European Social Survey

European Research Infrastructure Consortium (ESS ERIC)

Research Ethics Committee
Terms of Reference

December 2017

Role:

The role of the ESS ERIC Research Ethics Committee (REC) is to:

- Provide advice on the possible ethical implications of research carried out by or on behalf of ESS ERIC.
- Review and then approve or reject applications for research studies involving human participants and/or the processing of personal data which are contracted directly by ESS ERIC.

It is anticipated that around 3-4 applications for ethical approval will be submitted to the REC during each two-year survey lifecycle. This will include plans for questionnaire pre-testing in each survey round plus any new data collection projects contracted directly by ESS ERIC. New questions for each round will also be submitted to the REC prior to the finalisation of the source questionnaire.

Outside of formal applications for ethical approval, the ESS ERIC Director may wish to consult the REC, for advice on ethical matters. This may include, but is not limited to, asking the REC to review the text outlining ethical requirements in the ESS Specification to countries or to provide informal advice on new projects prior to submission of a formal application for ethics approval.

The REC is convened by the ESS ERIC Director on behalf of the ESS ERIC General Assembly.

Codes of Practice:

In accordance with the ESS ERIC Statutes (Article 23.3), the ESS ERIC subscribes to the Declaration on Professional Ethics of the International Statistical Institute.

Membership:

- Membership of the Committee will consist of:
    - One member of the ESS ERIC Methods Advisory Board;

- One member of the ESS ERIC Scientific Advisory Board;
- Three external members with appropriate expertise in both research ethics and survey research;
- One ESS ERIC National Coordinator;
- The ESS ERIC Data Protection Officer (ex-officio).

- Members will be appointed by the ESS ERIC Director in consultation with the Deputy Director - Methodological and Deputy Director - Scientific from applications received. Appointments will be made on the basis of relevant experience whilst taking account the need to maintain a balance in terms of gender and geographic representation.
  - The external members will be selected from applications to an open call advertised via the ESS website, ESS ERIC committee mailing lists and relevant professional mailing lists (e.g. ESRAnet);
  - The NC representative will be selected from applications to a separate call open to all National Coordinators of ESS member or observer countries in post at the time the call is issued;
  - Members of the Methods and Scientific Advisory Boards interested in serving will be invited to submit their application to the ESS ERIC Director.

- Members will serve for a four year term (renewable).

- Members will be responsible for electing their own Chair from among the appointed members. The Chair will serve for four years (renewable). If the Chair is unavailable the Members may elect another to serve as Chair until the Chair is available for their duties.

- A member of research staff at ESS ERIC Headquarters will act as secretary to the REC and manage the receipt and circulation of ethics applications to and feedback from the REC.

Operational details:

- Following an initial face-to-face meeting the business of the REC will normally be conducted by email or virtual meeting. In exceptional circumstances, if a research project is considered to pose significant ethical challenges requiring additional

scrutiny or discussion, the Chair may request a face to face meeting of the REC before reaching a decision.

- Applications for ethics approval of research projects directly contracted by ESS ERIC will be submitted to the REC in advance of the research commencing using a standard form. The current form is provided in Annex 1.
    - Applications will be sent to the REC by the secretary. The Chair is responsible for collating comments from REC members and agreeing on an official response to the application. The Chair will then communicate this response to the REC secretary. This response may take the form of:
        - Approval of the application
        - Approval of the application subject to further clarification/
        - amendment
        - Rejection of the application

    - Each application must be reviewed by and receive approval from at least one ordinary member of the REC, plus the Chair and Data Protection Officer.
    - The REC should provide a response to applications within three weeks of receipt. Justification for the REC's decision should be provided.
    - Ethics applications will be accompanied (where relevant) by a detailed Data Handling Protocol. This protocol will be reviewed, agreed and monitored by the Data Protection Officer.

- Once an approved project is in progress, ESS ERIC will undertake to inform the REC if the implementation needs to change significantly from the approach outlined in the ethics application. The Chair, in consultation with other REC members, will review the proposed changes and notify ESS ERIC if, in their view, the revised approach raises any additional ethical considerations that have not been addressed.

- A record of all applications to and correspondence with the REC will be maintained by the REC secretary.

- Requests for informal advice will be circulated to the REC via email. Any member willing and able to provide advice should respond directly to the REC secretary.

Remuneration:

- Members will serve in a voluntary capacity though any travel expenses incurred in pursuit of the role will be reimbursed by ESS ERIC in line with City, University of London procedures.

- ESS ERIC will purchase insurance to indemnify members of the REC in the conduct of their duties.

ANNEX I: Research Ethics Application Form

For the attention of: ESS ERIC Research Ethics Committee

Application for Approval of Research Involving Human Participants commissioned/funded by ESS ERIC

Project Title:
Name of Principal Investigator(s):
ESS ERIC Institution
ESS ERIC HQ, Email contact details of responsible staff member(s):
External Body details
Date of Submission of Application:

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1. Project details

Title (no more than 80 characters)

Lay Summary / Plain Language Statement (no more than 400 words)

2. Investigators

Please describe the role(s) of all the investigators including external co-investigator(s) in the project, especially with regards to interaction with study participants.

(i) Information on ESS ERIC investigators

(ii) Information on external investigators

For each Name and email address Planned role:

2.a Application Details

2.1 Is this application, or any part of this application, being submitted to any other ethics committee, or has it been previously submitted to an ethics committee?
YES ☐ NO ☐

If yes, please provide details for the Secretary for the relevant authority/committee, as well as copies of any correspondence setting out conditions of approval.

2.3 Other approvals required – has permission to conduct research in, at or through another institution or organisation been obtained? **YES ☐ NO X**

If yes, please provide details and include correspondence

2.5 Duration of Project
Start –end dates

2.b Funding Details

2.6
ESS ERIC Work Programme YES ☐ NO ☐

Horizon 2020 Grant YES ☐ NO ☐

Other YES ☐ NO ☐

2.6a Total amount of funding for this project

2.6c Does the funding body have any requirements regarding retention, access and storage of the data? **YES ☐ NO ☐**

If yes, please provide details

2.c International Research

2.7 Is any part of the research taking place outside of England/Wales? (if not go to section 3) **YES ☐ NO ☐**

If yes, please provide details of where it will take place

2.7a Have you identified and complied with all local requirements concerning ethical approval & research governance*? **YES☐ NO ☐**

2.7b Has the contractor/tenderer been required to identify and comply with all local requirements concerning ethical approval & research governance*? **YES☐ NO**

For 2.7a and 2.7b Please provide details

2.7c Please give contact details of a local person identified to field initial complaints so the participants can complain without having to write to or telephone the UK

*Please note many countries require local ethical approval or registration of research projects., Some require specific research visas. If you do not abide by the local rules of the host country you may run the risk of legal action within the host country.

3. Project Details

3.1 Provide the background, aim and explanation for the proposed research.

3.2 Provide a summary and brief explanation of the design, methodology and plan for analysis that you propose to use.

3.3 Please explain your plans for dissemination, including whether participants will be provided with any information on the findings or outcomes of the project.

3.4 What do you consider are the ethical issues associated with conducting this research and how do you propose to address them?

3.5 How is the research intended to benefit the participants, third parties and/or local community?

3.6a Will invasive procedures (for example medical or surgical) be used?
YES ☐ NO ☐

3.6b If yes, what precautions will you take to minimise any potential harm?

3.7a Will intrusive procedures (for example psychological or social) be used?
YES ☐ NO ☐

3.7b If yes, what precautions will you take to minimise any potential harm?

N/A

3.8a In the course of the investigation might pain, discomfort (including psychological discomfort), inconvenience or danger be caused? YES ☐ NO ☐

3.8b If yes, what precautions will you take to minimise any potential harm?

N/A

3.9 Please describe the nature, duration and frequency of the procedures?

N/A

4. Information on participants

4.1a Planned number of participants:

4.1b What is the age group and gender of the participants?

4.1c Explain how you will determine your sample size and the selection criteria you will be using. Specify inclusion and exclusion criteria. If exclusion of participants is made on the basis of age, gender, ethnicity, race, disability, sexuality, religion or any other factor, please explain and justify why.

4.2 How are the participants to be identified, approached and recruited, and by whom?

4.3 Describe the procedure that will be used when seeking and obtaining consent, including when consent will obtained. Include details of who will obtain the consent, how are you intending to arrange for a copy of the signed consent form for the participants, when will they receive it and how long the participants have between receiving information about the study and giving consent.

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4.4 How will the participant's physical and mental suitability for participation be assessed? Are there any issues related to the ability of participants to give informed consent themselves or are you relying on gatekeepers on their behalf?

4.5 Are there any special pressures that might make it difficult to refuse to take part in the study? Are any of the potential participants in a dependent relationship with any of the investigators (for instance student, colleague or employee) particularly those involved in recruiting for or conducting the project?

4.6 Will the participant's doctor be notified? **YES ☐ NO ☐**
(If so, provide a sample letter to the subject's GP.)

4.7 What procedures are in place for the appropriate referral of a study participant who discloses an emotional, psychological, health, education or other issue during the course of the research or is identified by the researcher to have such a need?

4.8 What steps will be taken to safeguard the participants from over-research? (I.e. to ensure that the participants are not being used in multiple research project.)

4.9 Where will the research take place?

4.10 What health and safety issues, if any, are there to consider?

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4.11 How have you addressed the health and safety concerns of the participants, researchers and any other people impacted by this study? (This includes research involving going into participants' homes.)

4.12 Has a risk assessment been undertaken for the project?

YES ☐ NO ☐

4.13 Are you offering any incentives or rewards for participating? YES ☐ NO ☐

If yes please give details

5. Vulnerable groups

5.1 Will persons from any of the following groups be participating in the study? (if not go to section 6)

Adults without capacity to consent	☐
Children under the age of 18	☐
Those with learning disabilities	☐
Prisoners	☐
Vulnerable adults	☐
Young offenders (16-21 years)	☐
Those who would be considered to have a particular dependent relationship with the investigator (e.g. those in care homes, students, employees, colleagues)	☐

5.2 Will you be recruiting or have direct contact with any children under the age of 18?

YES ☐NO ☐

5.2a If yes, please give details of the child protection procedures you propose to adopt should there be any evidence of or suspicion of harm (physical, emotional or sexual) to a young person. Include a referral protocol identifying what to do and who should be contacted.

5.2b Please give details of how you propose to ensure the well-being of the young person, particularly with respect to ensuring that they do not feel pressured to take part in the research and that they are free to withdraw from the study without any prejudice to themselves at anytime.

5.3 Will you be recruiting or have direct contact with vulnerable adults? YES ☐ NO X

5.3a If yes, please give details of the protection procedures you propose to adopt should there be any evidence of or suspicion of harm (physical, emotional or sexual) to a vulnerable adult. Include a referral protocol identifying what to do and who should be contacted.

5.3b Please give details of how you propose to ensure the well-being of the vulnerable adult, particularly with respect to ensuring that they do not feel pressured to take part in the research and that they are free to withdraw from the study without any prejudice to themselves at anytime. You should indicate how you intend to ascertain that person's views and wishes.

5.4 Will you be recruiting any participants who fall under the Mental Capacity Act 2005?
YES ☐ NO ☐

If so you MUST get approval from an NHS NRES approved committee (see separate guidelines for more information).

6. Data Collection

6.1a Please indicate which of the following you will be using to collect your data
Please tick all that apply

Questionnaire	☐
Interviews	☐
Participant observation	☐
Focus groups	☐
Audio/digital-recording interviewees or events	☐
Video recording	☐
Physiological measurements	☐
Quantitative research (please provide details)	☐
Other	☐
Please give details	

6.1b What steps, if any, will be taken to safeguard the confidentiality of the participants (including companies)?

6.1c If you are using interviews or focus groups, please provide a topic guide

7. Confidentiality and Data Handling

7.1 The provisions of the relevant Data Protection legislation will be adhered to:
YES ☐ NO ☐

7.1a Will the research involve:

• **complete anonymity of participants** (i.e. researchers will not meet, or know the identity of participants, as participants, as participants are a part of a random sample and are required to return responses with no form of personal identification)**?**	☐
• **anonymised sample or data** (i.e. an *irreversible* process whereby identifiers are removed from data and replaced by a code, with no record retained of how the code relates to the identifiers. It is then impossible to identify the individual to whom the sample of information relates)**?**	☐
• **de-identified samples or data** (i.e. a *reversible* process whereby identifiers are replaced by a code, to which the researcher retains the key, in a secure location)?	☐
• **subjects being referred to by pseudonym in any publication**	☐

arising from the research?	
• **any other method of protecting the privacy of participants?** (e.g. use of direct quotes with specific permission only; use of real name with specific, written permission only)	☐
Please give details of 'any other method of protecting the privacy of participants' is used	

7.1b Which of the following methods of assuring confidentiality of data will be implemented?
Please tick all that apply

• data to be kept in a locked filing cabinet	☐
• data and identifiers to be kept in separate, locked filing cabinets	☐
• access to computer files to be available by password only	☐
• storage at City University London (Host institution of ESS ERIC HQ)	☐
• stored at other site	☐
If stored at another site, please give details	

7.1c Who will have access to the data?
Access by named researcher(s) only **YES** ☐ **NO** ☐
Access by people other than named researcher(s) **YES** ☐ **NO** ☐

If people other than the named researcher(s), please explain by whom and for what purpose

7.2a Is the data intended for reuse or to be shared as part of longitudinal research?
YES ☐ **NO** ☐

7.2b Is the data intended for reuse or to be shared as part of a different/wider research project now, or in the future? **YES** ☐ **NO** ☐

7.2c Does the funding body (e.g. ESRC) require that the data be stored and made available for reuse/sharing? **YES** ☐ **NO** ☐

7.2d If you have responded yes to any of the questions above, explain how you are intending to obtain explicit consent for the reuse and/or sharing of the data.

7.3 Retention and Destruction of Data
7.3a Does the funding body or your professional organisation/affiliation place obligations or recommendations on the retention and destruction of research data?
YES☐ **NO** ☐

If yes, what are your affiliations/funding and what are the requirements? (
The default requirement is retention of data for 10 years

7.3bHow long are you intending to keep the data?

7.3c How are you intending to destroy the data after this period?

8. Curriculum Vitae

Brief descriptions of expertise to undertake the research

9. Declarations by Investigator(s)

- I certify that to the best of my knowledge the information given above, together with any accompanying information, is complete and correct.
- All data handled by the ESS ERIC research team will be anonymised prior to receipt
- I have attempted to identify all risks related to the research that may arise in conducting the project.
- I understand that **no** research work involving human participants or data can commence until **full** ethical approval has been given

Confirmation of adherence to the International Statistical Institute's Declaration of Professional Ethics ***(available on the ESS website: see http://www.europeansocialsurvey.org/about/index.html)***

Adherence to the ISI Declaration of Professional Ethics YES ☐ NO ☐

	Print Name	Signature
Principal Investigator(s)		
Date		

Researcher's checklist for compliance with the Data Protection Act, 1998

This checklist is for use alongside the *Guidance notes on Research and the Data Protection Act 1998*. Please refer to the notes for a full explanation of the requirements.

You may choose to keep this form with your research project documentation so that you can prove that you have taken into account the requirements of the Data Protection Act.

	REQUIREMENT	Insert X	Status
A	***Meeting the conditions for the research exemptions:***		
1	The information is being used *exclusively* for research purposes.		Mandatory
2	You are not using the information to support measures or decisions relating to *any* identifiable living individual.		Mandatory
3	You are not using the data in a way that will cause, or is likely to cause, substantial damage or substantial distress to any data subject.		Mandatory
4	You will not make the result of your research, or any resulting statistics, available in a form that identifies the data subject.		Mandatory
B	***Meeting the conditions of the First Data Protection Principle:***		
1	You have fulfilled one of the conditions for using personal data, e.g. you have obtained consent from the data subject. Indicate which condition you have fulfilled here:		Mandatory
2	If you will be using sensitive personal data you have fulfilled one of the conditions for using sensitive personal data, e.g. you have obtained explicit consent from the data subject. Indicate which condition you have fulfilled here:		Mandatory if using sensitive data
3	You have informed data subjects of: i. What you are doing with the data; ii. Who will hold the data; iii. Who will have access to or receive copies of the data.		Mandatory unless B4 applies
4	You are excused from fulfilling B3 only if all of the following conditions apply: i. The data has been obtained from a third party; ii. Provision of the information would involve disproportionate effort; iii. You record the reasons for believing that disproportionate effort applies, please also give brief details here: N.B. Please see the guidelines above when assessing disproportionate effort.		Required only when claiming disproportionate effort
C	***Meeting the conditions of the Third Data Protection Principle:***		
1	You have designed the project to collect as much information as you need for your research but not more information than you need.		Mandatory

D	***Meeting the conditions of the Fourth Data Protection Principle:***		
1	You will take reasonable measures to ensure that the information you collect is accurate.		Mandatory
2	Where necessary you have put processes in place to keep the information up to date.		Mandatory
E	***Meeting the conditions of the Sixth Data Protection Principle:***		
1	You have made arrangements to comply with the rights of the data subject. In particular you have made arrangements to: i. Inform the data subject that you are going to use their personal data. ii. Stop using an individual's data if it is likely to cause unwarranted substantial damage or substantial distress to the data subject or another. iii. Ensure that no decision, which significantly affects a data subject, is based solely on the automatic processing of their data. iv. Stop, rectify, erase or destroy the personal data of an individual, if necessary. Please give brief details of the measures you intend to take here:		Mandatory