	Yes	No

If you have answered '**No**' to all of the questions above, your study is assumed to be LOW RISK. Please go to **Section B**.

If you answered '**Yes'** to ANY of questions **1-8**, your study is assumed to be HIGH RISK. Please go on to **Section C**.

SECTION B – LOW RISK APPLICATIONS (CUHSR LEVEL 1)		
B.1 Data Collection and Analysis (Please provide full details)		
1. Participants: How many people do you envisage will participate, where are they from and how will they be selected?		
2. Recruitment: How will participants be approached and recruited – e.g. will you be requesting to use the ESADE Decision Lab subject pool?		
3. Payment: If you will compensate participants, please detail payment procedures and rate(s) you will use. (refer to the Decision Lab manual)		
4. Method: What research methodology are you planning on using?		
5. Location: Where will the project be carried out e.g. public place, in researcher's office, in private space at organisation, in the ESADE Decision Lab?		
B.2 Confidentiality and Anonymity		
6. Will questionnaires be completed anonymously and returned indirectly?	Yes	No
7. Will questionnaires and/or interview transcripts only be identifiable by a unique identifier (e.g. code/pseudonym)	Yes	No
8. Will lists of identity numbers or pseudonyms linked to names and/or addresses be stored securely and separately from the research data?	Yes	No
9. Will all place names and institutions which could lead to the identification of individuals or organisations be changed?	Yes	No
10. Will all personal information gathered be treated in strict confidence and never disclosed to any third party?	Yes	No
11. Can you confirm that your research records will be held in accordance with the data protection guidelines?	Yes	No
12. Can you confirm that you will not use research data for any purpose other than that which consent is given?	Yes	No
12a. If you answered NO to any of the above (or think more information could be useful to the reviewer) please explain here:		
B.3 Informed Consent and Recruitment of Participants		
13. Will all participants be given and Information Sheet[1] and be given adequate time to read it before being asked to agree to participate?	Yes	No
14. Will all participants taking part in an interview, focus group, observation (or other activity which is not questionnaire based) be asked to sign a consent form? If you are obtaining consent in another way, please explain under 15a below.	Yes	No
15. Will all participants self-completing a questionnaire be informed that returning the completed questionnaire implied consent to participate?	Yes	No

[1] This may be in paper format or included as a pre-sreen for computer-based tasks

16. Will all respondents be told that they can withdraw at any time, ask for their data to be destroyed and/or removed from the project until it is no longer practical to do so?	Yes	No
16a. If you answered NO to any of the above (or think more information could be useful to the reviewer) please explain here:		
B.4. Context		
17. Are any other ethical permissions required?	Yes	No
17a. If YES please give further details here:		
18. Does the research involve any fieldwork – overseas or in Spain?	Yes	No
18a. If YES please give further details here:		
19. Will any researchers be in a lone working situation?	Yes	No
19a. If YES please give further details here:		
B.5. Data Protection, Confidentiality and Records Management		
20. Will you ensure that the processing of personal information related to the study will be in full compliance with EU Regulation 2016/679 on the protection of personal data:	Yes	No
20a. If you are processing any personal information outside of the European Economic Area (EEA) you must explain how compliance with the DPA will be ensured.		
21. Will you take steps to ensure the confidentiality of personal information?	Yes	No
21a. Please provide details of anonymization procedures and of physical and technical security measures here:		
22. Will all personal information related to this study be retained and shared in a form that is fully anonymised?	Yes	No
23. Will the Principal Investigator take full responsibility during the study, for ensuring appropriate storage and security of information (including research data, consent forms and administrative records) and, where appropriate, will the necessary arrangements be made in order to process copyright material lawfully?	Yes	No
23a. If you answered NO to the above question, please give further details:		
24. Who will have access to personal information relating to this study?		
25. Data management responsibilities after the study. State how long study information including research data, consent forms and administrative records will be retained, in what format(s) and where the information will be kept. State if any of the data will be used in publications, or made available via open-data repository.		
B.6. Any further concerns		

26. Are there any other ethical considerations relating to your project/study not covered above?	Yes	No
26a. If YES please give further details here		

Thank you for your answers. Please now go to Section D and sign the form.

SECTION C – HIGH RISK APPLICATIONS (CUHSR LEVEL 2)		
C.1 Risk Checklist - Participants		
1. Does the study involve participants who are particularly vulnerable, or unable to give informed consent, or in a dependent position (e.g. children (under 18), people with learning difficulties, over-researched groups or people in care facilities, including prisons)?	Yes	No
2. Will participants be asked to take part in the study without their consent or knowledge at the time (e.g. covert observation of people) or will deception of any sort be involved?	Yes	No
3. Could the study induce psychological stress or anxiety, or produce humiliation, or cause harm or negative consequences beyond the risks encountered in normal life?	Yes	No
4. Are alcoholic drinks, drugs, placebos or other substances (such as food substances or vitamins) to be administered to the study participants?	Yes	No
5. Can you think of anything else that might be potential harmful to participants in this research?		
C.2 Risk Checklist – Researcher(s) Safety and Wellbeing		
6. Does the project involve working with any substances and/or equipment which may be considered hazardous?	Yes	No
7. Could the nature of subject of the research potentially have an emotionally disturbing impact on the researcher(s)?	Yes	No
7a. If YES, briefly describe what measures will be taken to help the researcher(s) to manage this		
8. Could the nature or subject of the research potentially expose the researcher(s) to threats of physical violence and/or verbal abuse?	Yes	No
8a. If YES, briefly describe what measures will be taken to help the researcher(s) to mitigate this		
9. Does the research involve any fieldwork – Overseas or in Spain?	Yes	No
9a. If YES please give further details here:		
10. Will any researchers be in a lone working situation?	Yes	No
10a. If YES please give further details here:		
11. Can you think of anything else that might be potential harmful to participants in this research?		
C.3 Data Collection and Analysis (Please provide full details)		
12. Participants: How many people do you envisage will participate, where are they from, and how will they be selected?		
13. Recruitment: How will participants be approached and recruited – e.g. will you be requesting to use the ESADE Decision Lab subject pool?		

14. Payment: If you will compensate participants, please detail payment procedures and rate(s) you will use. (refer to the Decision Lab manual)		
15. Method: What research methodology are you planning on using?		
16. Location: Where will the project be carried out e.g. public place, in researcher's office, in private space at organisation, in the ESADE Decision Lab?		
C.4 Ethical Considerations (Please provide full details)		
17. INFORMED CONSENT: Please describe the process you will use to ensure your participants are feely giving informed consent to participate. This will usually include the provision of an Information Sheet and will normally require a Consent Form unless it is a purely self-completion questionnaire based study or there is justification for not doing so. (Please state this clearly).		
18. RIGHT OF WITHDRAWL: Participants should be able to withdraw from the research at any time. Participants should also be able to withdraw their data if it is linked to them and should be told when this will no longer be possible (e.g. once it has been included in the final report). Please describe the exact arrangements for withdrawal from participation and withdrawal of data for your study.		
19. OTHER ETHICAL ISSUES: If you answered YES to anything in C1 you must specifically address this here. Please also consider whether there are other ethical issues you should be covering here. Please also make reference to the professional code of conduct you intend to follow in your research.		
C.5. Data Protection, Confidentiality and Records Management		
20. Will you ensure that the processing of personal information related to the study will be in full compliance with EU Regulation 2016/679 on the protection of personal data::	Yes	No
20a. If you are processing any personal information outside of the European Economic Area (EEA) you must explain how compliance with the DPA will be ensured.		
21. Will you take steps to ensure the confidentiality of personal information?	Yes	No
21a. Please provide details of anonymization procedures and of physical and technical security measures here:		
22. Will all personal information related to this study be retained and shared in a form that is fully anonymised?	Yes	No
23. Will the Principal Investigator take full responsibility during the study, for ensuring appropriate storage and security of information (including research data, consent forms and administrative records) and, where appropriate, will the necessary arrangements be made in order to process copyright material lawfully?	Yes	No
23a. If you answered NO to the above question, please give further details:		
24. Who will have access to personal information relating to this study?		

25. Data management responsibilities after the study. State how long study information including research data, consent forms and administrative records will be retained, in what format(s) and where the information will be kept. State if any of the data will be used in publications, or made available via open-data repository.		
C.6. Other Ethical Clearances and Permissions		
26. Are there any other ethical considerations relating to your project/study not covered above?	Yes	No
26a. If YES please give further details here		

Thank you for your answers. Please now go to Section D and sign the form.

SECTION D: Signatures

- 'Electronic signatures' can be accepted.
- If you have obtained handwritten signatures, please scan all pages to create a single PDF document and email it to the CUHSR

Please ensure this checklist is signed by:

For staff research:	**For student research**:
1. **Principal Researcher**	1. **Principal Researcher (project supervisor)**
	2. **Director of MRes/PhD Programme**
	3. **Student researcher**

1. **Principal researcher signature/supervisor signature (if student research)**

I understand my responsibilities as principal researcher.

I declare that the answers above accurately describe the research as presently designed, and that a new checklist will be submitted should the research design change in a way which would alter any of the above responses so as to require completion of Level 2 application form. I will inform CUHSR if I cease to be the principal researcher on this project and supply the name and contact details of my successor if appropriate.

Signature: ……

Print name (block capitals): …… **Date**: ……..

2. **Director MRes / PhD Programme signature (if student research)**

I have read the research project application named above. On the basis of the information available to me, I:

(i) consider the principal researcher to be aware of her/his ethical responsibilities in regard to this research;
(ii) consider that any ethical issues raised have been satisfactorily resolved or are covered by relevant professional guidelines and that it is appropriate for the research to proceed (noting the principal researcher's obligation to report should the design of the research change in a way which would alter any of the above responses so as to require completion of a Level 2 full application);
(iii) am satisfied that: the proposed project design and scientific methodology is sound;

Signed by Director of MRes / Director or PhD Programme *(delete as appropriate)*

Signature: ……

Print name (block capitals): …… **Date**: ……..

3. **Student signature (if student research)**

I understand the questions and answers that have been entered above describing the research, and I will ensure that my practice in this research complies with these answers, subject to any modifications made by the principal researcher properly authorised by the CUHSR.

Signed by student: ……

Date: ……..

Print name (block capitals): ……

SUBMITTING THE COMPLETED CHECKLIST	**Please mark 'X'**
1. Check you have completed all relevant sections (A,B, D / A,C,D) 2. Ensure your application is signed by you, and/or your supervisor (if student) 3. **Please attach all supporting documents (Information Sheet, Consent Form(s), etc).** If the appropriate supporting documentation is not included with your application, you will then be asked to provide this separately. **This may well delay the ethical review process, and thus the start of your research.** Applications must be sent by email. Please do not send applications by post.	