UNICEF PROCEDURE FOR ETHICAL STANDARDS IN RESEARCH, EVALUATION, DATA COLLECTION AND ANALYSIS

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I. Rationale

To underpin its programmes, policy and advocacy work, UNICEF invests substantially in conducting, as well as commissioning, research, evaluation and data collection and analysis in order to create a strong evidence base to support the realization of the rights of every child, especially the most disadvantaged.

In light of UNICEF’s strategic agenda to harness innovation and deepen and widen the evidence base to drive and sustain global progress towards the realization of children’s rights, ensuring ethical conduct in evidence generation is imperative. This is necessary both in its own right and as a significant contributor to ensuring quality and accountability in the evidence generation process, especially when it involves children.

Ethical reflection and conduct in evidence generation is requisite in an equity based framework. A focus on the most marginalized, and frequently, the most vulnerable population groups necessitates measures to ensure that participants are respected and that they are protected throughout the process. Further, efforts must be taken not only to mitigate against risks to participants, but also to staff and to the organization as a whole.¹

In order to ensure the protection of, and respect for, human and child rights within all research, evaluation and data collection processes undertaken or commissioned by UNICEF, this procedure is designed to achieve the following objectives:

- To establish minimum and binding standards for ethical research, evaluation and data collection and analysis processes in UNICEF globally; and
- To ensure effective processes and accountability for ethical oversight of these processes.

This procedure is complemented by, and builds on, the pre-existing Strategic Guidance Note on Institutionalizing Ethical Practice for UNICEF Research² and the Evaluation Technical Note No. 1, Children Participating in Research, Monitoring and Evaluation (M&E) — Ethics and Your Responsibilities as a Manager, UNICEF Evaluation Office, 2002.

¹ While this procedure applies to research, evaluation and data collection and relevant analysis, ethical considerations and principles can and should be considered within UNICEF’s broader programmatic and advocacy work as reflected and articulated in the Human Rights Based Approach to Programming and the broader agenda for human rights mainstreaming.

² Recommended and shared by Deputy Executive Director - Programmes on 30/10/ 2013. This guidance document outlines considerations relating to ethical research involving children.
II. Applicability / Scope

i. All UNICEF research, evaluation and data collection and analysis involving human subjects or the analysis of sensitive secondary data as outlined in Figure 1.

ii. All research, evaluation or data collection processes (identified in para i. above) that are carried out, or commissioned by UNICEF sections – including Country Offices (COs), Regional Offices (ROs), and Headquarters sections (HQ) – both in partnership and independently. Where a UNICEF partner has its own mechanisms for ethical review, they may substitute for this procedure but only in the instances where partner ethical review processes meet the minimum standards laid out in this procedure.

iii. This procedure will be reviewed within two years.

III. Audience

All UNICEF staff involved in the development and implementation of research, evaluations or data collection and analysis processes, most notably project managers for evidence generation projects, country focal points for particular data collection projects, as well as Country Representatives, Regional Directors and Heads of Divisions who will be responsible for ensuring and maintaining the highest ethical standards in all the evidence generation endeavours of UNICEF units, offices and divisions.

IV. Definitions

**Assent** – Assent is the willingness to participate in research, evaluations or data collection by persons who are by legal definition too young to give informed consent according to prevailing local law but who are old enough to understand the proposed research in general, its expected risks and possible benefits, and the activities expected of them as subjects. Assent is similar to the process of informed consent. Assent by itself however, is not sufficient, however. If assent is given, informed consent must still be obtained from the subject's parents or guardian or a responsible adult.

**Confidentiality** – Confidentiality is the process of protecting an individual’s privacy. It pertains to the treatment of information that an individual has disclosed in a relationship of trust, with the expectation that this information will not be divulged to others without permission.

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3 This includes studies.
4 National Committees are also encouraged to apply the standards in this Procedure to the research they carry out or commission through partners.
5 Includes research carried out by partners using UNICEF support.
Evaluation – Evaluation is a systematic and objective effort to determine the relevance, appropriateness, effectiveness, efficiency, impact and sustainability of development efforts, based on agreed criteria and benchmarks among key partners and stakeholders. It involves a rigorous, systematic and objective process in the design, analysis and interpretation of information to answer specific questions. It provides assessments of what works and why, highlights intended and unintended results, and provides strategic lessons to guide decision-makers and inform stakeholders.

Ethical evidence generation – Ethical evidence generation follows widely-held guidelines about what is ethical, moral and responsible (e.g. not plagiarizing others’ work, not submitting questionable data, avoiding doing harm, ensuring just distribution of the benefits and risks of the research etc). Ethical evidence generation is reflective and explicitly considers its impact on both participants and the broader community throughout the research cycle from planning through to dissemination and monitoring and evaluation.

Evidence generation activities – For the purpose of this procedure, research, evaluations, data collection and analysis are collectively referred to as evidence generation activities.

Final report – For the purposes of this procedure a final report is a publically available report or a report targeted to a specific stakeholder (e.g. government) that is produced consequent to the interim or final findings of research, evaluation and data collection and analysis processes.

Informed consent – The voluntary agreement of an individual, or his or her authorized representative, who has the legal capacity to give consent, and who exercises free power of choice, without undue inducement or any other form of constraint or coercion to participate in research. The individual must have sufficient knowledge and understanding of the nature of the proposed evidence generating activity, the anticipated risks and potential benefits, and the requirements or demands of the activity to be able to make an informed decision.

Institutional Review Boards (IRBs) or Ethical Review Boards (ERBs) or Committees – A specifically constituted review body established or designated by an institution to protect the rights and welfare of human subjects recruited to participate in biomedical or behavioral or social science research. IRBs attempt to ensure, both in advance and by periodic review, protection of subjects by reviewing research proposals and related materials. IRB protocols assess the ethics of research, evaluations or data collection and analysis and their methods, promote fully informed and voluntary participation by prospective subjects capable of making such choices (or, if that is not possible, informed permission given by a suitable proxy), and seeks to maximize the safety of subjects. In this procedure IRBs will be included in the term Ethical Review Boards.

Privacy – The ability of an individual to control the extent, timing, and circumstances of sharing themselves (physically, behaviorally, or intellectually) with others. Privacy refers to the right of individuals

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8 This could include a private organization.
to limit access by others to aspects of their person that can include their thoughts and identifying information.

**Primary data** – The creation of new data via first-hand collection.

**Proposal** – For the purposes of this procedure a proposal is a detailed overview of a planned research, evaluation or data collection and analysis project. Therefore, within this procedure, a protocol for research or data collection, or an inception report for an evaluation, would be considered a proposal.

**Research** – The systematic process of the collection and analysis of data and information, in order to generate new knowledge, to answer a specific question or to test a hypothesis. Its methodology must be sufficiently documented to permit assessment and replication. Research at UNICEF should examine relevant issues and yield evidence for better programme and policy advice.

**Secondary data** – Information gathered from pre-existing sources or databases.

### V. The Principles Guiding this Procedure

The minimum standards and procedures outlined in this document are guided by the following three principles as laid out in the *Belmont Report on Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (1979). It should be noted that while these principles apply to all participants involved, children may be particularly vulnerable in the evidence generation process and appropriate considerations as elaborated in the *Strategic Guidance Note on Institutionalizing Ethical Practice for UNICEF Research* and the *Evaluation Technical Note No. 1, Children Participating in Research, Monitoring and Evaluation (M&E) — Ethics and Your Responsibilities as a Manager* can and should be reflected in the process. The following are the three principles that should inform ethical evidence generation:

1. **Respect**: All evidence generating activities should ensure respect for all persons. Respect demands that individuals be treated as autonomous agents. An autonomous agent is an individual capable of deliberation about personal goals and of acting under the direction of such deliberation. To respect autonomy is to give weight to autonomous persons’ values, preferences, and beliefs and to recognise their capability for self-legislation, their ability to make judgments, to state their opinions and to make choices.

   In respecting an individual’s autonomy, recognition is required that personal agency may be limited due to age, circumstance or personal capacities. In this context, respect for autonomy requires recognition of capabilities, power differentials and the degree of agency that an individual may have. In the context of children and other vulnerable groups respectful evidence generation needs to be situated in their lived experience with recognizing the reality of unequal relationships of power that frequently exist, creating environments that support these individual’s personal agency and dignity.

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2. Beneficence and Non-maleficence

**Beneficence** - The principle of beneficence refers to the requirement that actions within evidence generating activities promote the well-being of individuals, communities or society as a whole. The principle of beneficence requires the identification of clear benefits likely to arise from evidence and to reconsider proceeding if these cannot be articulated. Beneficence includes the concept of reciprocity, whereby the evidence generated is conveyed back to the participants so that they may triangulate findings, contextualize their participation and potentially gain from the knowledge disseminated.

**Non-maleficence** - The principle of non-maleficence, doing no harm, requires avoiding harm or injury to participants, both through acts of commission or omission. While the primary purpose of research, evaluation and data collection and analysis is to generate new evidence, this goal should never take precedence over the rights of individual participants. Non-maleficence requires an examination of the profile, competencies and skills of researchers and enumerators to ensure no harm comes to participants by virtue of inappropriate, unskilled or incompetent researchers or enumerators. It also requires explicit consideration of means to ensure the privacy of participants, their safety and any possible negative impacts arising from participation.

3. Justice: The principle of justice requires that consideration is given to who benefits and who bares the burden of the evidence generation. This requires that due reflection is given to determining the appropriateness of proposed methods of selecting participants. Selection should not result in unjust distributions of the burdens and benefits of evidence generation. Such considerations are required to avoid the injustice that arises from social, racial, sexual, and cultural biases institutionalized in society.
FIGURE 1: Does this UNICEF Ethics Procedure Apply to your Work?

Does your project involve commissioning, funding or undertaking data collection and analysis, research or evaluation?

- YES

Does it involve human subjects? (Primary data)

Examples:
- Surveys, questionnaires, focus groups, interviews, surveillance data;
- Case studies;
- Story telling that will or may draw broad conclusions about the population, cultures, norms and practices;
- Games, experiments in physical or in electronic environments;
- Physical or biomedical procedures – imaging, scanning, blood collection, anthropomorphic procedures;
- Diet and nutrition studies;
- Studies examining effectiveness of educational tools or curricula;
- Use of instruments or devices, including phones, to collect data or monitor or influence behavior;
- Passive observation of public behaviour (in physical or online environments, including social media);
- Studies examining individuals’ responses to manipulation of their physical or online environment;
- Another activity that involves observation of, or interaction with, individuals to gather information.

- NO

Does it involve....?
- Secondary data analyses involving "restricted-use" data – data that are distributed to investigators with the understanding that use is restricted and secured from unauthorized use.
- Secondary analyses involving survey or other data where data records of individuals are not anonymous.
- Secondary analysis that involves merging community, census tract, company, neighbourhood, or geographical data to an existing survey of identified individuals.
- Projects that involve secondary analysis for which the findings may negatively impact on vulnerable stakeholders and communities.

- NO

Project does not need to meet the requirements of this procedure (though reflection is encouraged).

- YES

Project needs to adhere to the requirements of this procedure

- YES
VI. Procedural Statements

The following are the minimum standards and required procedures for research, evaluation and data collection and analysis undertaken or commissioned by UNICEF (including activities undertaken by individual and institutional contractors, and partners) involving human subjects or the analysis of sensitive secondary data. These standards explicitly recognize and reflect the spirit and intention of the Declaration of Helsinki (1964) and its attendant amendments, emphasizing the importance of respect for and protection of human rights. More specifically, as relates to the involvement and focus on children in research, evaluation and data collection and analysis, these standards attempt to reflect the United Nations Convention on the Rights of the Child’s (UNCRC) principles of the best interests of the child, non-discrimination and participation.

Within this procedure the principles and requirements for evidence generation are applied to four core ethical issues, namely; Harms and Benefits, Informed Consent, Privacy and Confidentiality, and Compensation and Payment. In addition, they also specifically articulate UNICEF’s position on conflicts of interest and ethical funding of evidence generating activities.

Core Procedures

i. All proposals for research, evaluation and data collection processes that involve human subjects or entail analysis involving sensitive secondary data as described in Figure 1 must include a section identifying anticipated or actual ethical issues throughout the programme as well as the measures and methods anticipated or adopted to address or mitigate against these issues.

ii. All reports produced by UNICEF or by an individual or institution contracted by UNICEF relating to the above-described evidence generating activities (as highlighted in the scope of the procedure and in Figure 1 above), must include a section identifying anticipated or actual ethical issues throughout the project as well as the measures and methods adopted to mitigate against these issues.

iii. Consistent with the UNICEF Procedure for Quality Assurance in Research and the quality assurance guidance for evaluation: Evaluation “Step by Step”, ethical considerations must be explicitly considered and reviewed as part of broader quality assurance processes within the originating office.

iv. Where pre-existing legislation and policies exist in relation to local ethical standards for evidence generation, UNICEF relevant evidence generation programmes must comply with these standards. However, should local standards fail to meet those established within these procedures, the UNICEF standards must still be met by staff undertaking or commissioning those research and evidence generation programmes covered by this procedure.
v. Prior to the development of a proposal, all Terms of Reference must be reviewed by an internal staff member within the office or unit. This review must be undertaken by a staff member with either relevant ethics training or sufficient technical expertise and knowledge to appreciate the ethical dimensions of the proposed evidence generation activity. TORs must explicitly reflect on the likely ethical issues that may arise and the consequent competencies required by potential consultants.

vi. All Terms of Reference for contracted research, evaluation or data collection covered by this procedure must include a section that requires contractors to:

*clearly identify any potential ethical issues and approaches, as well as the processes for ethical review and oversight of the research/evaluation/data collection process in their proposal.*

In the assessment of contractor proposals, articulation of ethical implications and mitigation strategies for the design and implementation of research, evaluation, data collection and analysis should be given appropriate weighting.

vii. Researchers, evaluators or enumerators involved in primary data collection involving human subjects must have undertaken basic ethics training. In the instance where no previous training has been undertaken either the implementing parties or the relevant UNICEF unit could provide this as a standalone training programme or as part of a broader training programme on the data collection process.

viii. All proposals involving research, evaluations or data collection and analysis covered by this procedure, and meeting one or more of the following criteria must go through a relevant external ethical review board or panel.

A. *Evidence generation that involves vulnerable cohorts whose personal agency is limited due to age, situation or capabilities and for whom an additional duty of care is required.* This includes research, evaluation and data collection and analysis that undertakes primary data collection and:
   - Involves children as participants, researchers and data collectors;
   - Specifically targets persons with an illness, disability or mental health issue as participants;
   - Targets and involves a group that may be perceived as vulnerable within the local context (examples include; women, minority groups, persons with HIV/AIDS, the economically and educationally disadvantaged, persons in institutions) as participants;
   - Involves persons within humanitarian contexts as participants (e.g. children, young people and adults in refugee camps; in conflict and post conflict transition settings and in disaster settings).

B. *Evidence generation involving primary data collection that has the potential to result in direct harm to the participant during the course of the programme (through physical or psychological tests, measures or lines of questioning).* This includes evidence generation activities that:
   - Specifically explore issues related to violence, abuse or trauma;
   - Provide health-based assessment, diagnoses and treatments as part of the programme.

10 This internal staff member cannot be the instigating staff member for the project, nor be the party responsible for drafting the Terms of Reference.
C. Evidence generation that has the potential to compromise the privacy of subjects and the confidentiality of data including:

- Data analysis of restricted access or non-anonymised data of individuals;
- The measurement and collection of health-related data, including assessments, diagnoses and the collection of biological samples;
- Issues noted in D below.

D. Evidence generation that has the potential to compromise the safety and well-being of individuals in their context. This includes primary and secondary data collection that involves questions on socially or politically sensitive issues such as:

- Violence
- Abuse
- Prostitution
- Female Genital Mutilation
- Political views
- HIV/AIDS
- Reproductive, sexual and mental health
- Other information that may be perceived as private or sensitive within the social context
- Opinions for which fear may exist of public disclosure resulting in limitations to future freedoms and access to services.\(^\text{11}\)

E. Evidence generation that involves non-universal distribution of resources (ie. RCTs involving the provision of cash transfers, or other goods and services, to one group and not to another group).

ix. In the instances of routine programme monitoring and data collection, these need not go through an external review board. However, the principles, considerations and requirements of this procedure still apply.

x. Where an external ethical review is required this may involve a national ethical review board or an institutional review board of a contracting organization. Where the project is not required by law or, in accordance with institutional requirements to be submitted for review to these bodies, the originating unit, office or division should engage either a pre-existing ethical review board or committee whose standards are consistent with those of these procedures\(^\text{12}\) (for example, a local university-based or a national ethical review board) to undertake the ethical review process. Alternately, an ethical review panel can be established either for the specific project or for the broader unit or office, consisting of no fewer than three appropriately qualified or experienced members\(^\text{13}\) who are external to the originating unit, office or division.\(^\text{14}\) (Annex (A)) Which External Review Mechanism to Utilise).

\(^\text{11}\) This list is not exhaustive but rather indicative.
\(^\text{12}\) For a compilation of health-related ethics review committees in countries globally see https://healthresearchweb.org/en/regulation_and_ethics_review_of_research
\(^\text{13}\) In this procedure “appropriately qualified or experienced” members refers to individuals with appropriate expertise in areas such as: evidence generation methodologies, technical subject matter and in working/undertaking research with relevant participant groups e.g children, adolescents, minority groups etc.
\(^\text{14}\) This can include academics/researchers, relevant members of civil society and UNICEF staff who are external to the originating unit, office or division.
xi. All evidence generating activities meeting the criteria highlighted in paragraph viii. above cannot commence until a proposal has been submitted to a relevant panel and approval has been received.

xii. Where a project is required by law or in accordance with institutional requirements to be submitted to bodies whose standards do not fully meet the requirements of this procedure, projects must still meet the standards outlined in this procedure.

Procedures specifically relating to Harms and Benefits

i. All proposals must justify why the evidence generation processes covered by this procedure are being undertaken. The justification must take into account pre-existing evidence or gaps in the evidence, and must explicitly reflect on the data sources and the particular methodology applied in order to ensure that the specific approach adopted has minimized any negative impacts on participants and their communities.

ii. All proposals must justify why certain groups are included or excluded. The rights of vulnerable and marginalized groups to participate must be recognized and respected and, more particularly, measures should be taken to support the involvement or representation of under-researched groups. Respecting groups’ and individuals’ participation rights however needs to be weighed against any potential harms that may come to these groups consequent to their involvement or representation in evidence generating activities.

iii. In justifying the evidence generation process involving human subjects or involving sensitive secondary data, efforts must be made to ensure that the evidence or the data to support the evidence is not already available and publically accessible.

iv. Throughout the evidence generation process, and articulated in both the proposal and the final report, should be consideration of any potential harms and benefits for participants, their families or wider community groups. An assessment of potential harms and benefits can and should be supported by a situational analysis (using available data) including local consultation. In the instance of local consultation (particularly with implementing partners), power relationships and their dynamics should be explicitly factored into the selection of stakeholders consulted.

v. At the proposal stage, where the potential risks outweigh the potential benefits, consideration must be given to the modification or withdrawal of the proposal.

vi. Throughout the evidence generation process and articulated in both the proposal and the final report are the methods or practices adopted to ensure that participants are not harmed as a consequence of their participation from the outset of the project through to its completion and dissemination.
vii. All programmes must design and utilize appropriate methods, practices and data collection environments\textsuperscript{15} that minimize stress for participants. These processes must be explicitly noted in both the proposal and the final report.

viii. Protection protocols for children and, where relevant, other vulnerable groups, must be in place to provide safe environments for data collection, to safeguard them from abusive or incompetent researchers/evaluators/enumerators, to respond to any safety concerns or grievances, and to refer them to local supports both during and after the evidence generation activity if necessary, given due consideration to the particular vulnerability of children and young people. For further information regarding measures to protect vulnerable participants in evidence generation processes see Annex (B) Privacy and Confidentiality.

ix. When there is conclusive proof of definitive negative outcomes for participants or their communities during the course of the evidence generation, protection protocols should be enacted and an assessment undertaken by the project managers whether the project can be modified to prevent further negative outcomes or whether the project must be stopped.

x. In all reports produced consequent to findings of research, evaluation or data collection and analysis, the privacy and confidentiality of participants should be assured with data de-identified at the individual level, or findings summarized to an appropriate level of aggregation, particularly in the instance of clear negative impacts such as stigma and reprisals.

The implications of the findings and any potential negative repercussions for particular groups should be considered and measures taken to frame the findings in such a way as to avoid these consequences. Where findings will significantly impact (negatively) on the health and well-being of groups or individuals, public disclosure and, where relevant, disclosure to specific stakeholders should be reconsidered.

These issues and relevant measures should be anticipated and noted in the proposal and (in the case of unanticipated challenges that arise post the proposal stage) addressed as they arise.

Procedures relating to Informed Consent

i. When engaging human subjects, informed consent must be sought from all participants. The nature of the informed consent must be noted in the ethics section of the proposal and any final report.

ii. Any project seeking to involve children as either participants, researchers or data collectors must, at minimum, comply with local legislation regarding the age or circumstances which allow for informed consent. In the absence of this legislation, evidence generation involving children and young people under the relevant age of majority as defined by local law must take into account their competencies and the circumstances relating to their autonomy, and, where autonomy is limited or where cultural

\textsuperscript{15} This can refer to the visibility and audibility of the location, the researchers, family and community members present during data collection, the facilities and amenities present etc.
norms dictate, consent sought from a guardian, parent, or, when these are unavailable or inappropriate, a relevant caregiver or person responsible for the child’s well-being.

iii. In the instance where consent is required from a parent, guardian, caregiver or person responsible for the child’s or the individual’s well-being, where possible, and reflecting their capacities, assent must still be sought from the child or the individual themselves. In all evidence generating activities children and, where relevant, adults, must be fully informed, utilizing tools that are reflective of their capacities as to the purpose of the activity and what their involvement will be.

iv. Potential participants must be made aware of the voluntary nature of their participation. The decision whether to participate, including dissent or unwillingness to participate, must be respected. Participants must be appropriately informed that consent is negotiable and that they can withdraw at any point without any negative consequences.

v. Local consultation should be undertaken to ascertain if informed consent needs to be obtained from community leaders, representatives or heads of households with due consideration of the prevailing power structures and hierarchies within communities and households. This consideration is required to ensure that marginalized groups and individuals are not prevented from participation due to the personal, political and social agendas of gatekeepers.

Procedures relating to Privacy and Confidentiality

i. Measures must be taken, particularly in sensitive contexts where participants are likely to be highly vulnerable, to ensure participants’ privacy during and after the data collection process.

ii. In the data collection and collation process such measures to be taken may include de-identification of data and, in the instance where GPS collections are taking place, scrambling of co-ordinates, de-linking of data or assignation of broader geographical references.

iii. Confidential participant information or data that is collected must be securely stored, protected and disposed of. This would include limiting access to raw identifying data through password protection of electronic data, physical locks and restricting staff who can access the identified data. For further information regarding measures to protect data see Annex (C) Anonymising and Storing Data.

iv. Participants should be given a clear indication of who will have access to their private data and in what form.

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16 In this context, ‘inappropriate’ can be defined as instances relating to a conflict of interest between the best interest of the child and consent being sought from a parent or guardian. For example, in the instance where the evidence generation relates to violence or abuse and it is known that the parent/guardian is the perpetrator of this abuse. In these circumstances, the competency of the child or young person as relates to their capacity to consent needs to be considered, and where relevant, consent sought from an alternative responsible adult that is trusted by the child or young person (this could include a teacher or a relative).

17 This could involve a simplified explanation of the evidence generation processes, oral rather than written explanations and indications of assent, use of signs to indicate understandings etc.
v. Any assurance to participants about confidentiality must also include explicit mention of the limits to this, with relevant staff prepared to act sensitively on safety concerns in accordance with the project protection protocols and local legislation pertaining to the reporting and disclosure of abuse.

vi. Issues and measures taken to ensure privacy and confidentiality of participants must be noted in the ethics section of the proposal and the final report.

Procedures relating to Payment and Compensation

i. Payment must not be used to coerce, pressure or bribe adults or children to participate or to influence the nature of their responses.

ii. Evidence generation processes must take social and cultural contexts into account and consult locally about payment and other forms of reciprocity to determine the nature or need for reimbursement, compensation or recognition.

iii. In providing payment and compensation, explicit consideration must be given to the possibility and implications arising from the fact that payment may directly or indirectly raise unrealistic expectations or cause disappointment. In these instances, mitigation strategies must be explored and developed.

iv. Explicit consideration needs to be given to the form, timing and amount of payment or compensation to ensure that financial costs are appropriately reimbursed and that the amount does not distort the decision to participate or the responses given.

v. Issues and decisions related to payment and compensation must be noted in the ethics section of the proposal and the final report.

Procedures relating to Conflict of Interest and Funding

i. Any proposal presented to the senior management of a unit, office or division as well as proposals presented to review boards must include information regarding funding, sponsors and institutional affiliations.

ii. Any actual or potential conflicts of interests relating to specific member/s of an ethical review board or panel existing or arising consequent to specific research, evaluations or data collection and analysis projects must result in the exclusion of the board member from all deliberations and consultations pertaining to the project/s in question.

iii. Any actual or potential conflicts of interests relating to staff, contractors, contracting institutions or funders existing or arising consequent to research, evaluations or data collection and analysis must be disclosed in any proposal in accordance with UNICEF (2012) Financial Disclosure and
Declaration of Interest Statements, Executive Directive CF/EXD/2012-003\(^{18}\) to determine whether it is appropriate for the project to proceed see ANNEX (D) for further detail.

iv. Where an evidence generation project is given appropriate authority to proceed, conflicts of interest should still be noted in all relevant proposals to ethical review boards or panels and research publications in accordance with the Procedure Relating to Quality Assurance for UNICEF Research.

v. Funding for evidence generation must not be sourced from industry sectors or organizations identified within UNICEF’s policy of zero tolerance as laid out in Building Alliances for Children – UNICEF Guidelines and Manual for Working with the Business Community (2001) and revised in Briefing Note on Screening Criteria for the Development of Corporate Partnerships. Further, all prospective funding bodies and institutions must follow the appropriate screening process undertaken by the Corporate Intelligence Fundraising unit of the Private Fundraising and Partnership section\(^{19}\) of UNICEF.

### VII. Accountabilities, Roles and Responsibilities

**Establishing and Ensuring Appropriate Procedures relating to Ethical Oversight**

(a) The role of the project manager for the specific evidence generation project under consideration, or the country focal point for a particular data collection project that meets the requirements of this procedure, will be to ensure that their project is in compliance with this procedure. Where projects meet the criteria established in section v. of the core procedures and are not part of routine data collection and monitoring and evaluation, and in the instance where a formal ethical review process is not required by a national or institutional ethics review board, the project manager must ensure that either (a) a local national ethics review board or other institutional review board is sought out to undertake the ethical review or (b) that an external ethics review panel as prescribed is established.

The project manager or country focal point will be required to ensure the protection of staff, participants and relevant communities throughout the project from the outset of implementation through any monitoring and evaluation phases and finally in the dissemination of findings. During the implementation and delivery of the project, ethical review boards must be notified of any issues arising relating to the violation of the current procedure during the course of the project. In these instances, the project manager will also be responsible for undertaking immediate action involving appropriate modifications or implementation of relevant protection protocols and procedures. If significant negative outcomes cannot be avoided, the project manager or country focal point will be required to ensure the immediate cessation of the project, informing relevant managers, participants and review boards or ethics panels.

\(^{18}\) Further advice regarding conflict of interest can be found in UN (2013) Standards of Conduct for the International Civil Service, International Civil Service Commission, New York.

Maintaining Highest Ethical Standards in all Evidence Generation

(a) **The Country Representative** will be responsible for ensuring and maintaining the highest ethical standards in all country office evidence generation endeavours. They are responsible for ensuring appropriate processes are undertaken and resources allocated to meet these standards and the protocols contained herein.

(b) **Regional Directors** and **Heads of Divisions** will be responsible for ensuring and maintaining the highest ethical standards in all the evidence generation endeavours of UNICEF units, offices and divisions. They are responsible for ensuring appropriate processes are undertaken and resources allocated to meet these standards and the protocols contained herein.

Organizational Support for Ensuring Ethical Evidence Generation Programmes

(a) **HQ, ROs, the Office of Research (OoR), the Evaluation Unit, and the Data and Analytics section** are responsible for providing other parts of UNICEF with relevant support for ethical research, evaluations and relevant data collection and analysis processes as set out in their mandates, Standard Operating Procedures (SOP), and other strategic documents.

(b) **The Office of Research** is responsible for providing advice, capacity building support and tools to facilitate ethical research and evidence generation.

Audit of the Procedure

(a) Compliance with this procedure may be subject to internal audits
### VIII. Risk Management

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<tr>
<td>• Lack of appropriate oversight for ethical processes.</td>
<td>• Requirement for ethical review of projects meeting criteria as stated in procedure.</td>
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**2. Funding and External Stakeholder Relations**

- Managing expectations of time frames of funders and stakeholders consequent to the additional processes required for appropriate ethical review.
  - Graded requirements for ethical oversight in accordance with the determination of the depth of the review process by a review board.
  - Clear articulation to funders and stakeholders of the value of ethical oversight in ensuring the rigour and external validity of the research.
  - Appropriate accountabilities established as noted in section VI. above.

**3. Budget and Cash Management**

- In light of the additional requirements/recommendations including internal and external (where relevant) reviews, the time frames and resources for research programmes may increase.
  - Clear articulation to funders and stakeholders of the value of ethical oversight in ensuring the rigour and external validity of the research.
IX. ANNEX

Annex (A) Which External Review Mechanism to Utilise

If you are undertaking research in multiple sites across regions external review is currently required at each site, not for the programme as a whole.

- Does your contracting organization have a recognized institutional ERB process that it is required to submit its ethics approval to?
  - Institutional ERB:
    - University ERB
    - Sector/Industry Board ERB
    - Hospital IRB

- Are you required under legislation to submit your proposal to a national ERB?

- Are you required by funders to submit your proposal to a particular institutional/national ERB?

- Do you have access to a recognized local/institutional ERB, that has the technical expertise and rigour to undertake an ethical review process that is consistent with these procedures?
  - National ERB
    - Pre-existing UNICEF Regional/Country office external review boards (if they meet the standards outlined in this procedure)
      - or, if not present
    - Establish expert ethical review panel at local (likely national) level.

- None of the above apply
Annex (B) Privacy and Confidentiality

Privacy and Confidentiality when Collecting Data from Human Subjects

The following are some key considerations when collecting data from human subjects.

1. Will participants be uncomfortable or feel unsafe with other individuals knowing that they are participating? Have you consulted the local community, relevant individuals and organizations and undertaken a situational analysis to determine the likely local perceptions of the evidence generation process? If concerns are raised, some of these options that could be considered include; (this list is indicative not exhaustive)

   a. Use secondary data to source information if available; e.g. systems data from service providers (ensuring de-identification of data if necessary).
   b. Do not undertake research if it could validly place subjects in danger.
   c. If consent is given by participants consequent to full disclosure of evidence generation processes and dissemination by enumerators/evaluators/researchers and, if the research is particularly sensitive, consider framing the research to the broader community in such a way that non participants are less likely to respond negatively, e.g. in a study that has a focus on violence against women you could consider including some general questions on health and well-being and promote/explain the programme to the broader community in terms of health and well-being rather than on violence.
   d. Undertake research in contexts where privacy is relatively easy to ensure or in locations that will ensure privacy but where participants may attend as part of their day to day lives that will not draw public attention, i.e. in health and community centres etc.

2. Consider the cultural context in which you are collecting data – is this a collective or individualistic culture? If it is the former, what are likely attitudes towards privacy? Are family or community members going to insist or presume attendance when survey/interview/focus group/tests are undertaken? If yes:

   a. Consider if there are any contexts or approaches in which this can be avoided such as:
      i. a polling booth
      ii. a location outside the local area (with respect to children and other vulnerable groups, additional measures may need to be taken such as inclusion of a trusted adult). This may be qualified by the fact that this may serve to increase speculation and concern among the broader community.
      iii. utilisation of technology such as computers and mobile phones.

   b. Consider if explicit questions are required. For the safety and privacy of the individual it may be worthwhile reframing questions so that they are generalised rather than personal. E.g. ‘Have you experienced violence in the home’ versus ‘Do you think violence in the home is common in your community?’
Annex (C) Anonymising and Storing your Data

1. Anonymising Data

Quantitative data
- Remove or do not collect direct identifiers (e.g., personal information such as names and addresses). Where this is not possible, i.e., in the instance of panel surveys, data access, storage and security becomes even more critical and those who have access to the identified data should be limited (see data access, storage and security section below for more detail).
- Aggregate or reduce the precision of variables that might be identifiable (such as postcode).
- Generalise text variables to reduce identifiability (in reports).
- Restrict continuous variables (examples of continuous variables include height and age – i.e. anything that is measurable and therefore identifiable), to reduce outliers (those variables that are outside the norm and therefore easily identifiable).
- Pay particular attention to anonymising relational data – some anonymised variables may become identifiable when considered in combination.
- In the instance of geo-referenced data, use encryption coding to transmit information and consider de-identifying, de-locating data or, if not feasible, the assignation of data to broader geographical areas.

Qualitative data
- Anonymisation of qualitative data can be particularly complex, and is not simply a matter of removing personal information such as names or addresses, or of using pseudonyms. A distinctive event or combination of descriptions in a qualitative account could make somebody recognizable. These concerns can mean that qualitative data can need some editing to ensure their anonymity but the UK Data Archive warns that:
  - Whenever editing is done, researchers need to be aware of the potential for distorting the data. For example, deleting all possible identifiers from text or sound recordings is a simple but blunt tool that creates data that are confidential but may be unusable.

2. Data Access, Storage and Data Security

Whether you are collecting new data or accessing existing data, you need to consider:
- how data will be stored;
- who will have access to the data; and
- how they will be able to access data.

Remember, research ethics is all about unanticipated events – so you need to plan for unexpected and undesirable events.

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Your planning should take account of what you need to do with hard copies (such as paper notes of interviews), computer files with anonymised data that are not identifiable, and computer files with personal or identifiable data.

**Hard copies** such as interview notes, prints of photographs, or video or audio tapes need to be kept securely locked away – for example in a locked filing cabinet that can only be accessed by agreed members of the research team. Ask yourself:

- Who needs to have access to hard data?
- Will these data be anonymised before they are stored? If not, why not?
- Will these data be stored separately from personally identifying data?
- Where will the key be stored?
- Could anyone (outside key personnel) find and access the data?
- How will you deal with hard copies in the period between data collection and data storage?

**Files – including computer files – that contain personal or identifiable data (such as names).** These files need to be encrypted or password protected, and only accessed by agreed members of the team. Particular care needs to be taken if you are sharing files within the research team – e.g. on shared computer drives, or by email – or if you are transferring personal data beyond the research team (e.g. if a gatekeeper is giving you a list of contacts).

Computer files including anonymised data still need to be held securely, and can only be shared according to the terms of your consent from participants. Thus, for example, you need to get prior consent from participants if you plan to archive data for use by other researchers. To ensure that anonymised or personal data are only accessible to those who have been agreed (such as your immediate team) you may need help to set up additional security systems. Consider the following example:

A research team is conducting a mixed methods study, collecting quantitative and qualitative data from elderly participants in residential care. The study is concerned with the effect that physical exercise has on their health, and so is collecting biomedical data (e.g., blood pressure, cortisol levels) as well as conducting in-depth interviews about participants’ day to day lives. So the team has a number of data sets: personal information about participants, and where they live; quantitative data from biomedical tests; and digital audio-recordings and transcripts of interviews. These data give rise to two key considerations:

1. Data should be accessible to team members, but no one else. The team work across two institutions: both have computer servers with shared drives that are accessible to all staff within the institution. The researchers need to set up secure systems (a) to ensure that other staff within their institutions cannot access their data via the shared staff drives, and (b) to ensure secure data transfer between institutions. Cloud based storage with limited sharing rights could be considered in this instance.

2. Different data files need to be link-able, they need to be held separately so that they can only be linked purposely, by researchers who are authorised to do so. There is also a need to ensure that data cannot be removed from secure systems in ways that might compromise data security. For example, if anonymised data sets might become identifiable in combination, they should not be downloaded onto the same USB stick – what if it was lost and found or misused by someone else?
Annex (D): Conflict of Interest


Section 2.1 and 2.2

UNICEF staff members must avoid actual and potential conflicts between their personal interests and those of UNICEF. This is a primary element of a staff member’s obligation to maintain the integrity, independence and impartiality required of the international civil service.

An actual conflict of interest occurs when, by act or omission, a staff member’s personal interests cause him or her to discharge his or her official duties and responsibilities in a manner that is inconsistent with the interests of the organisation. A potential conflict of interest occurs where a staff member finds himself or herself in a situation where his or her personal interests might be inconsistent with the interests of the organisation. By way of example, an actual or potential conflict of interest arises when (a) a staff member is actively associated with the management of, or holds a financial or other interest in, any profit-making business or organisation; (b) and it is possible for the staff member, or the profit making business or organisation, to benefit from such association or financial interest; (c) and this is by reason of the staff member’s position.
Annex (E): Documentation of Procedural Requirements in Research, Evaluations, and Data Collection Involving Human Subjects or Sensitive Secondary Data Analysis

The following identifies the requirements for documenting ethical considerations. Where projects are overseen by a national or institutional review board the templates for the research proposal and data collection processes will be provided by the relevant institution.

<table>
<thead>
<tr>
<th><strong>Research Proposal</strong></th>
<th><strong>Data Collection and Analysis</strong></th>
<th><strong>Final Report or Data Publication</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>In Ethics Section</strong></td>
<td><strong>UNICEF staff, contractor or</strong></td>
<td><strong>In Ethics Section (include relevant sections from</strong></td>
</tr>
<tr>
<td>• Identify any conflicts of interest</td>
<td>partner must design and</td>
<td>those listed below) identify:**</td>
</tr>
<tr>
<td>• justify why it is being done (inclusions and exclusions)</td>
<td>provide participants with an</td>
<td>• Any conflicts of interest</td>
</tr>
<tr>
<td>• Note any potential harms and benefits</td>
<td>informed consent (IC) form</td>
<td>• Any potential future or actual harms and benefits</td>
</tr>
<tr>
<td>• Note the methods or practices to be adopted to ensure no harm and minimize stress</td>
<td>provided in a format that is consistent with the capabilities (including literacy) of participants. The IC must provide information regarding:</td>
<td>• Protection protocols utilized and any relevant issues</td>
</tr>
<tr>
<td>• Highlight the presence and development of protection protocols (and any relevant details)</td>
<td>• The nature and purpose of the activity, including contact details for further information</td>
<td>• Mechanisms or approaches adopted to address or mitigate any ethical issues relating to dissemination and any relevant issues</td>
</tr>
<tr>
<td>• Note ethical issues related to dissemination and the mechanisms or approaches to be adopted to address or mitigate against these issues</td>
<td>• Information regarding voluntary and negotiable nature of the process and any payment or compensation</td>
<td>• How informed consent was obtained and any relevant issues</td>
</tr>
<tr>
<td>• Identify the likely nature of informed consent</td>
<td>• Protection of privacy in data collection and storage</td>
<td>• Measures taken to protect privacy of participants and relevant issues</td>
</tr>
<tr>
<td>• Identify the likely mechanism to protect privacy of participants</td>
<td>• Any follow-up to the programme or project</td>
<td>• Nature of storage of data</td>
</tr>
<tr>
<td>• Identify the means to secure storage of data</td>
<td>• Relevant dissemination processes</td>
<td>• Payment and compensation provided and justification and any relevant issues</td>
</tr>
<tr>
<td>• Identify and justify the likely nature of any payment of compensation.</td>
<td>• Any approval for future anonymised use of data.</td>
<td>• Any potential conflicts of interest arising from the programme involving staff, contractors or funding bodies.</td>
</tr>
</tbody>
</table>

**NB:** All research products, including findings, media and any other publically available data arising from the research must be reviewed to ensure the protection of relevant stakeholders, communities and the reputation of UNICEF.
Annex (F): Resources for supporting Ethical Practice in UNICEF Evidence Generation Processes involving Children and Young People

- The Ethical Research Involving Children Compendium is the result of a partnership between the Office of Research, Southern Cross University, the University of Otago and the Childwatch International Research Network. It articulates the key ethical considerations, challenges and best practices to support ethical research involving children and young people. It should be part of an essential reference package for individuals or teams to inform and guide routine research planning, commissioning, reviewing and dissemination activities. See [http://childethics.com/wp-content/uploads/2013/10/ERIC-compendium-approved-digital-web.pdf](http://childethics.com/wp-content/uploads/2013/10/ERIC-compendium-approved-digital-web.pdf)

- The Getting Started Tool and Case Studies of the Compendium: These two components of the Compendium guide the ethical decision-making by research teams, external contractors and partners throughout the research phases.

- The Charter: The charter is an aspirational statement calling for collaborative action within the child research community to uphold seven core commitments for fulfilling their responsibility to undertake quality, ethical research, irrespective of context. It is a tool for advocating ethical and high quality research during engagements with governments, CSOs, funders, individual researchers, research organizations and networks, local and international child rights champions, as well as relevant local ethics review committees.

- The Interactive Website (accessible at [http://childethics.com/](http://childethics.com/)). The website seeks to engage with, and learn from, the external research community and UNICEF experience on ethical issues relevant for child research; facilitates the submission of ideas for new case studies and contributions to the case studies’ series and forum discussions based on personal experiences regarding challenges, breakthroughs and insights relevant for ethical research practice. UNICEF teams are encouraged to make use of this platform.
