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### Why we consider ethics

Ethics approval is needed for any research that involves human participants, their tissue and/or their data

- ➤ Nuremberg Code (1947)
- > Helsinki Declaration (1964)
- > Human Tissue Act (2008)

For research to result in benefit and minimise risk of harm, it must be conducted ethically



# Key principles of ethical research with human participants

- The research participants' welfare
- Vulnerable groups
- Equitable distribution of benefits and burdens
- Informed consent (opt out / deception)
- Confidentiality and privacy
- Data protection
- The researcher's welfare



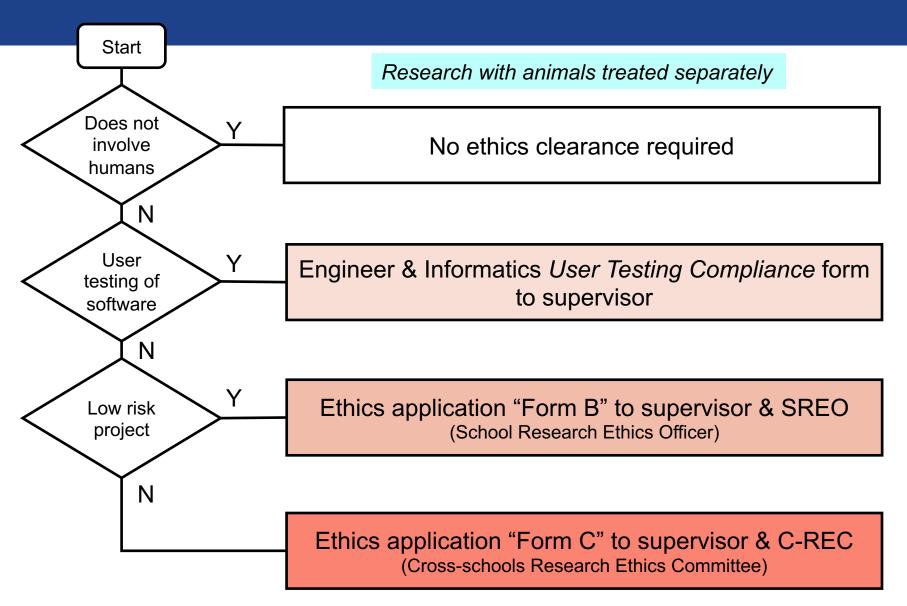


# Failing to obtain ethics approval

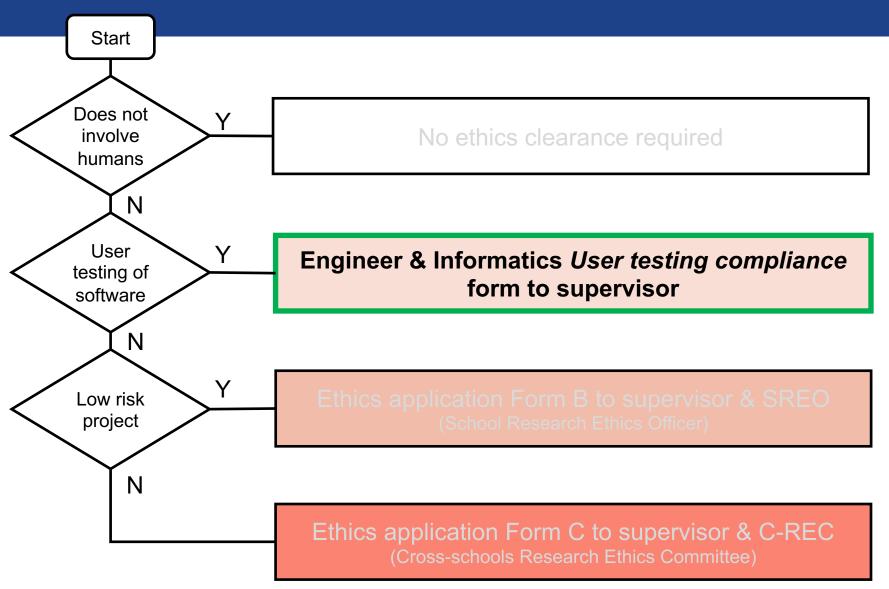
- Serious consequences if you failure to obtain ethics approval when it is required
- An academic offence that may lead to deduction of marks
- University Governance office may investigate the case
- School must report all such cases to the University
- Do not start any work with human participants until you have (a)
   User Testing Compliance or (b) Ethical review approval



# Does my project need ethics approval?



# User testing compliance



# User Testing Compliance (a)

### By the end of your project you will be able to confirm your compliance with the twelve conditions for user testing:

- 1. Participants were not exposed to any risks greater than those encountered in their normal working life.
- 2. The study materials were paper-based, or comprised software running on standard hardware.
- 3. All participants explicitly stated that they agreed to take part, and that their data could be used in the project.
- 4. No incentives were offered to the participants.
- 5. No information about the evaluation or materials was intentionally withheld from the participants.
- 6. No participant was under the age of 18.



# User Testing Compliance (b)

#### Continued . . .

- 7. No participant had a disability or impairment that may have limited their understanding or communication or capacity to consent.
- 8. Neither I nor my supervisor are in a position of authority or influence over any of the participants.
- 9. All participants were informed that they could withdraw at any time.
- 10.All participants have been informed of my contact details, and the contact details of my supervisor.
- 11. The evaluation was described in detail with all of the participants at the beginning of the session, and participants were fully debriefed at the end of the session. All participants were given the opportunity to ask questions at both the beginning and end of the session.
- 12.All the data collected from the participants is stored securely, and in an anonymous form.

# User Testing Compliance (c)

### What to do:

- Discuss the ethics issues / user testing requirements with your supervisor early in the project
- Download and carefully read the Ethical review guidance for student projects
- If appropriate download the User Testing Compliance Form for UG and PGT Projects
- Complete the form (see next slide)
- Prepare your introduction and debriefing scripts
- Sign and submit the form and scripts to your supervisor
- After your supervisor has signed and returned the form you may start your testing
- Add User Testing Compliance for as an appendix to your final report

# Completing the compliance form

2. The study materials were paper-based, or comprised software running on standard hardware.

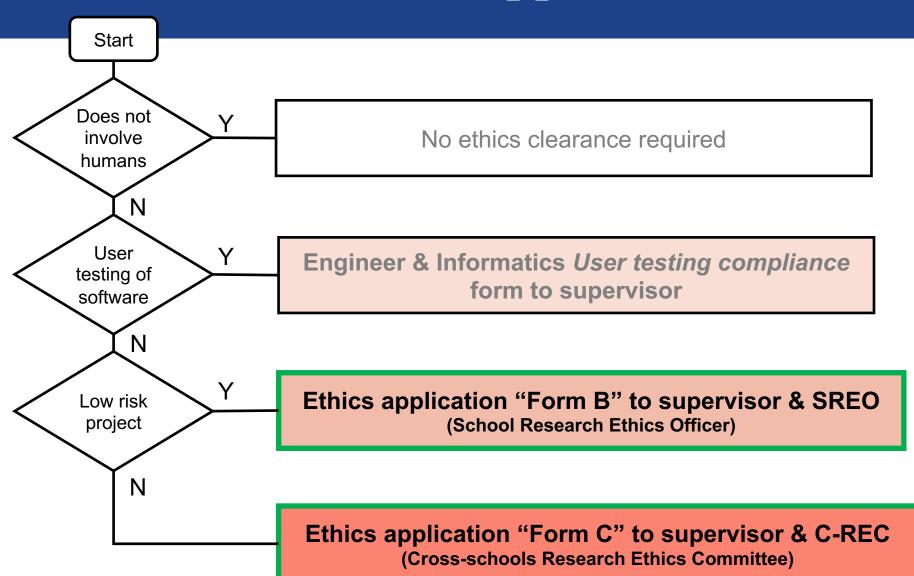
Participants should not be exposed to any risks associated with the use of non-standard equipment: anything other than pen-and-paper, standard PCs, mobile phones, and tablet computers is considered non-standard.



**Recommendation**: in the form, replace each description with a brief statement of what will happen your project.



# Full ethics approval



### Research involving human participants

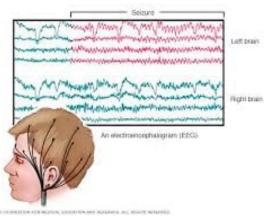














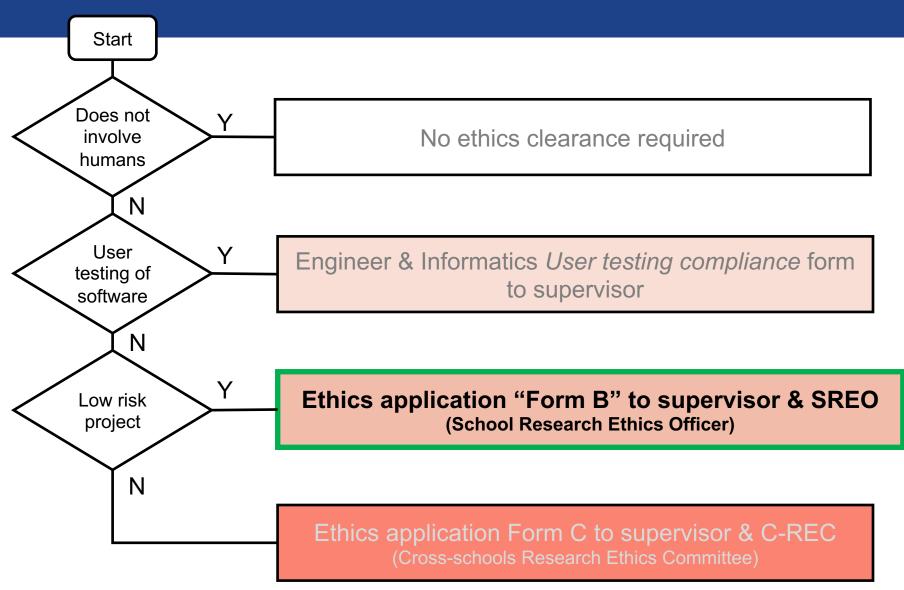




# Do you need ethics approval for your research project (low or high risk)?

Question	Y/N
a) Will the research project involve human participants, with or without their knowledge or consent at the time? (This includes yourself if you are the main subject of the research).  b) Will the research project involve animals?	
2. Is the research project likely to expose any person, whether or no a participant, to physical or psychological harm?	t
Will you have access to personal information and/ or data that allows you to identify individuals or to confidential corporate company information?	
Does the research project present a significant risk to the environment or society?	
5. Are there any ethical issues raised by this research project that require further ethical review?	

# Low risk ethics approval



# Nine +1 criteria for low risk projects

- All these criteria must apply for a project to be low risk
- 1. Not vulnerable groups and able to give consent
- 2. Not covert study and no deception
- 3. Participants' anonymity in research outputs
- 4. Does not induce psychological stress/anxiety, or humiliation, or harm or negative consequences
- 5. No risk of disclosure of beliefs, illegal actions or activities that are a treat/harm to participants or others
- 6. Not collecting personal special category information (see next slide)
- 7. No administration of drugs, placebos or substances, nor invasive or harmful procedures
- 8. Project does not involve substances/equipment considered hazardous
- 9. No taking or storage of human tissue

See next slide for full specifications

+1. Social media data – small quantities of data only — new

# Full low risk project checklist

None of these must apply for a project to be deemed low risk

case that you have made.

» Checklist	
A1. Will your study involve participants who are currently or potentially vulnerable or unable to give informed consent or in a dependent position (e.g. people under 18, people with learning difficulties, over-researched groups or people in care facilities)?	No
A2. 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? Please refer to the British Psychological Society Code of Ethics and Conduct (or similar guidelines) for further information.	No
A3. Unless specifically and clearly consented (e.g. a media release form), will it be possible, through a research output, to identify participants in any way? (This does not include taking email details for participant prize draws or identifying participants from signed consent forms or holding identity encryption spreadsheets that are stored securely separate from the research data).	No
A4. Might the study induce psychological stress or anxiety, or produce humiliation or cause harm or negative consequences beyond the risks likely to be encountered in the everyday life of the participants?	No
A5. Is there a risk that the research topic might lead to disclosures from the participant concerning their beliefs, involvement in illegal actions or any other activities that may represent a threat to themselves or others?	No
A6. Will the study involve collecting any <i>personal special category information*</i> in a form that could allow the participant/ participants to be identified?  [* identifiers relating to race, ethnic origin, politics, religion, trade union membership, philosophical beliefs, genetics, biometrics, health, sex life or sexual orientation]	No
A7. Will any drugs, placebos or other 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 will be used?	No
A8. Will your project involve working with any substances and / or equipment which may be considered hazardous?	No
A9. Will your study involve the taking and/or storage of human tissue that falls under the Human Tissue Act (HTA)? http://www.sussex.ac.uk/staff/research/governance/erp_overview/humantissue	No
» Risk Assessment	

A10. If you have answered Yes to ANY of the above questions, your application may be considered as HIGH risk. If, however you wish to make a case that your application should be considered as LOW risk please enter the reasons here. Researchers should note that SREOs or C-RECs may decide NOT to agree with the

# Some examples titles of low risk Engineering and Informatics ethics applications

The Impact of Technological innovation and changes on Organisation Performance in CoPS

A Textspeak
Dictionary
Extension for
Google

User study for a 3D music sequencer, to investigate its effects on the composition of music.

Question Generation and Entity Recognition to Aid in Diagnosis

Investigating the
Effects of Force
Feedback on Virtual
Reality Shooting
Games

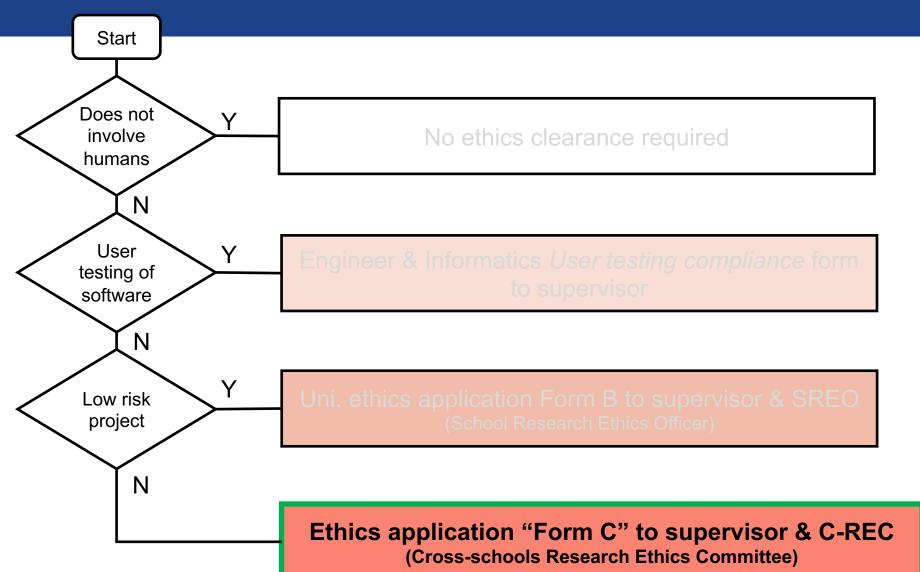
Human Computer Interaction Project



Place-based narratives: supporting creative re-use of digital cultural assets

Privacy awareness of users relating to the terms and conditions of online social networks

# High risk ethics approval



# High risk projects

In general, avoid projects that are high risk ethically, because . . .

- Demand very high-quality applications:
  - Real benefit of the research, which is justified
  - Project design must very well specified
  - Include full mitigations of risk
  - High standard of writing (clear and detailed)
- Decisions take longer:
  - Go for full ethics panel review (2+ reviewers)
  - Normally involve 1+ cycle of revision and resubmission

#### One exception . . .

- Social media data analysis where all the low risk criteria are met
- But there is a large amount of data covered by University classification and handling policy
- Submit a high risk ethics application (form C) to provide details of data handling arrangements
- Reviewed by Chair of C-REC and SREO

# Low risk v high risk

# A visualisation for recipe instructions

Low risk study where participants take part in an experiment cooking a recipe to textual instructions or to visualised instructions, followed by self-completion interviews and interviews.

Final year Product Design Project: Improving motorcycle riding conditions for people with upper limb loss(es).

Simulated riding only but study was high risk because . . .

it involved collecting personal special category information about health/disability in a form that could allow the participants to be identified



# Ethics application process (low and high risk projects)



# Ethical review process

- Complete on line application form
  - Title and project description: use this section to tell the reviewer the 'what/why/how'
  - Checklist: this decides automatically if your application is high or low risk.
- ➤ Low risk = Part B of the application form
  - Student projects reviewed at School level by your supervisor and the School Research Ethics Officer (SREO)
- High risk = Part C of the application form
  - Student projects reviewed by your supervisor and the Cross-Schools Ethics Committee (C-REC)
- Review outcomes: Approve, Revise, Reject
- Certificate of approval: you receive this when your project is approved
  - Append certificate and copy of application to your final report



### What makes a good ethics application?

Explain your objective(s) and methods clearly and fully

- Lack of detail & clarity main reason for return of applications
- Reviewer will imagine the worst in cases of ambiguity

### Say **how** you will:

- Protect the care and welfare of participants; minimising all risk of physical and mental discomfort, harm or danger to yourself, and others
- Ensure confidentiality and anonymity of participants
- Get informed consent
- Collect and store data securely
  - **'**

Tip: Write from the perspective of what the participant will experience - put yourself in their shoes!



### Supporting documents

Ensure all supporting documents are attached:

#### Always:

- Information sheet and consent form (use UoS templates)
- Recruitment materials; e.g. poster or advert
- Questionnaire / survey / task description / interview questions

### As applicable, for example:

- Debrief document for participants
- Permission letter from the gatekeeper organisation
- Health & Safety Risk Assessment form
- Protocol (step-by-step researcher instructions)



### Templates and useful links

### **Eng & Inf ethics pages:**

http://www.sussex.ac.uk/ei/internal/research/researchgov

#### **University ethics pages:**

http://www.sussex.ac.uk/staff/research/governance/apply

### Psychology ethics pages (accessible to all Schools):

http://www.sussex.ac.uk/psychology/internal/hse

#### **Ethics A-Z:**

http://www.sussex.ac.uk/staff/research/governance/apply/ethics\_a\_z

### **Information and Classification Handling Policy:**

http://www.sussex.ac.uk/ogs/documents/information-classification-and-handling-policy---feb-21-final.pdf



# Questions?

