Research Protocol Development and Registration Policy: Metadata

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Childlight Global Child Safety Institute

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1 Introduction

1.1 Purpose

This policy defines the requirements for protocol development at Childlight. Developing a protocol is a mandatory initial stage in all research studies under the Childlight banner. Protocols establish the methodological and conceptual foundations of a study, ensuring clarity, transparency, and accountability from the outset.

1.2 Scope

This policy applies to all research studies conducted or commissioned by Childlight, including literature reviews, quantitative, qualitative, or mixed-methods studies, and those led by Childlight or by our hubs or other research partners.

1.3 Alignment

This policy ensures standardisation across diverse methodologies, setting expectations for what protocol content must include, the steps for review and approval, registration requirements, and making sure different studies are comparable in structure. It reflects Childlight's commitment to research integrity, reproducibility, and transparency.

2 Definitions

Protocol:	A formal, written plan for a research study that states the rationale, objectives or hypotheses, detailed methodology, ethical considerations, sample criteria, data analysis plans, and other essential features. It documents what will be done, why, and how.
OSF (Open Science Framework):	A platform for managing research projects with tools for registration, version control, sharing, and collaboration. Childlight's preferred portal for registering study protocols.
Protocol Registration:	The formal process of making a protocol publicly available via a searchable portal (such as OSF or PROSPERO) prior to analysing data. This ensures transparency, enables verification, and helps reduce bias.

Principal Investigator (PI):	The researcher who has ultimate responsibility for the design, conduct, and integrity of the study.
Lead Researcher:	A person delegated by the PI to lead the drafting and finalisation of the protocol.
Protocol Amendment:	Any change made to a protocol after it has received final approval (and, if relevant, registration). Amendments may be major or minor, depending on whether they fundamentally alter core aspects of the study.

3 Roles and Responsibilities

Principal Investigator (PI):	The Principal Investigator (PI) is responsible for ensuring that each study has a protocol, which must be developed, reviewed, approved and, where required, registered prior to any data analysis commencing. Although the PI may delegate drafting duties to a Lead Researcher, the PI retains overall accountability for the accuracy, completeness, and ongoing maintenance of the protocol. It is also the PI's responsibility to submit amendments when required, and to ensure all versions are properly version-controlled in line with Childlight's document management procedures.
External Reviewers:	External reviewers provide critical feedback on protocol drafts. These reviewers must be independent of Childlight meaning that they cannot be employed by or formally engaged with Childlight and bring expertise in either the methodological approach or in the substantive subject area of the study. All their comments must be documented, and the PI must address them, where appropriate, in revisions.
Global Director of Data (GDD):	The Global Director of Data, or their designated deputy (for example a Hub Director or Regional Director), oversees final oversight and sign-off of protocols. They ensure that internal and peer review processes have been followed, that the protocol meets minimum content standards, and that registration (if required) has been completed satisfactorily.

4 Protocol Development

4.1 Minimum Required Content

All protocols must include, at a minimum:

- Author list: Should include contact details of PI and affiliations and names in order of all co-investigators, funding sources, and any stated conflicts of interest
- Background and Rationale: Why the study is being done; what existing literature or gaps motivate it.
- Research Questions: What the study aims to answer or test.
- Study Design and Methodology: Sampling strategy (including inclusion/exclusion criteria), tools/instruments, data collection methods, data sources.
- Ethical Considerations: Data governance, participant protections, team wellbeing measures (including mitigating risks of exposure or distress) among any other ethical considerations.
- Limitations: Identification of limitations and risks, and strategies to mitigate them.
- Dissemination and Pathways to Impact: How findings will be shared and who might benefit.
- Conclusion: A summary of expected contributions and main elements of design.

4.2 Use of Template

Researchers can use Childlight's technical note template, if it is useful. Otherwise, please design the template with the required content in mind (section 4.1).

4.3 Version Control

Protocols must comply with Childlight's Document Management Policy. Only the final approved version of a protocol is considered the controlled version. Drafts, working versions, and earlier iterations should be clearly labelled (e.g., controlled version "Title v1.0", Working version "Title v0.1"), and stored in the designated shared folder system related to the study.

5 Protocol Review and Approval

5.1 Internal Review

During drafting, the PI (or Lead Researcher) may consult their line manager or subject area lead to review key elements of the protocol. This internal review serves as support and helps ensure alignment with methodological norms and organisational priorities. For instance, in studies addressing technology-facilitated CSEA, the subject area lead (e.g. Elena) might review; in studies using administrative data, the lead in that domain (e.g. Inga) would be appropriate.

5.2 Peer / Expert Review

Every protocol must be reviewed by at least one external expert who has no formal association (employment or contractual) with Childlight. This might be a specialist in the methodology being used or in the substantive topic of the research as identified by the PI. In many cases the advisory committee for the study can serve this function. Feedback provided by the peer/expert reviewer must be formally recorded (for example, in a marked-up document or via a tracked comments file or spreadsheet), preserved in the study's documentation folder (e.g. SharePoint), and the PI or Lead Researcher must document how each comment was addressed in subsequent revisions of the protocol.

5.3 Ethical and Childlight Approvals

If required by the nature of the study, the protocol can be submitted to a formal ethics committee for approval as part of the suite of documents provided. All protocols, once finalised, must also receive sign-off from the Global Director of Data or their delegate (Hub/Regional Director) before they may proceed. This ensures that the protocol meets Childlight's standards for quality, ethical conduct, risk management, and compliance with registration requirements.

6 Protocol Registration

6.1 When to Register

The protocol must be registered only after Childlight's final approval process has been completed and before any data analysis begins. In exceptional cases, such as where non-disclosure agreements or sensitive methodology prevent public registration, the necessity for not registering might be reviewed and approved on a case-by-case basis.

6.2 Where to Register

Childlight's preferred portal is the Open Science Framework (OSF). Systematic reviews may also be registered via PROSPERO, particularly when the review meets PROSPERO's criteria. Here are relevant how-to guides:

- OSF: Start a Registration guide — OSF: How to Start a Registration
- General OSF registration / preregistration info — OSF: Registrations & Preregistrations overview
- PROSPERO: How to register a systematic review protocol — PROSPERO Help / Register page

6.3 Registration Requirements

Below are key requirements for registering protocols in OSF and PROSPERO:

OSF Requirements:

- Choose or create a project or component in OSF, then use "Registrations" to start a new registration.
- Select an appropriate registration template corresponding to your study type. There are different forms for e.g. hypotheses testing, project plans, etc.
- Fill in metadata (title, authors, affiliations, ORCID if available, study timeline, methods, data analysis plan, ethical approvals, etc.) and attach necessary documents.
- Set visibility: make sure the registration is public or visible (unless there is an appropriate reason for embargo). Ensure that other researchers can find the registration.
- Registrations cannot be edited once submitted. Once an OSF registration is submitted, it becomes a frozen, time-stamped record.
- Registrations cannot be edited once submitted. Amendments or updates must be documented either through an "OSF Registration Update," by creating a new registration linked to the same OSF project, or by uploading supplementary files to the project page. The preference for most amendments would be to fill out a registration update (sometimes called "update registrations"): a way to publicly note changes, e.g. adding new information or clarifying an amendment.

PROSPERO Requirements (for specific Systematic Reviews):

- The review must include at least one health-related outcome.
- The protocol should be complete and ready before starting the systematic review (i.e. before screening, data extraction etc.).
- You must provide contact details and affiliations, funding sources, conflicts of interest.

- Clearly defined inclusion and exclusion criteria; clear search strategy; description of the outcome(s) to be measured; specifics of how data will be analysed.
- Review title, anticipated start date, estimated completion date, named members of the review team.
- PROSPERO registrations must be submitted via their online portal, and you should check first that a similar review is not already registered.

6.4 Link to Publications

For all Childlight outputs arising from a study (whether reports, internal technical notes, Searchlight, Into the Light Index, etc.), researchers must include the public registration link of the protocol. The registration information should also be included in any journal article or public write-up.

7 Protocol Amendments

7.1 Major Amendments

A major amendment is any change that alters the core of the study. For example, modifying the sample size, changing the research question(s), altering the main analytical approach, or changing data governance practices. If such changes become necessary after approval, the researcher must submit the revised protocol for a fresh sign-off and registered amendment, ensuring that stakeholders, including external reviewers and Childlight oversight, are aware of and agree to the change.

7.2 Minor Amendments

Minor amendments are adjustments that do not fundamentally affect the core methodology or outputs of the study. These might include revisions to the advisory group membership, tweaks in dissemination plans, or non-methodological clarifications. While these must be documented in the study folder, they do not require full re-approval or re-registration. If there is any uncertainty about whether a proposed amendment is major or minor, the researcher should consult their line manager or subject area lead.