# Human Participant Research at FIE[1] Policy

Last Updated: September 2023 by BS

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## Summary/Purpose Statement.

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The '**Human Participant Research at FIE'** policy offers a full outline of:

- Ethical conduct procedures
- Purpose of research
- Search committee information
- Templates

1 Based upon the Birkbeck University of London School of Social Sciences, History and Philosophy procedures: http://www.bbk.ac.uk/sshp/our-research/sshp-ethics-committee-and-procedures ii

## Section 1: Ethical Conduct

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All research that is carried out by FIE faculty, staff, and students that involves intervention or interaction with human participants, or the collection and/or study of data derived from living human participants, requires ethical approval no matter where the investigations are carried out or if ethical approval has been given by some other institution. There are not, and possibly cannot be, a completely firm set of criteria for classifying research as ethically acceptable. FIE faculty, staff, and students are required to abide by ethical principles such as justice, truthfulness, confidentiality, and respect for persons, but also to attend to the evolving understanding of how these principles are expressed in society at a particular time.

## Section 2: FIE's Research Committee

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The procedures of FIE's Research Committee are intended to balance the need to safeguard participants and researchers with an efficient and workable set of arrangements. In applying their procedures, the Committee members take account of the law as it applies to health and safety, and the protection of young people, together with the notion of 'reasonable precautions' against threats to the wellbeing of participants. The Committee has the duty to scrutinise all research involving human participants. When necessary the Committee shall call upon any other persons with proper expertise to assist them with their decisions. It has the power to approve or reject research on grounds of ethical acceptability. No research shall commence until it has met the conditions laid down by the Committee. FIE's Research Committee is made up of members of FIE's Teaching and Learning Committee. For Routine research three members will assess an application whereas for Non-Routine research the full committee will assess the application. For Routine applications two of the three reviewers must approve the submission and for Non-Routine research two-thirds of the full committee must approve the submission.

## Section 3: Classification of Proposed Research (Routine or Non-Routine)

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Faculty and staff members in the first instance are responsible for assessing the ethical status of their research and the research for those whom they supervise (see below for student projects) with reference to peers and appropriate ethical and professional codes. Faculty and staff must ensure that full records are kept of their assessment and they should follow the steps listed under 'Proposal Procedures'. Each project or piece of new research should be classified into one of two categories, as below:

### 3.1 Routine

This includes research projects which so closely follow previous research already given ethical approval that the ethical issues are identical, and projects that meet the Economic and Social Research Council's (ESRC) definition of having less than 2 minimal potential risk of harm to participants and others affected by the proposed research. The ESRC's guidance on what would normally be considered more than minimal risk is given in Section 1.2.3 of their Framework for Research Ethics. Such routine or minimal risk projects will likely be approved by FIE's Research Committee upon receipt of a completed Proposal Form.

### 3.2 Non-Routine

Research which has not previously been scrutinised by FIE's Research Committee and which cannot be classified as Routine. This also includes circumstances where:

- participants are to be subjected to questions, or other procedures which carry a risk of being harmful to their physical or mental wellbeing
- specific advice is needed on the nature of ethical problems and their solution
- during peer review or complying with the ethical principles outlined in this document unresolved ethical issues are apparent
- vulnerable populations are involved
- research involving groups where permission of a gatekeeper is normally required for initial access to members
- research which might appear to involve deception or which is conducted without participants' full and informed consent at the time when the study is carried out
- research involving access to personal information or confidential information on identifiable living individuals
- all cases of predictable media interest or sensitivity
- all cases where there is a conflict of interest
- an external agency requires certification of ethical approval

The Proposal Form and supporting documentation should be submitted as early as possible before the intended start date of the project as the faculty/staff/student researcher will be required to attend an FIE Research Committee meeting to discuss the proposal. As part of the proposal, applicants must confirm approval of sites for study. (For approval to conduct studies at FIE approval is granted by the FIE Leadership Team)

### 3.3 Student Projects

Student projects should be reviewed by the student's faculty supervisor before submission of the Proposal Form that must be countersigned by the supervisor(s). Faculty supervisor(s) are expected to attend an FIE Research Committee meeting along with the student if the project is deemed Non-routine.

### 3.4 A note about 'clinical' projects

By clinical, we mean projects which would require getting NHS ethics approval (now referred to as NRES) for research on patients or NHS staff.

**FIE faculty, staff, or students are not allowed to embark on projects requiring NRES.**

## Section 4: Proposal Procedures

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Complete a proposal form available from the Virtual Faculty Lounge on Moodle. Do not attach any documents; instead make sure all the relevant information is included in this form (e.g. interview questions or questionnaires). Electronically sign the form and if you are a student, pass it on to your faculty supervisor who must iii make sure, before electronically signing and emailing the form to academics@fie.org.uk, that they are satisfied that ethical issues have been properly considered and, if necessary, discussed in detail.

Please note that FIE does not permit any research with minors.

Completed proposals are submitted electronically (by the faculty supervisor in the case of student projects) to the FIE Research Committee via academics@fie.org.uk

### 4.1 Possible Outcomes

- Rejection of the proposal on ethical grounds. This would only occur if there were fundamental ethical issues with the research, as defined in this policy and by professional ethical guidelines.
- Referral back to the researcher or student so that the proposal can be amended to address ethical concerns. It is the responsibility of the applicant to make any recommended changes and re-submit the proposal form together with supporting documentation.
- Acceptance of a proposal as submitted.

### 4.2 Timeline

FIE's Research Committee attempts to give an initial response within one week of submission of a proposal but that response may be a request for more information from the researcher, required changes to the application, or notification of a Non-Routine review that involves the researcher meeting with the Research Committee. Should a full review be undertaken it could take up to a month to schedule a meeting with the Research Committee who then may ask for revisions and resubmission. Researchers should allow at least six weeks from initial submission of the proposal to obtaining Research Committee approval and beginning the research.

References:


- American Psychological Association. (1982) Ethical Principles in the Conduct of Research with Human Subjects
- Economic and Social Research Council web pages: http://www.esrcsocietytoday.ac.uk/about-esrc/information/researchethics.aspx
- Gregg, V.H. & Jones, D. (1990). Ethics Committees. The Psychologist, 3, 162-165
- The Research Ethics Guidebook web pages on permission and approval: http://www.ethicsguidebook.ac.uk/Permission-and-approval-Key-questions-79
- UK University Research Ethics Committees Forum web pages hosted by King's College London: http://www.kcl.ac.uk/research/ethics/training/ukurecforum.html
- The following are in the Birkbeck Library:
    - Bersoff, D.N. (1995). Ethical conflicts in Psychology
    - Kimmel, A.J. (1996). Ethical issues in behavioral research: a survey
    - Walrond-Skinner, S. & Watson, D. (1987). Ethical issues in family therapy

## Appendix 1: FIE: Foundation for International Education Proposal to Conduct Research Involving Adults (over 18 years) Submission to FIE's Research Committee

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Please note:

- FIE does not permit research involving minors or requiring NRES (clinical) approval
- Do not attach any documents; instead make sure all the relevant information is included in this form (e.g. interview questions or questionnaires)
- Faculty/Staff must complete all the relevant sections in this form
- Student's ethics form can only be submitted by a faculty supervisor not the student.
- Expand sections for answers as necessary. Do not remove any questions – you must answer them all.

1. Name of researcher:

2. Status (e.g. faculty, staff, student):

3. Name of faculty supervisor/mentor (if researcher is student/staff member):

4. Course (if FIE class-based research) and/or Home Campus (of student or faculty mentor):

5. Contact address for researcher:

6. Telephone number: Mobile: Email:

7. Date of Application: Proposed research starting date:

8. Reference Number(s) of any previous related applications:[2]

9. Is any other Research/Ethical Committee involved? ☐Yes ☐No

If YES, give details of committee, stage of process/decision, enclosing any relevant documentation:

10. Title of study:

11. Aims/objectives of the study (Max 1 page):

12. Rationale: Which are the main theoretical debates or research traditions within which your research question is framed and becomes relevant? (Max 1 page):

[2] Only for 'routine' proposals

## 1.1 Participants

13. How will participants be selected?

14. Any inclusion/exclusion criteria?

15. Where will the study be conducted?

16. Do you have advance permission to conduct your research at all of your locations? ☐Yes ☐No

If YES, provide name(s) and position(s) for each site:

## 1.2 Materials and Procedures

17. Briefly describe what participating in the study will involve. (Max 1 page):

18. Equipment/facilities to be used (if not included in answer to 16). Please provide details of questionnaires[3], interview schedules etc., and include copies. Comment on content area of questionnaires, could any questions cause distress or offence? Invade privacy? Is there a strong rationale for conducting this research in spite of this risk? How would this risk be managed? (Max 2 pages):

When thinking about this question please bear in mind that according to ethics guidelines researchers have a duty of care towards the participants, FIE, and their own safety. (Please read carefully the Ethics guidelines at the end of this document for further details). Additionally, you are required to be mindful of another criterion as described in the Section 1.2 of the College Ethics Responsibilities and Procedures:

1.2 Ethical requirements arise from an evolving understanding of the rights and duties of human beings. Ethics are broader than law, though the law can both reflect and clarify ethical duties. School staff are part of a changing social system. They are, therefore, required not only to abide by ethical principles such as justice, truthfulness, confidentiality and respect for persons, but also to attend to the evolving understanding of how these principles are expressed in society at a particular time.

Researchers are required to demonstrate a critical stance towards the assumptions and beliefs underpinning their proposal, so not to reproduce stereotypical and prejudicial views of participants. This is particularly crucial when dealing with vulnerable and disadvantaged populations.

19. How will you find/access potential participants? (Include details of any relevant documentation e.g. letter to manager, advert, notice to go on notice board.):

[3] Please note that some questionnaire studies (e.g. when questionnaires are non-contentious, are administered anonymously and online) are likely to be 'routine'

## 1.3 Informed Consent

20. Potential participants must give free and informed consent. You need to provide sufficient information about your study in an information sheet or note for participants. This needs to explain confidentiality and right to withdraw. Please modify the template information sheet at the end of the form so it is appropriate for your study.

Tick one entry here to explain how you will use the information sheet:

☐ Information sheet distributed to each participant

☐ Information sheet displayed on screen for all participants

☐ Information included in header of questionnaire

☐ Other (specify):

21. Participants must sign a consent form to indicate consent. Participants must sign two copies – participant keeps one, you keep the other. Please modify the consent form at the end of this application form so it fits your study. The only exception to this is if you do not meet your participants because you send a questionnaire through the post to participants, or they respond to an online questionnaire, or the questionnaire is administered face to face in the street, in which case their completion of the questionnaire signals consent. In all these cases, you will need to ensure that participants have read or otherwise been informed of the consent statement contained below. How will you obtain consent?

☐ Signed consent form attached to end of this application form

☐ Postal or online questionnaire study

## 1.4 Confidentiality

22. It is important that you respect the confidentiality of your participants. [4] You should only record identifying information if necessary and wherever possible it should be kept separate from the data. Possible ways of doing this are: data is coded and the key linking the code and the participants' identities are kept in a separate locked cabinet from the data. All data with identifying information must be kept in a locked cabinet. Particular care needs to be taken with interviews. Names should be changed on transcripts and tapes locked up. Please describe here how you will maintain the participants' confidentiality in this particular study?

[4] If anonymity is not required, or if knowing the identity of the participant is integral and necessary information for the project, you will need to clearly state why this is the case. In such circumstances, you will need to provide participant's written consent to their names or other identifiers being used or detail how you will use pseudonyms to protect participants' true identities.

23. If the answer to any item below is YES please give details and outline how you will ensure the participant's well-being. Does the study involve:

(a) Unpleasant stimuli or unpleasant situations? ☐

(b) Invasive procedures? ☐

(c) Deprivation or restriction (e.g., food, water, sleep)? (d) Drug administration? ☐

(e) Any procedure which could cause harm to the participant? ☐

(f) Any groups of participants whose physical/mental health could be put at risk? ☐

(g) Actively misleading or deceiving the participants? ☐

(h) Withholding information about the nature or outcome of the study? ☐

(i) Any inducement or payment to take part in the study ☐

(j) Any procedure that might inadvertently cause distress to the participant? ☐

If the answer to (j) is YES; you will need to prepare for the possibility of a participant becoming distressed. We suggest the following: if the participant shows any sign of distress, their wellbeing, rather than data collection, has to be your priority. It is advisable to ask the participant if they would prefer to stop the process. They might want to talk to you about what is distressing them. Be mindful of boundaries and that the participant might benefit from professional help which you are not in the position, nor under obligation to provide. In such eventuality, you need to have information about support services available to offer to the participant in the unlikely event that they do indeed become very upset.

Outline how you will ensure the participant's wellbeing here:

Please consult your supervisor or experienced colleagues to prepare yourself before embarking on your research.

24. If you feel the proposed investigation raises other ethical issues please outline them here:

My study conforms to the expectations of ethical psychological/social/ sociological research

Electronic SIGNATURE of investigator: Date:

If this is a student project, the supervisor must read the application carefully, and answer the following questions and sign below.

It is the supervisor's responsibility to send proposals to FIE's Research Committee for approval

I have read the application and/or discussed its ethical implications with the student and confirm that in my view all ethical issues have been addressed: ☐

I consider the application routine because it does not raise ethical issues beyond those of a study which has already received school ethics approval: ☐

I consider the application non-routine and believe it needs to be assessed by FIE's Research committee: ☐

Electronic SIGNATURE of supervisor: Date:

Completed forms should be sent ELECTRONICALLY ONLY to FIE's Research Committee: academics@fie.org.uk

Researcher: keep a copy of the form for your files.

Allow sufficient time for this process.

You MUST NOT begin collecting data from participants until approval has been received.

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For Research Committee Use:

FIE Research Committee Reference Number:

Routine / Non-Routine

Approved: Yes / No / With Revisions

Do Revisions require re-submission: Yes / No

Comments:

## Appendix 2: Template Information Sheet and Consent Form

** These should be completed/modified so they fit your own study**

Sample information sheet

FIE: Foundation for International Education

Foundation House

114 Cromwell Road

London

SW7 4ES 0207-591-7750

Title of Study:

Name of researcher:

As a student of this study is being done as part of my London study abroad experience for course. The study has received ethical approval from FIE's Research Committee.

This study seeks to explore

If you agree to participate you will agree a convenient time and place for me to interview you for about . You are free to stop the interview and withdraw at any time.

Every attempt will be made to ensure the information you provide remains anonymous.

The analysis of our interview will be written up in a report of the study for my course. You will not be identifiable in the write up or any publication which might ensue.

The study is supervised by who may be contacted at the above address and telephone number.

Thank you for your time and consideration.

Sample Consent Form

Title of Study:

Name of researcher:

I have been informed about the nature of this study and willingly consent to take part in it.

I understand that every attempt will be made to ensure the information I provide will remain anonymous.

I understand that I may withdraw from the study at any time.

I am over 18 years of age.

Name _____

Signed _____

Date _____

There should be two signed copies, one for participant, one for researcher.

## Appendix 3: Research Ethics General Guidance

Ethical approval for all research. Ethical approval is required for all research that involves human participants. This includes research where there is no face-to-face interaction between researcher and participants (e.g., postal questionnaires, telephone interviews, and Internet surveys).

Protection of participants. All researchers are obliged to protect the physical, social, and psychological wellbeing of their participants, to preserve their dignity and rights, and to safeguard their anonymity and confidentiality.

Informed consent. Article 17 of the Protocol to the Convention on Human Rights in Biomedicine or Biomedical Research states: 'No research on a person may be carried out without the informed, free, express, specific and documented consent of the person'. This places a legal obligation on researchers to obtain and record consent from participants or their guardians, on the basis of information that should be given to them before their participation begins.

No coercion. There should be no coercion in the recruitment of participants.

The right to withdraw. There is an obligation on participants to participate in research for which they have volunteered. Nevertheless, participants must be given the right to withdraw from any given research, at any time without penalty and without providing reason. Participants can also require that their data are withdrawn from the study.

Anonymity and confidentiality. Participants must be assured that all information they give will be treated with the utmost confidentiality and that their anonymity will be respected at all times unless otherwise determined by law (for example, in the case of records maintained by the Prison Service). Where relevant, participants should be told about where information about them will be stored, who will have access to it, and what use will be made of it. Procedures for data storage must conform to the Data Protection Act. Express permission must be obtained for any non-confidential use of participant information. Express permission must also be obtained for access to specified information from confidential records, e.g. medical notes, or educational attainment records. Where relevant, any limitations to confidentiality (for example obligations under law, or where there may be a threat to self or others) must be explained.

Appropriate exclusion criteria. Recruitment of participants for a given study should apply exclusion criteria that protect the health and well-being of participants (for example, exclusion on the grounds of psychological vulnerability or a pre-existing medical condition).

Monitoring. Researchers are obliged to monitor ongoing research for adverse effects on participants and to stop the research if there is cause for concern about their well-being.

Duty of care. There is a duty of care on researchers to ameliorate any adverse effects of their research on participants (either personally or by referral to an appropriately qualified person). As a general rule, researchers should debrief participants at the end of the research either verbally or in writing.

Additional safeguards for research with vulnerable populations. Special safeguards need to be in place for research with vulnerable populations. Vulnerable populations include schoolchildren, people with learning or communication difficulties, patients in hospital, or people under the care of social services, people in custody or on probation, and people engaged in illegal activities, such as drug abuse. For example, research with vulnerable populations may require Criminal Records Bureau clearance; research with schoolchildren also requires that parents or guardians be informed d about the nature of the study and the option to withdraw their child from the study if they so wish.

Appropriate supervision. Student investigators must be under the supervision of a member of Academic Staff. It is the supervisor's responsibility to ensure that the student is aware of relevant Guidelines and of the need to observe them.

How to obtain informed consent: In order that consent be 'informed', consent forms may need to be accompanied by an information sheet for participants setting out information about the proposed study (in clear and simple terms) along with details about the investigators and how they can be contacted. If applicable, this sheet may also make reference to any screening procedures, the confidentiality of the data, any risks involved, and any other points which participants might reasonably expect to know in order to make an informed decision about whether they wish to participate, and which are not included on the informed consent form.

A checklist of points on the informed consent form that participants are expected to sign might typically include: (a) That their participation is voluntary, (b) That they are aware of what their participation involves, (c) That they are aware of any potential risks (if there are any), (d) That all their questions concerning the study have been satisfactorily answered. Documented consent may be signed or initialled (if participants wish to maintain anonymity). In situations where information about the research and participant consent is conveyed verbally, it is recommended that the information be recorded on and read from or cued by a written information sheet; verbal consent should also be taped in order to provide a record.

Added safeguards may be required to obtain informed consent with vulnerable populations. For example, research with children in schools cannot take place without the permission of the head teacher and teacher responsible for the children. Where they are competent to give it, informed consent should also be obtained from the children themselves. In addition, parents or guardians should be given all relevant details of the study (in a letter) along with an opportunity to withdraw their child from the study if they so wish (passive consent). If the school requires it, parents may also be required to return signed consent forms (active consent).

This document is modified from the Guidelines for minimum standards of ethical approval in psychological research, British Psychological Society:
www.bps.org.uk/downloadfile.cfm?file_uuid=2B522636-1143-DFD0-7E3DE2B3AEFCACDE&ext=pdf

Further detailed recommendations regarding ethical considerations can be found in the Statement of ethical Practice for the British Sociological Association:
www.britsoc.co.uk/equality/Statement+Ethical+Practice.htm