Childlight Research Ethics Policy: Metadata

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If you require this document in an alternative format, please email Childlight@ed.ac.uk or write to Childlight Global Child Safety Institute, University of Edinburgh, Third Floor, St John's Land, Holyrood Road, Edinburgh, UK, EH8 8AQ.

Childlight Global Child Safety Institute

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1 Introduction

Research is broadly conceived to include any form of disciplined inquiry undertaken by staff and students that aims to contribute to a body of knowledge or theory. Some consultancy, and knowledge exchange and impact activities, including public engagement, may also include activities that may be categorised as research. Research ethics involves the application of ethical principles to these research activities. These ethical principles are applied throughout the lifetime of a research project: from conception and design, via data collection and analysis, to dissemination, archiving of research materials, and beyond. Researchers have a responsibility to undertake their research with due diligence of all relevant ethical considerations.

Ethics is also a cornerstone of research integrity, with policies and procedures in place to support those undertaking high quality research. Researchers have an individual responsibility to ensure that they have an up-to-date working knowledge of relevant ethical issues for their research area, and that they have undertaken all mandatory research training required for their role (e.g., Data Protection Training, Information Security Essentials, Health and Safety), as well as specialist training relevant to their field or methods. Additionally, research leaders and supervisors have a responsibility to support others to work ethically. Researchers are responsible for ensuring that all of their research activities have undergone active, proportionate and appropriate consideration of ethical issues, risk/benefit balance, and are conducted in accordance with relevant University and national policy/guidelines. Where their research is subject to research ethics review, researchers have a responsibility to engage with the ethical review process in a respectful and conscientious manner.

All research activity within Childlight must have a proactive and deliberate ethics assessment. This includes, but is not limited to, Searchlight research projects, Into the Light global index research, external consultations and workshops, and public polling. This document sets out the mandatory steps and expectations for Childlight researchers based at the University of Edinburgh in understanding, seeking, obtaining and maintaining research ethics approval.

2 Research Ethics Committee

The Childlight Research Ethics Sub-Committee (CRESC) provides interdisciplinary review of research ethics applications for projects undertaken by Childlight researchers and, where

appropriate, postgraduate students whose projects fall fully under Childlight's governance. In most cases, student research projects will be reviewed through the School or College-level processes of their programme of study; however, CRESC may act as the review body for Childlight-governed student projects.

Governance

CRESC evaluations align with recognised standards for research ethics and integrity, including the [University of Edinburgh Research Ethics Policy](#) (December 2022) and relevant disciplinary guidelines. The CREASC evaluates ethics applications for research conducted by Childlight at, or in the name of, the University of Edinburgh, and is a Sub-Committee of the MHSES Ethics Committee, who formally provides the ethical governance for Childlight as the host School. The review process undertaken by the CRESC has been approved by the MHSES Ethics Committee, the Associate Dean for Research Ethics and Integrity, and the Dean of Research in CAHSS.

Membership and Expertise

CRESC brings together experts in fields relevant to Childlight's work on child sexual exploitation and abuse, including law, social work, childhood studies, and digital research. The group reviews its training needs annually, for example in relation to ethics or child sexual abuse research.

Remit

The remit of CRESC is to:
- Evaluate research ethics applications for research conducted by Childlight staff and students.
- Provide advice and support to Childlight researchers, to facilitate ongoing improvement in ethical aspects of research by means of contributing expert interdisciplinary perspectives on the ethics forms reviewed.
- Advise and support the Childlight Research ethics Sub-Committee Chair in ensuring continuous improvement of ethical review processes within CRESC.
- Stay informed of University, College, and external guidance on research ethics and integrity.
- Promote best practice in ethics and integrity across Childlight's research.
- Advise on professional development needs for the reviewer team.
- Liaise with the School and College Research Ethics Committees as required.

Operations

CRESC meets up to four times per calendar year. Lead researchers should plan ethics applications in advance to align with Sub-Committee group meeting dates. Meeting dates and submission deadlines are agreed between the Chair of the Childlight Research Ethics Sub-Committee and the Childlight Quality and Compliance Manager and communicated to staff via email and the Childlight Teams Channel.

3 Research Ethics Levels

There are three levels of increasing review that a research project may fall in to, as well as the option to request an exemption from ethics review. These levels are determined based on the perceived level of risk associated with a project.

The following categories of risk are indicative of those considered in determining ethics review level at Childlight. They should be taken into account when designing, reviewing, and conducting research. This list is not exhaustive but provides a framework to guide proportionate review and risk mitigation:

- Privacy and Confidentiality Risks
- Psychological and Emotional Risks
- Physical Risks
- Technology and Surveillance Risks
- Legal and Social Risks
- Integrity and Transparency Risks
- Researcher Safety Risks
- Benefit–Risk Balance

3.1 Exemption

3.1.1 Exemption based on methodology

Research that only uses scoping review or literature review methodology may be exempted from CRESC review, on the grounds that the data being used is already in peer-reviewed published form and therefore has gone through its own level of data cleansing or preparation for publication.

3.1.2 Exemption based on lead research organisation

Collaborative projects which have received ethical approval from another institution may be exempted from local MHSES review. Evidence for external review and a favourable outcome will need to be provided (application, approval letter and other documentation). This documentation will be considered by at least one reviewer with relevant disciplinary and/or methodological expertise for the project under consideration, and either confirm the exemption, or request that the project is taken for ethics review.

See Appendix 2 for further information on how to request an exemption from Childlight Research Ethics Sub-Committee review.

3.2   Level 1 (two reviewers)

Level 1 ethics review applies to research which meets all of the following criteria:
- There are negligible or low reasonably foreseeable risks to the participants, researcher/s, or third parties.
- Data processes do not pose a challenge to individual data security.
- There is no (reasonably perceived) conflict of interest.
- The data does not concern groups that may be construed as terrorist or extremist.

3.3   Level 2 (two reviewers)

Level 2 ethics review applies to research that may potentially carry low or moderate reasonably foreseeable risks to the participants, researcher/s, or third parties. Level 2 ethics review may also be applied where:
- Data processes do not pose a (or pose a mitigatable) challenge to individual data security.
- There is no (reasonably perceived) conflict of interest.
- The data does not concern groups that may be construed as terrorist or extremist.

3.4   Level 3 (full CRESC review)

Level 3 ethics review applies to research that carries moderate but highly likely risk - or a severe and reasonably foreseeable risk. This risk can be to participants, researcher/s, or third parties). Research may also be assessed as requiring Level 3 review where:

- Data processes pose a challenge to individual data security.
- There may be a (reasonably perceived) conflict of interest.
- The data concerns group/s that may be construed as terrorist or extremist.

- There are multiple complexities, risks, or new ethical challenges which have not been commonly seen in research practice previously or have not been fully explored within established pathways of ethical reflection.

Level 3 ethics applications will be presented by two lead ethics reviewers to the Childlight Research Ethics Sub-Committee, for discussion.

In the case of applications assessed as Level 3, CRESC may ask for external input from experts on the areas of ethical complexity (if such expertise does not already sit on the Childlight Research Ethics Sub-Committee).

Level 1 and 2 applications can be approved without a Childlight Research Ethics Sub-Committee meeting, but this does not preclude these coming to Committee. If the reviewers feel that there are ethical issues that would benefit from Committee discussion, Level 1 or 2 ethics forms may also be brought to a Childlight Research Ethics Sub-Committee meeting.

4 Childlight Research Ethics Sub-Committee Application

All researchers must receive ethics approval (or confirm an exemption from ethical review) before the project can start. Once a research project has been approved through the Childlight Tasking & Coordination process, the lead researcher will prepare for the Research Project Initiation checkpoint (the full process for which can be found in the Research Project Set-Up and Initiation Policy). This checkpoint includes an assessment of the proposed project against the checklist criteria in Appendix 1 to determine level of research ethics review, or if an exemption is appropriate.

During the Project Initiation Checkpoint process, the Quality & Compliance Manager will log the expected research ethics review level and liaise with the Chair of the Childlight Research Ethics Sub-Committee to provide a pipeline of reviews required and provide an early check of the expected review level. The Quality & Compliance Manager will work with the Chair of the Childlight Research Ethics Sub-Committee to schedule research project reviews with the Committee as required.

Once the research project has passed the Project Initiation Checkpoint, the lead researcher may prepare for research ethics review and complete the research ethics application form. This includes sections on:

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- Project summary and methodology
- Data access, collection, storage, handling, processing and use
- Risk assessment and mitigation
- Research findings outputs and dissemination
- Copyright
- Access to and use of security-sensitive material
- Collaborations and partnerships
- Intellectual property ownership
- Risks to participants, data subjects and researchers (Level 2 only)
- Participant and data subject recruitment, reciprocation and consent (Level 2 only)
- Participant and data subject needs, including safeguarding (Level 2 only)

Depending on the theme and methodology of the research project, the application <u>may</u> also require:

- Data Management Plan through the [DMPOnline](#) tool (mandatory for all research projects – see the Data Management Policy for further details)
- Data Protection Impact Assessment, based on data sensitivity (see the Data Management Policy for further details)
- Participant Information Sheet
- Consent form
- Recruitment email
- Data collection tools e.g., interview guide
- External approvals, e.g.,
  - Sponsorship letter – for all research that is healthcare and/or social care related
  - Caldicott approval – for the collection, use and transfer of personally identifiable data within or outside an NHS organisation
  - Integrated Research Application System (IRAS) via the NHS Health Research Authority – for all health, social and community care research in the UK

The Quality & Compliance Manager can provide advice and guidance to the lead researcher in completing these documents and the application form.

Once the research ethics application form is completed, the lead researcher must obtain review and sign off from the Global Director of Data or designated depute. Following any further edits, the final ethics review application is shared by the Childlight Administrative Officer (not by the lead researcher) to the Research Ethics Administrator at MHSES-Ethics@ed.ac.uk.

At this point, the Chair of the Childlight Research Ethics Sub-Committee formally logs the project, checks the completeness of the application and associated documents, and assigns reviewers. Following review, the Chair of the Childlight Research Ethics Sub-Committee will either:

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1. Approve the ethics application

OR

2. Provide questions and comments back to the lead researcher

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In the case of approval, the Chair of the Childlight Research Ethics Sub-Committee will confirm that approval to the lead researcher and provide a confirmation letter with an approval reference number.

If the CRESC reviewers have further questions or comments, these will be provided back to the lead researcher. The lead researcher should respond to all reviewer comments and questions, ideally within a one-week timeframe. Where edits or amendments are required to the application, these should be made as tracked changes in the application form and supporting documents. Any edits must be reviewed and signed off by the Global Director of Data or designated depute, before the updated application is shared back with the Research Ethics Administrator (MHSES-Ethics@ed.ac.uk) by the Childlight Administrative Officer.

When final ethics approval has been received, the confirmation letter should be logged on the CPMS and the reference number logged in the centralised Research Portfolio Tracker by the Quality & Compliance Manager.

5 Amendments

The nature of research means that there are likely to be changes to a project. Amendments to ethics applications can take several forms, including changes to staff, data provider, key elements of the research question, or timescales, among other areas. Any change to a research project or deviation from the original approved ethics application should be logged, reviewed, and approved.

In the first instance, the lead researcher should inform the Quality & Compliance Manager that they require an ethics amendment. The Quality & Compliance Manager will log the amendment centrally on the amendment tracking sheet.

The lead researcher should provide a cover letter that outlines the changes required, and the rationale for the change. They should also provide an updated ethics application [including supporting information and documents] with changes tracked for clarity.

The Global Director of Data or designated depute must review and sign off any proposed changes, before submission to the Research Ethics Administrator (MHSES-Ethics@ed.ac.uk). The Chair of the Childlight Research Ethics Sub-Committee will review the amendment request and confirm one of the following outcomes:

1. The amendment is accepted, and written confirmation is provided acknowledging the change. This is logged centrally and the written confirmation stored on the CPMS.

OR

2. The amendment is determined to be a fundamental change to the project, and a new research ethics application is required. The lead researcher commences a new research ethics application process.
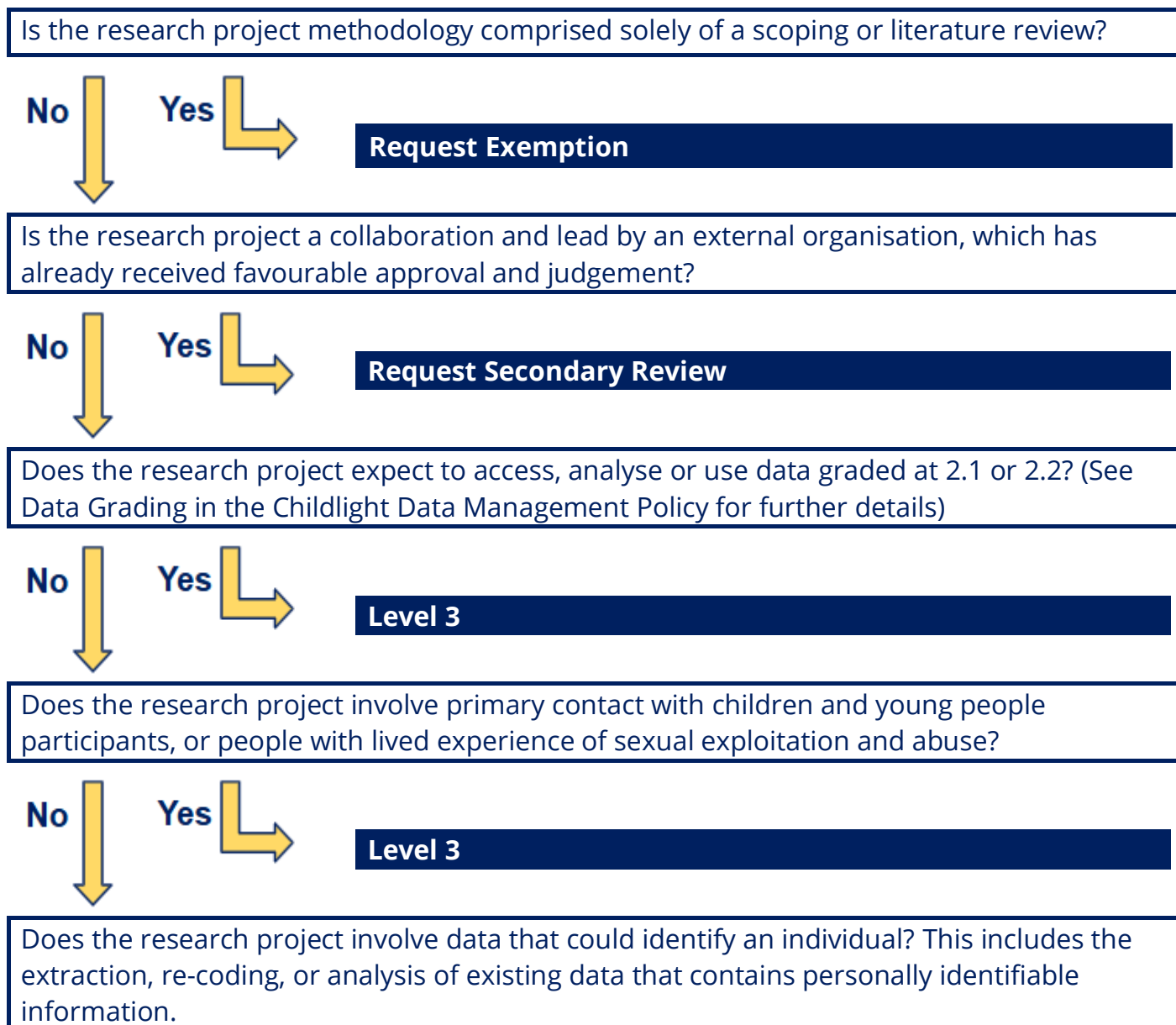
6 Roles and Responsibilities

Role	Responsibility
Principle Investigator (who may delegate to a Lead Researcher)	• Initial assessment of research ethics review level as part of project initiation and planning • Assessment of data grading and associated data management plan • Completion of ethics application and supporting documents • Review of and response to Sub-Committee comments • Consider ongoing ethical implications throughout a project lifecycle • Identify changes and submit amendments for review • Adherence to the University of Edinburgh Research Ethics Policy • Ensure entire research team, including any external partners, has reviewed and signed off on the ethics application and will adhere to the ethics elements proposed therein
Global Director of Data or designated depute	• Review and approval of all ethics applications before submission to the Chair of the Childlight Research Ethics Sub-Committee • Mentorship in ethics application completion • Identification of research ethics training needs for Childlight researchers and Ethics reviewers
Childlight Administrative Officer	• Packaging application documents together • Sharing application packages with the Chair of the Childlight Research Ethics Sub-Committee
Childlight Quality & Compliance Manager	• Review of draft research ethics applications and documents, including a quality review • Maintaining a central Childlight log of research ethics status and approval references for each Childlight research project • Guidance on supporting documents required • Guidance on the completion of application forms, including data governance and management
Chair of the Childlight Research Ethics Sub-Committee	• Identification of reviewers • Management and coordination of the review process, including sharing comments and questions back to the lead researcher • Confirmation of final ethics review acceptance and provision of a confirmation letter and reference number

7 Appendices

Appendix 1: Research ethics level assessment checklist

Review the proposed research against the questions below, starting from the top and moving down until you answer "yes" to a question. This approach identifies the highest level of risk within a research project and therefore the most appropriate and proportionate level of ethics review required.

This flowchart is intended to assist researchers in identifying the appropriate ethics level, but there may be additional considerations which impact on deciding the level of risk. Please note that the ethics level classification will be reviewed as part of the ethics review process, and reviewers may suggest a change to the indicated level.

Is the research project methodology comprised solely of a scoping or literature review?

No Yes → **Request Exemption**

Is the research project a collaboration and lead by an external organisation, which has already received favourable approval and judgement?

No Yes → **Request Secondary Review**

Does the research project expect to access, analyse or use data graded at 2.1 or 2.2? (See Data Grading in the Childlight Data Management Policy for further details)

No Yes → **Level 3**

Does the research project involve primary contact with children and young people participants, or people with lived experience of sexual exploitation and abuse?

No Yes → **Level 3**

Does the research project involve data that could identify an individual? This includes the extraction, re-coding, or analysis of existing data that contains personally identifiable information.

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No   **Yes**   →   **Level 3**

Does the research project involve an underrepresented community or group, where the findings of the research could increase discrimination against or put the safety of that group at risk?

No   **Yes**   →   **Level 3**

Does the research project expect to uncover tactics that might be used by offenders to facilitate or commit abuse against children?

No   **Yes**   →   **Level 3**

Does the research project involve sensitive data that is likely to be traumatic to researchers, for example graphic descriptions, file names, or cases?

No   **Yes**   →   **Level 3**

Does the research result in a conflict of interest between the researcher and the data / subject matter / partners that cannot be mitigated?

No   **Yes**   →   **Level 3**

Does the research collect or generate new data from or about human participants?

No   **Yes**   →   **Level 2**

Does the research analyse secondary (archival) data that is routinely collected, or is an existing anonymised dataset?

No   **Yes**   →   **Level 1**

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Does the research collect new data BUT an external ethical review board (such as NHS IRAS, UK HEI – for multi-site studies, etc) has fully reviewed the project and generated a favourable opinion?

Yes →

Level 1

Appendix 2: Exemption process

A review process can be undertaken to determine whether a given project can be considered exempt from the full university ethical review process. There are two categories of Exemption:

1. Exemption from full review based on methodology ("Exempt")
2. Exemption from full review based on lead research organisation ("Secondary Review")

Exempt

Research that only uses scoping review or literature review methodology may be exempted from Childlight Research Ethics Sub-Committee review, on the grounds that the data being used is already in peer-reviewed published form and therefore has gone through its own level of data cleansing or preparation for publication.

Secondary Review

This document outlines a process for the consideration of an exemption from standard University of Edinburgh ethics processes, for Childlight collaborative projects which have received ethical approval from another institution. While this document presents indicative circumstances for the consideration of an exemption where a project has been reviewed elsewhere, it does so with the understanding that:

a. the MHSES Ethics Director will form the final judgement on the application of this process in any given specific circumstance, informed by recommendations from the reviewers assessing the application in question and;
b. there may be circumstances where the UoE researcher(s) leading the connection to the project request a full University of Edinburgh review of a project despite meeting conditions for an exemption.

To make a case for exemption by Secondary Review, the staff member leading the University of Edinburgh connections to the project would submit the following documentation to the MHSES-Ethics@ed.ac.uk email address. This documentation will be considered by at least one reviewer with the relevant disciplinary and/or methodological expertise for the project under consideration:

- Title of Project
- Start and end dates of Project

- Attachment of a document providing a brief statement outlining why they feel an exemption from University of Edinburgh ethical review processes is applicable to the Project. This statement should include:
  - o Identifying the institution that is responsible for the ethics of the project.
  - o Explaining the specific activities of UoE researcher/s on the project.
  - o Noting that the activities of UoE researcher/s are covered by original (PI institution) ethical review process.
  - o Where applicable, noting any ways in which the existing ethical process/expectations deviate from those of the University of Edinburgh. There are instances where the values and practices of different ethical processes vary, including where the ethical values and practices of the original granting institution take precedence (e.g., when conducting research overseas and where the review has occurred at the site of research). Describing a deviation from UoE practices does not automatically indicate that a full UoE review will be required).
- Attachment of documentation submitted to the institution where the primary review was completed, including a copy of the ethics review where possible.
- Attachment of evidence that the reviewing institution has provided a favourable ethical opinion (or 'approval', for those institutions that use this terminology).
- Researchers may also be asked to provide feedback or review comments from the original reviewing institution.

Documents need to be provided in English language or translation, unless otherwise agreed with the Chair of the Childlight Research Ethics Sub-Committee.

An Exemption for a Collaborative project not led by the University of Edinburgh is potentially applicable if:

- The Principal Investigator (PI) of the project is from a non-UoE institution; OR,
- The project has been reviewed within a relevant institution at the research site (e.g., an overseas NGO, where data is solely being collected in or by that NGO); AND,
- The project does not require UoE sponsorship;
  AND,
- The originally reviewing institution upholds ethical standards of equivalent or greater rigour to the relevant UoE processes.

In addition:

- The originally reviewing institution undertakes the ethical and governance responsibility for the project.

- The Childlight researcher/s ensure other research governance processes for which the University of Edinburgh is responsible are in place (this may include research and/or travel insurance, data management plan, data transfer agreement, collaboration agreement, contracts, intellectual property agreement, etc.).

Conditions under which a full review may be recommended

There are some circumstances where the PI is not a Childlight staff member or student but where a full review may be deemed reasonable. These include:

- Where the specific strand (or work package in, for example, a large European Commission project) of work to be undertaken by Childlight staff/students is not fully covered by the PI institutional review.
- Where the PI institutional review was not undertaken by an appropriate discipline-specific committee (e.g., provided by a medical institution's Institution Review Board that does not review qualitative research, where the qualitative strand of research is being led by Childlight researcher/s).
- Where the depth, focus or remit of the original ethical review does not meet the standards of the University of Edinburgh ethical review process.
- Where local School/ Research Ethics Committee processes, requires a student to submit an ethics form as part of learning aims and objectives, although the project might have been exempt if conducted by a member of staff.
- Where required by a funder or collaborator.
- Other conditions or circumstances as determined by the member/s of the Research Ethics Committee vetting the request.

Outcomes to an application for Exemption

Outcomes to an application for Exemption may include:

- Notification via email that the submitted documentation satisfies University of Edinburgh Ethics processes and that the submitted documentation from the other institution will be archived in the MHSES Ethics archive.
- A request for specific further information to fully determine the case (e.g., around an area of ethics practice that was not covered by the original review, or for clarification on a point of information).
- A recommendation that the project needs to undergo a full University of Edinburgh review. (In this case, the ethics reviewers considering the application will provide information informing the applicant of the reasons underlying this decision).

Applications for secondary review will be reviewed on a rolling basis and will be looked at in a timely fashion (with a result expected within 2-3 weeks). Applications which qualify for an exemption will be listed as exempt at the next Childlight Research Ethics Sub-Committee meeting. Those applications that require full University of Edinburgh review
will follow the standard Childlight process for this

Joining the UoE with an ethically reviewed project

If a PI has joined the UoE from another UK Higher Education Institute and is seeking to transfer a study which has received a favourable ethical opinion elsewhere, the MHSES Research Ethics Committee may agree to provide an Exemption (as outlined above). This is applicable where the study has entered the recruitment and/or data collection phase prior to the PI joining the University of Edinburgh. If the study was submitted for review at the prior institution but not yet started, the PI will need to apply for University of Edinburgh review. Please also note that the project may need to undergo a transfer of Sponsorship (please seek advice of the CAHSS Ethics & Governance Team at cahss.res.ethics@ed.ac.uk in this instance).