IICSA

Ethical Approval Form

When completing this form please ensure that you read and comply with the following:

Researchers must demonstrate clear understanding of and engagement with the following ethical principles :

- ***Respect*** for the autonomy, privacy and dignity of individuals and communities - maximising benefit and minimising harm, including providing appropriate support for those that wish to provide information to the Inquiry;
- ***Ensure*** that data will be stored, shared, preserved and disposed of in an appropriate and responsible manner;
- ***Demonstrate*** clearly the steps taken to ensure confidentiality of data provided to the IICSA and/or those working on behalf of the Inquiry and the circumstances in which confidentiality may be overridden; and
- ***Ensure*** that information provided to the Inquiry is only used in published research with the informed consent of those providing the data.

General Information

Please return the completed Ethical Approval Form to research@iicsa.org.uk. The form will be submitted to the IICSA Research Ethics Committee for consideration and approval.

Title of Research:
Main contact in the research team:
Please provide names of any collaborators/consortium members:
Proposed study start date:
Proposed study end date:
Signature of lead researcher: **Date:**

Ethical Approval from other sources		**Evidence to be provided**
1) Does the research require approval from an ethics or research governance committee external to the Inquiry?	Yes ☐ No ☐	Please include list of all relevant ethical bodies
2) Has ethical approval for this research been granted by a Research Ethics Committee external to the Inquiry?	Yes ☐ No ☐	Please provide copy of ethical approval or application documents, if awaiting approval and estimated date of approval.

Research staff		**Evidence to be provided**
3) Have all staff involved in the research been properly trained and briefed about the content of the study e.g *(Research methods, Data Protection training, child protection training, procedures for dealing with disclosures of abuse)*	Yes ☐ No ☐	Please provide details.
4) Have all staff involved in undertaking this research been subject to appropriate checks i.e. for most projects and for any projects involving research directly with children or vulnerable adults, staff must have DBS clearance.	Yes ☐ No ☐	Provide details/copies of checks.

Routing Questions	**Yes/No**
5) Does the study involve analysis of personal information, whether primary or secondary data? This would not usually include tertiary analysis, where only existing published literature is being synthesised.	Yes ☐ No ☐
If YES: Go to Section 1 **If NO: Go to Section 5**	

Section 1 Recruitment and consent			
	Yes/No	**Information to be provided**	**Evidence to be provided**
5) Does your research involve human participants?	Yes ☐ No ☐	Confirm that informed consent will be obtained.	Consent forms and information sheets to be included.
6) Are participants volunteering to participate in the research?	Yes ☐ No ☐	Provide details of sample frame, recruitment, whether an opt in or opt out process, inclusion and exclusion criteria and your procedures for gaining informed consent.	Recruitment flow diagram/description; consent forms and Information sheets to be included.
7) Are vulnerable adults or groups involved in the research? *Vulnerable individuals include: children and young people, elderly, offenders, those with illness (physical or mental*	Yes ☐ No ☐	If no, please state why you do not feel your participants are vulnerable. Provide details on type of vulnerability.	Consent forms and Information sheets to be included. Information in relation to recruitment procedures to

cognitive) people at risk of exploitation, homeless people, victims/survivors of abuse).		Provide details of recruitment, inclusion and exclusion criteria, steps you are taken to enable participation, and informed consent procedures. These must demonstrate appropriate efforts to ensure people are fully informed of the implications of participation.	be included. Provide copies of NRES Committee approval (if applicable).
8) Are participants children young people?	Yes ☐ No ☐	Provide details on age of children/young people. Provide details of children/young people assent procedures and parental consent. Provide details of measures intended to take to ensure welfare of children/young people. Provide details where children/young people are in care or custody, including whose consent will be sought.	Details of how consent from responsible adult will be obtained to be included. Information in relation to measures to protect and promote the welfare of children/young people to be provided.
9) Are participants unable to give independent informed consent? (including children/young people) *Please see Appendix 1 for additional information and guidance regarding consent and refer to Gillick competency assessment in determining ability to consent.*	Yes ☐ No ☐	Provide details of procedures for obtaining approval from guardian/legal representative and agreement of children. Provide details on measures you intend to take to ensure that there is no coercion on participants and how consent from both	Informed Consent forms and Information sheets to be included.

		the guardian and young person will be obtained independently.	
10) Are participants able to withdraw consent from the research?	Yes ☐ No ☐	Please provide details of how withdrawal of consent will be communicated to participants and details of any restrictions on withdrawal (e.g. timeframes).	Please provide details of procedures for withdrawal of consent.
11) Will the research make use of gatekeepers or third parties to access participants?	Yes ☐ No ☐	Provide details of how third parties or gatekeepers will be involved and how they will gain consent from participants.	Provide copy of signed gatekeeper consent or set out intended process for obtaining this
12) Will information be gathered on participants from a third party?	Yes ☐ No ☐	Please give details of what will be gathered from the third party and how consent and safeguarding issues will be addressed.	
13) Will it be necessary for participants to be involved without consent? (e.g. analysis of open source online material, covert observation in public places)	Yes ☐ No ☐	If Yes: Provide details of how you will access the data covertly and any safeguarding processes to prevent harm to participants.	
14) Will the research investigate/ potentially uncover any illegal activity/ identify children or adults at risk of significant harm? *Please see Appendix 2 for a definition of risk of significant harm in relation to children.*	Yes ☐ No ☐	Provide a disclosure protocol that sets out detail of when and how confidentiality agreements may need to be breached and procedures for reporting illegal activity to the relevant authorities. Please provide safeguarding procedures for the protection of children or adults at risk of	Please provide details of steps to be taken if children or adults at risk of significant harm are identified during research.

		significant harm identified during research.	
15) Will the research involve intrusive interventions? (e.g. provision of drugs to participants, hypnosis, physical exercise, blood or tissue sampling)	Yes ☐ No ☐	Provide copies of Ethical approval to undertake interventions	Provide details for obtaining informed consent.
16) Will any incentives or inducements be offered to participants?	Yes ☐ No ☐	Please provide details of type and amount of incentive.	
17) What have you done to make sure that all people in your research population can take part in the research (e.g. language issues, communication aids, out of working hours appointment times etc)?		Please provide details of steps taken to facilitate participants to take part in research.	
18) Has a complaints procedure has been put in place to deal with complaints raised by research participants?	Yes ☐ No ☐	Please provide details of the complaints procedures.	Include information sheets which will be supplied to research participants.
Section 2: Managing sensitive topics			
19) Please outline any sensitive topics covered by the study. *It is anticipated that all research projects undertaken by or on behalf of IICSA will cover sensitive topics. Please consult the list in Appendix 3 at the end of this form for further information regarding what may constitute a 'sensitive' topic.*		Provide outline what sensitive information you will be asking about.	
20) Have arrangements been put in place to deal with any difficult dynamics (people who may become upset, uncomfortable, defensive or angry)?	Yes ☐ No ☐	Please detail how dynamics will be managed when covering sensitive topics.	
21) Could this research cause psychological stress or anxiety, or cause harm or negative consequences to participants beyond the risks in everyday life?	Yes ☐ No ☐	If yes, please describe the harm or distress that could be caused by taking part in the research and how you plan to deal with this. If no, please explain why you don't think that there is a risk of harm to	

		participants in the study.	
22) Are appropriate personal and confidential support services in place to support participants.	Yes ☐ No ☐	Please detail the support services available to participants - outline immediate and longer term support needs	
Section 3: Burden on participants			
23) Has consideration been given to the particular needs of participants in terms of the length, format and venue for interviews/participation?	Yes ☐ No ☐	Please provide details of how the venue and format of the interviews/survey completion/other form of participation will accommodate the needs of participants - e.g. allowing for comfort breaks, environment for interviews and convenience of venue etc.	
24) How many times will an individual be interviewed, observed or asked to complete a questionnaire?			
25) How long will the total interview/questionnaire/focus group/observation take?			
26) Please give details on the length of the interview/questionnaire/focus group. If it is longer than 60 minutes please outline what is being done to reduce burden on participants?		Please provide detail of anticipated length of time.	
27) Does this study follow-up people from a previous study?	Yes ☐ No ☐	If yes, please give details of participants' previous involvement and whether they have given consent to be contacted again.	
Section 4: Protection of Personal data			

28) Does your research involve personal data collection and/or further processing of previously collected personal data ('secondary use') (including use of pre-existing data sets or sources, merging existing data sets)?	Yes ☐ No ☐	Details on the source of the data. Details on procedures for data collection, storage, protection, retention, transfer, destruction or re-use (including, collection methodology (digital recording, picture, etc.), methods of storage and exchange (LAN, cloud, etc.), data structure and preservation (encryption, anonymisation, etc.), data-merging or exchange plan, commercial exploitation of data sets, etc.). Details on your data safety procedures (protective measures to avoid unforeseen, usage or disclosure, including mosaic effect, i.e. obtaining identification by merging multiple sources). Outline procedures for ensuring that participants anonymity is preserved in the publication of final reports. Set out arrangements for obtaining consent. Where applicable, confirm permissions by the owner/manager of the data sets.	
29) Does your research involve the collection or processing of sensitive personal data (e.g. health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction)	Yes ☐ No ☐		
30) Does your research involve covert or overt tracking or observation of	Yes ☐ No ☐	Details on methods used for tracking or observing	

participants (e.g. analysis of open source online material, covert observation in public places, surveillance or localization data, and Wan data, such as IP address, MACs, cookies etc.)?		participants and any safeguarding processes to prevent harm to participants.	
31) Will information be gathered on participants from a third party?	Yes ☐ No ☐	Please give details of what will be gathered from the third party and how consent and safeguarding issues will be addressed.	
Section 5: Risk to researchers		**Information to be provided**	**Evidence to be provided**
32) Has the potential physical and/or psychological harm to researchers, for example, through exposure to sensitive topics, been considered?	Yes ☐ No ☐	If Yes, outline the risk and how it will be managed?	Please outline the procedures to be followed to minimise risk of physical and psychological harm to researchers.
33) Have appropriate personal and confidential support services been put in place to support research staff undertaking the research.	Yes ☐ No ☐	Please detail the support services available to researchers.	

Section 6: Impact of publication of findings		**Information to be provided**	**Evidence to be provided**
34) Has the potential for a negative impact on victims/survivors of Child sexual abuse from the publication of the research been considered?	Yes ☐ No ☐	Outline how the dissemination of your research findings will address and mitigate the potential negative impact on victims and survivors.	

Agreement Regarding Intellectual Property

All Intellectual Property Rights in relation to information and findings of research commissioned by the Independent Inquiry into Child Sexual Abuse (IICSA) shall vest in IICSA. As applicable, such information and findings will be subject to Data Protection Act requirements.

The terms and conditions of appointment for Researchers will contain relevant detailed provisions relating to Intellectual Property Rights.

Decision of Research Ethics Boards

Research Project approved by Research Ethics Committee Yes ☐ No ☐

If not approved, please explain reason for refusal:

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Date: Signature of Chair of Research Ethics Committee:

Appendix 1: Consent

Where information is to be collected from individual participants, other than in very particular circumstances, consent will have to be obtained from those participants for any use of their information. Where the research exposes its participants to a risk of harm, the researcher has an ethical duty to consider these risks. Some participants will have diminished capacity to give consent and are therefore less able to protect themselves and require specific consideration. Please refer to the Gillick competency when determining whether a participant has capacity to provide informed consent.[1] Active consent from individuals should be sought wherever possible, in preference to passive or group assent, including through a gatekeeper.[2]

In the case of children and young people, researchers should carefully consider the child or young person's capacity to consent in light of their specific characteristics and circumstances as well as the nature of the research itself. Seeking permission from parents or other responsible adults should also be considered and is usually good practice. However, the potential risk of harm to participants which could be caused by discussing participation with parents or other responsible adults in some cases should also be considered[3]. Guidance from the NSPCC Research Ethics Committee advises that children aged 16 and over may be able to consent independently without approval being sought from parents or guardians; for children aged 12-15, consent should usually be sought from a parent or appropriate adult in addition to the child; and for children under 12 years, consent should be sought from parents or guardians in addition to assent from the child. The child's wishes will always be paramount and where a child dissents to participate this should always overrule and consent given by a parent or guardian.[4]

Research that does not entail the direct participation of living human persons may nonetheless indirectly but significantly affect living persons. Researchers may be assessing information about identifiable individuals, the publication or analysis of which may have ethical (and indeed legal) implications. For example, collection and use of archive, historical, legal, online or visual materials may raise ethical issues (e.g. for families and friends of people deceased), and research on provision of social or human services may impact provision for individuals and groups of service users who did not contribute or consent to, or were not consulted about the research. Researchers should so far as possible consider and describe the steps proposed to manage such implications.

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[1] See NSPCC description of the Gillick competency: https://www.nspcc.org.uk/preventing-abuse/child-protection-system/legal-definition-child-rights-law/gillick-competency-fraser-guidelines/

[2] See ESRC ethics framework: http://www.esrc.ac.uk/funding/guidance-for-applicants/research-ethics/frequently-raised-topics/research-with-potentially-vulnerable-people/

[3] See ESRC ethics framework: http://www.esrc.ac.uk/funding/guidance-for-applicants/research-ethics/frequently-raised-topics/research-with-children-and-young-people/

[4] See NSPCC research ethics committee guidance for further information: https://www.nspcc.org.uk/globalassets/documents/evaluation-of-services/research-ethics-committee-guidance-applicants.pdf

Appendix 2: Definition of significant harm

Coram Children's Legal Centre (CLC) provide a definition of significant harm in relation to children (accessed 13/03/2017).
http://www.protectingchildren.org.uk/cp-system/initial-assessment/actual-or-likely-significant-harm/

The Children Act 1989 defines 'harm' as "ill-treatment or the impairment of health or development". 'Development' means physical, intellectual, emotional, social or behavioural development; 'health' means physical or mental health; and 'ill-treatment' includes sexual abuse and forms of ill-treatment which are not physical. As a result of the Adoption and Children Act 2002, the definition of harm also includes "impairment suffered by hearing or seeing the ill-treatment of another".

According to Working Together, significant harm refers to "the threshold that justifies compulsory intervention in family life in the best interests of children, and gives LAs a duty to make enquiries to decide whether they should take action to safeguard or promote the welfare of a child who is suffering or likely to suffer significant harm".

The legislation, however, does not define the line between 'harm' and 'significant harm'. As a practitioner, you should give 'significant' its ordinary meaning (i.e. considerable, noteworthy or important). The child's particular characteristics also need to be taken into consideration. For example, a child left home alone at the age of 3 could be at risk of significant harm, whereas a child aged 13 years may be less likely so. The test will be subjective to the particular circumstances.

Whether the harm is significant is determined by comparing the child's health and development with what could reasonably be expected from a similar child. For example, if a child is failing to meet developmental or physical milestones, it is necessary to determine whether this is the result of a lack of "good enough" parenting. There is no clearly defined criteria to judge whether harm meets the threshold of 'significant'—it can be the result of a traumatic event or a compilation of acute and long-standing events. As highlighted in Working Together, "Some children live in family and social circumstances where their health and development are neglected. For them, it is the corrosiveness of long-term emotional, physical or sexual abuse that causes impairment to the extent of constituting significant harm."

Working Together lists the following as factors to consider in understanding and identifying significant harm:

- The nature of harm, in terms of maltreatment or failure to provide adequate care;
- The impact on the child's health and development;
- The child's development within the context of their family and wider environment;
- Any special needs, such as a medical condition, communication impairment or
- disability, that may affect the child's development and care within the family;
- The capacity of parents to meet adequately the child's needs; and
- The wider and environmental family context.

'Likely to Suffer'

A child being 'likely to suffer significant harm' does not mean that there is a more than 50 percent chance that the child will suffer or that it is more likely than not that the child will suffer significant harm. Rather, 'likely' in S. 31 refers to a 'real, substantial risk.' If a Court considers the likelihood of harm to be based on past events regarding which there are disputed facts, it must first make a

finding of fact before treating the past event as a grounding of future risk, as has been held by the Supreme Court in Re. S-B [2009] UKSC 17.

Appendix 3: Sensitive topics

Research involving sensitive topics such as participants':
sexual behaviour;
their legal or political behaviour;
offending behaviour
their experience of violence, abuse or exploitation;
their mental health;
their personal or family lives;
their gender.
ethnic status;

Appendix 4: Personal Data

This section concerns research which involves collecting or processing of personal data, regardless of the method by which they are/were collected (e.g. through interviews, questionnaires, direct online retrieval etc.).

Personal data' means any information, private or professional, which relates to an identified or identifiable natural person (for the full definition, Data Protection Act, 1998).

Examples: name, address, identification number, e-mail, CV, bank account number, phone number, medical records.

There are various potential identifiers, including full name, pseudonyms, occupation, address or any combination of these.

Individuals are not considered 'identifiable', if identifying them requires excessive effort.

Completely anonymised data does not fall under the data privacy rules (as from the moment is has been completely anonymised).

'Processing of personal data' means any operation (or set of operations) which is performed on personal data, either manually or by automatic means.

This includes:

- collection (digital audio recording, digital video caption, etc.)
- recording organisation and storage (cloud, LAN or WAN servers)
- adaptation or alteration (merging sets etc.)
- retrieval and consultation
- use
- disclosure by transmission, dissemination or otherwise making available

(share, exchange, transfer)
- alignment or combination
- blocking, deleting or destruction

Examples: creating a mailing list or a list of participants; managing a database; accounting records on personnel costs; time-sheets; project planning with names.

Processing covers normally any action that uses data for research purposes (including if interviewees, human volunteers, patients, etc. are not actively included in the research).

Data may come from any type of research activity (ICT research, personal records (financial, criminal, education, etc.), lifestyle and health information, family histories, physical characteristics, gender and ethnic background, location tracking and domicile information, etc.).

Your research must comply with:
- ethical principles
- applicable international, EU and national law (in particular, Data Protection Act 1998, and EU Directive 95/46/EC).

Under this Directive, personal data must be processed according to certain principles and conditions that aim to limit the impact on the persons concerned and ensure data quality and confidentiality. Certain categories of data are more 'sensitive' than others (e.g. health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction) and these may only be processed according to specific rules.

The Directive is currently under revision. Any changes in the legislation will have an effect on your research, and must therefore be monitored.

You may collect and process data only if and insofar as it is really **necessary** for your research.

Collecting personal data (for example, on religion, sexual orientation, race, ethnicity, etc.) that is not essential to your research may moreover expose you to allegations of 'hidden objectives' or 'mission creep' — i.e. information being collected with permission for one purpose and being used or made available, including online, for another reason, without additional permission.

You must moreover obtain: the necessary notifications/authorisations for collecting and processing the data (including specific authorisations, if applicable) free and fully informed consent of the persons concerned ('data subjects') (see section 2).

Specific cases:
Secondary use — If you use secondary data in your research, it must originate from a public source or be authorised for use in your research (either specifically for your research or generally for any secondary use).

Recording of information — Recorded information (audio and/or visual) will need special consideration by your data controller, to ensure that privacy and personal identities are protected.

Sensitive data — If you collect or process sensitive data (e.g. health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction), you may require a specific authorisation by the national data protection authority. If you collect or process health data, you should refer to the processes recommended in the Ilves report on e-health.

Tracking or observing of participants may require a specific authorisation from the national data protection authority.

Electronic data — Regarding the processing of personal data and the protection of privacy in the electronic communications sector, as well as the retention of data generated or processed in connection with the provision of publicly available electronic communications services or of public communications networks (e.g. cloud, big data, open data, cookies etc.), your research must comply with the relevant legislation (in particular Data Protection Act, 1998, EU Directive 2002/58/EC and 2006/24/EC).

Your research proposal must include the information indicated in the ethics issues checklist and any of the documents that are already available.
(For documents that are not yet available, provide an approximate timeline for their submission.)

Examples: If you are collecting personal information, interviewing, observing or tracking people, or recording data or audio/visual information, you need fully informed consent (see section 2) from your research participants and provide a clear description of the procedures that you will use for data control and anonymisation.