UNICEF PROCEDURE ON ETHICAL STANDARDS IN RESEARCH, EVALUATION, DATA COLLECTION AND ANALYSIS (2021)

Document Number: CF/PD/DRP/2015-001 v.2 March 2021

Effective Date: April, 2021

RATIONALE

- 1. UNICEF's strategic agenda to harness the power of evidence to drive change for children makes ethical conduct in evidence generation¹ an organizational imperative. Ethical reflection and conduct as part of everyday evidence generation is necessary if we are to engage appropriately with all our stakeholders, including with the hardest to reach, the furthest from help and the most excluded.
- 2. Drawing on UNICEF global policy and the responsible data for children principles¹, this procedure establishes minimum and binding standards for ethical evidence generation and analysis processes in UNICEF globally. It does this to ensure:
 - 2.1. protection of, and respect for, human and child rights within all research, evaluation and data collection processes undertaken or commissioned by UNICEF
 - 2.2. effective processes and accountability for ethical oversight of these processes.

APPLICABILITY / SCOPE

- 3. This procedure applies to:
 - 3.1. All UNICEF research, studies, evaluation and data collection and analysis involving human subjects or the analysis of sensitive secondary data.
 - 3.2. All research, monitoring, evaluation or other data collection processes that are carried out or commissioned with UNICEF support including Country Offices (COs), Regional Offices (ROs), and Headquarters sections (HQ)2 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.
- 4. This procedure will be reviewed within two years. See **INSTRUCTION 2** to determine if the Procedure applies to your work.
- 5. This Procedure applies to All UNICEF staff, consultants, contractors and partners involved in the development and implementation of UNICEF and UNICEF supported research, evaluations or data collection and analysis processes. For accountabilities and responsibilities for implementation, please refer to <u>INSTRUCTION1</u> at the end of this Procedure.

GUIDING PRINCIPLES

6. The minimum standards and procedures outlined in this document are guided by the spirit and intention of the <u>Declaration of Helsinki (1964)</u>, the <u>Belmont Report on Ethical Principles and Guidelines for the Protection of Human Subjects of Research (1979)</u>, the <u>Convention on the Rights of the Child (1989)</u>, the <u>UNEG Ethical Guidelines for Evaluation (2020)</u>, the IASC Commitments on <u>Accountability to Affected People</u> and the <u>Responsible data for children principles (the 7 P's)</u>. While these principles apply to all participants involved, children may be particularly vulnerable in the evidence generation process and appropriate considerations should be taken.

¹ <u>www.rd4c.org</u>

² National Committees are also encouraged to apply the standards in this Procedure to the research they carry out or commission through partners.

- 7. Consistent with the above, the principles that must inform ethical evidence generation are:
 - 7.1. <u>Respect:</u> This principle involves engaging with all stakeholders in a way that honours their dignity, well-being, participation and personal agency. It also acknowledges any limitations to this agency. Respect requires responsiveness to sex, gender, race, language, country of origin, LGBTQ status, age, background, religion, ethnicity, ability and cultural, economic and physical environments.
 - 7.2. <u>Beneficence</u>: This principle means striving to do good for people and planet while minimizing harms arising from evidence generation. It requires the weighing of harms and benefits. The data collected must be purpose-driven (directly informed by the activity or benefit), and proportional (only collecting what is required) and protective of children's rights.
 - 7.3. Justice: The principle of justice requires that consideration is given to who benefits and who carries the burden of evidence generation and the broader equity of the project, its implementation and outcomes. The work should be "people-centric" ensuring the needs, interests and expectations of people—including children and their caregivers in particular—are prioritized by those handling data about them.
 - 7.4. **Integrity:** This principle necessitates the **active adherence to moral values** and professional standards, which are essential for all evidence that is commissioned or undertaken.
 - 7.5. <u>Accountability</u>³ is the obligation to be answerable for all decisions made and actions taken, and to be responsible for honoring commitments, without qualification or exception as well as to report potential or actual harms observed through the appropriate channels. The principle includes accountability to relevant populations.
- 8. The five principles should inform the day to day decision making of all those involved in evidence generation. Attention to each of these principles is reflected in the specific procedures highlighted below.

PROCEDURE STATEMENTS FOR ETHICAL EVIDENCE GENERATION

9. The following are the minimum required procedures for research, evaluation and data collection and analysis undertaken or commissioned by UNICEF involving human subjects or the analysis of sensitive secondary data. This includes activities undertaken by individual and institutional contractors, and partners. These standards emphasize the importance of respect for and protection of human rights and, more specifically, 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.

Core Management Procedures (see ANNEX II: Links to Key Documents)

- 10. Justify that evidence generation is useful, relevant, necessary and appropriately budgeted for.
- 11. An internal staff member must **review all Terms of Reference and Proposals**. The staff member must have either relevant ethics training or sufficient technical expertise and knowledge to appreciate the ethical dimensions of the proposed evidence generation activity and the corresponding competencies and backgrounds required of consultants.
- 12. Require potential contractors to document ethical issues and strategies in their proposal. This should be clearly laid out in the Terms of Reference.
- 13. All staff and contractors involved in UNICEF funded or instigated primary evidence generation must have completed UNICEF or other equivalent ethics training prior to commencement of work.
- 14. Embed reflection on ethics as part of broader quality assurance processes.

³ Noted in the Responsible Data for Children Principles as "professional accountability".

- Instigate ethical review for all sensitive evidence generation. Use the Instructions attached to determine whether you need ethical review (INSTRUCTION 3) and who will conduct it (INSTRUCTION 4). Do not commence until you have formal approval to proceed.
- 16. **Report all ethical considerations and mitigation strategies** in Proposals, Mid Term (where relevant) and Final Reports.
- 17. Take steps to **ensure both local and UNICEF ethics standards are met**. Where relevant and appropriate consider requesting that contractors sign the code of conduct (see <u>ANNEX III</u>)
- 18. In Humanitarian contexts, the commitments espoused in the IASC Accountability to Affected Populations must be reflected throughout the evidence process and beyond.
- 19. Establish mechanisms for **monitoring and reporting ethical issues** throughout the project and beyond.
- 20. Create an environment where ethical issues can be confidently raised and addressed.
- 21. Make all staff, contractors and partners involved in evidence generation aware of the basic principles and requirements of this Procedure and of the relevant terms highlighted in contracting and partnership agreements that specify adherence to these standards.

Procedures for Minimizing Harms and Maximizing Benefits (see ANNEX II: Links to Key Documents)

- 22. Undertake a systematic analysis of all potential harms and benefits, ensuring that benefits outweigh harms. Wherever possible, all relevant stakeholders must be consulted.
- 23. Take all necessary measures to ensure methodological choices, including choices of data sources, maximize benefits and minimize negative impacts on participants and their communities.
- 24. Explicitly consider actual and potential bias and implications and take all measures to prevent discrimination based on gender, race, religion, disability or any other factors, and, wherever possible, to ensure inclusiveness. Data collection and processing should ensure the respect, protection and promotion of human rights and international standards.
- 25. Ensure, to the greatest degree possible, that all relevant stakeholders are able to participate in the evidence generation and have their voices heard. Provide a clear justification as to who is or isn't included as participants and stakeholders in the evidence generation.
- 26. Take all necessary measures to ensure the accuracy, validity, completeness and reliability of the evidence.
- 27. Undertake Comprehensive Protection protocols prior to any requisite ethics review. (see INSTRUCTION 5 for further details).
- 28. Adhere to appropriate UNICEF or programme based guidelines and policies in relation to potential or actual human rights violations or data breaches.
- 29. Undertake vetting wherever possible and ensure that staff and contractors are aware of, and their conduct is consistent with, UNICEF policies on Safeguarding and International Civil Service Personnel Standards.
- 30. Respect and recognize the value of local field staff and implementing partners, take measures to address potential vulnerabilities arising from evidence programmes and where appropriate and possible, build capacity.
- 31. When negative events occur, undertake an assessment immediately to determine how or whether to continue and follow protocols for referrals to relevant services.
- 32. Establish clear pathways for discussion of ethical considerations arising, complaints and redress.
- 33. Notify and ensure adherence by all staff and contractors to UNICEF's policy of zero tolerance for sexual harassment abuse and exploitation and discrimination.

34. Undertake risk assessments where automated decision making is used and/or where big data sets are analyzed internally or by third parties.

Procedures for Informed Consent (see <u>ANNEX II:</u> Informed consent templates)

- 35. **Informed consent must be obtained from all participants** and reported in the proposal/inception and final report. This is applicable even in contexts where remote surveys are undertaken.
- 36. Ensure that informed consent relating to children is compliant with legislation where it exists and, where absent, takes into account competencies, cultural norms, agency and autonomy.
- 37. Obtain assent/consent from children even when informed consent is legally required from an adult.
- 38. Participation must be voluntary, negotiable and explained to participants.
- 39. Make clear to participants and make certain that participants understand that their participation will not affect their access to services or goods.
- 40. Undertake local consultation to determine if consent also needs to be sought from community leaders.
- 41. Explicitly note in the informed consent form whether data will be used again for other evidence generation projects and who will have access to this data and for what purposes.
- 42. Where third party data sets are used, ensure that information about the evidence generation project is noted on social media and on other relevant public sites or within relevant forums.
- 43. Note that data collected for the explicit purposes of provision of services is exempt from informed consent.

Procedures on Privacy and Confidentiality (SEE ANNEX II for Key Documents)

- 44. Adhere to UNICEF's Policy on Personal Data Protection (2020). This includes completion of a data privacy impact assessment (DPIA) for new data collection and analysis involving personally identifiable data, and when data collection and/or analysis is likely to involve high risk to the rights and freedoms of data subjects.
- 45. Consider personal as well as categorical privacy ⁴
- 46. Consider and **enact measures that provide for participant privacy**, before, during and after data collection.
- 47. In the case of data breaches, observe the UNICEF (2021) Personal Data Breach Procedure.
- 48. To the greatest extent possible, and unless absolutely requisite, de-identify data sets.
- 49. Confidential data must be securely stored, transmitted, protected and disposed of after an appropriate period.
- 50. Inform participants who data will be shared with (if shared) and why and the nature and duration of storage of that data.
- 51. Clearly articulate any limits to confidentiality to potential participants.
- 52. Sharing data with third parties must be clearly justified and the terms noted in a Non- Disclosure Agreement (NDA). Third parties should have in place or agree to rigorous and clear privacy, confidentiality and data security standards. These standards should be agreed to before collection, analysis or sharing takes place.
- 53. Confidentiality of participant data must be assured in reporting of findings.

⁴ The definition of "Categorical Privacy" referred to here indicates privacy concerns arising from association with a particularly category (e.g. postcode) which may inadvertently lead to discrimination even where individuals are not personally identifiable. This may occur consequent to the use of predictive algorithms. "Personal Privacy" in this Procedure refers to privacy concerns arising from collection and/or use of personally identifiable data (e.g. name, phone numbers etc.).

- 54. **Inform participants** that they can legitimately inquire about and request access, correction, deletion or objection to collection or processing of their personal data wherever feasible and where it does not infringe on others' rights.
- 55. Do not undertake sensitive data collection remotely if privacy is likely to be compromised.
- 56. Note privacy and confidentiality measures in the proposal and final report.

Procedures for Payment, Compensation and Reciprocity

- 57. **Provide compensation for reasonable out of pocket expenses** (e.g. transportation costs) arising from participation in evidence generation in a timely manner.
- 58. Explicitly consider the necessity and appropriateness of payment for participation in evidence generation. Avoid financial renumeration unless contextually unavoidable. Reflect on the need to compensate for potential lost wages.
- 59. Take into account the local context and rates prior to determining any payment or compensation.
- 60. Be clear that any payment or in-kind service or gift **should not and has not placed undue pressure** on participants to participate, cause community tensions or put persons at risk.
- 61. Note any payment or compensation in the proposal and final report.
- 62. Acknowledge the value of their participation to participants. Wherever possible, reciprocate through the provision of in-kind or non-material approaches including sharing of findings in accessible formats or directly addressing concerns raised through the evidence process.

Procedures on Professional Conduct

- 63. Act with honesty and integrity throughout the evidence generation process. This applies to all staff and contractors involved in evidence generation and includes.
 - 61.1 Disclosure of potential or actual conflict of interest (as noted below)
 - 61.2 Respectful behavior towards all stakeholders involved
 - 61.3 Clear disclosure of the limitations of the process, or findings of any evidence generation
 - 61.4 **Clear referencing** (not plagiarizing)
 - 61.5 Clear articulation of alternate or competing implications of findings
 - 61.6 Honest and sensitive presentation of findings.
- 64. Findings must be supported by **robust**, **verifiable methods** and, where relevant and appropriate, be provided to relevant stakeholders in an **accessible format** with the limitations clearly stated.
- 65. Make full disclosure of information relating to funding to senior management and review boards
- 66. Undertake discussions relating to any **potential or actual conflict of interest** prior to commencement and report on these in the final report.
- 67. Ensure evaluators are independent of the project that they are evaluating
- 68. Recuse ethics review panel members from reviewing specific projects where they may have a conflict of interest.
- 69. Due diligence reviews must be undertaken for all new funding sources. Funding however, must not be sourced from industry sectors or organizations identified within UNICEF's position on zero tolerance to particular industries and sectors.

RISK MANAGEMENT

Document Title: UNICEF PROCEDURE ON FOR ETHICAL STANDARDS IN RESEARCH, EVALUATION, DATA COLLECTION AND ANALYSIS (2021)

Corporate Risk Categories: Governance and Accountability, Misconduct, Wrongful and Negligent Behavior Towards Others, Information Management, Environmental and Social Sustainability, Organisation Resilience Management

Typical Risks	Minimum Expected Mitigation Measures
Lack of appropriate oversight for ethical processes	Clear delineation of accountabilities throughout the evidence generation programmes identified in s. VII above.
Reputational Risk resulting from violations or non-adherence to ethical standards	Requirement for ethical review of projects meeting criteria as stated in procedure Clear delineation of accountabilities throughout the evidence generation programmes identified in s. VII above.
	Requirement for ethical review of projects meeting criteria as stated in procedure.
	Clear guidelines on approach where UNICEF is a junior partner to an evidence programme, in case of ethics violations by staff (UNICEF can refer to clear approach to support compliance and awareness of ethical considerations). Also see instances of SEA and Child Safeguarding risk noted below.
Funding and External Stakeholder Relations Managing expectations and push back from funders and stakeholders consequent to the time lag from additional processes required for appropriate ethical review	Only sensitive subjects, vulnerable cohorts or risky contexts require external ethical review.
	Clear articulation to funders and stakeholders by staff of the value of ethical oversight in ensuring the rigour and external validity of the research.
	Clear articulation and staff training on external stakeholder relations and principles of partnership management for evidence generation activities
	Explicitly accounting for ethical review in time schedule of proposals
	Creation of capacity for low intensity review processes for small and rapid data collection project.
Budget and Cash Management In light of the additional requirements/ recommendations including internal and external	Clear articulation to funders and stakeholders of the value of ethical oversight in ensuring the rigour and external validity of the research
(where relevant) reviews, the time frames and	Explicitly costing ethical reviews in proposals

resources for research programmes may increase	
Data Breach	Clear reference to breaches in the Procedure and direct link to <u>UNICEF Standard on</u> <u>Information Security Incident Management</u> <u>guidance</u>
Instances of SEA and Child Safeguarding Issues	Clear linkages within the Procedure to Key PSEA Guidance, Reporting Protocols and Safeguarding Resources.
Staff do not adhere to, understand or apply to this procedure. Ethics seen by staff as an issue only to be addressed when a harm occurs rather than as part of everyday good evidence generation practice	Substantive awareness raising, capacity building activities, tools and resources to be undertaken by the Senior Advisor – Ethics in Evidence Generation as key responsibility of role. Evidence champions and focal points identified in RO's, Cos and evidence offices and engaged in technical assistance and referral to Senior Advisor.

INSTRUCTION 1: ACCOUNTABILITIES, ROLES AND RESPONSIBILITIES

This section clarifies the accountabilities, roles and responsibilities of all involved in evidence generation, at all levels, IF the evidence generation requires adherence to the Procedure, as per <u>INSTRUCTION 2</u> below.

1. Project Manager or Country Focal Points

The project manager or country focal point for the evidence generation project (inclusive of polls, rapid reviews, monitoring data collection and child consultations) is responsible for:

- 1.1 Establishing and ensuring appropriate processes relating to ethical implementation and oversight
- 1.2 Ensuring that their project is in compliance with this procedure and that consideration has been given as to whether the pledge of ethical behavior could be reasonably signed by consultants, contractors and partners in the project context (ANNEX III).
- 1.3 Ensuring the protection of staff, consultants, participants and relevant communities throughout the project
- 1.4 Ensuring that all staff and contractors are aware of and reflect on UNICEF's policy of zero tolerance for sexual harassment, abuse and exploitation and discrimination and that this is highlighted in any training undertaken. Ensure all staff involved in the evidence generation are informed of relevant channels and processes for reporting of complaints.
- 1.5 Establishing mechanisms for monitoring and reporting on ethical issues throughout the project or programme and beyond. This includes ensuring that clear reporting mechanisms, focal points and disciplinary measures are in place and that all staff and contractors are aware of the process.
- 1.6 Escalating breaches of this Procedure to the relevant focal point and notifying the ethical review board of any changes to the project or violation of procedures. Where necessary the project manager will be responsible for appropriate modifications to the project or implementation of relevant protection protocols and procedures. (Please see relevant section in this Procedure for actions required in accordance with the specific nature of the breach).
- 1.7 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.
- 1.8 Where UNICEF is undertaking evidence generation in partnership, the project manager or focal point should ensure that partners are made aware of the requirement to uphold the UNICEF Procedure for Ethical Standards.
- 1.9 Where UNICEF is the major partner / funding partner to the evidence endeavor, partners should be made aware of and agree to uphold the basic standards in the UNICEF Procedure.
- 1.10 Where UNICEF is a junior partner to the evidence programme (i.e. is not the implementing partner, funder, data processor or data owner e.g. MICS) and does not have ownership of the data or control of the process, the project manager or focal point should, at minimum strongly advocate for the principles and the procedure to be upheld, providing tools, capacity building

and advice wherever possible. Where there are likely to be significant violations of participant rights – suspension of the project should be strongly considered in conjunction with senior management.

2. Quality Assurance Committees in Countries or Regions

Quality assure implementation of appropriate ethics procedures and processes

2.1 As part of any broader quality assurance processes, research, evaluation and data committees are responsible for ensuring that proposals adhere to and ensure implementation of ethics requirements and policy/procedural requirements for child safeguarding, data protection and other relevant organizational requirements.

3. Country Representatives, Regional Directors and Heads of Division

Maintaining Highest Ethical Standards in all EvidenceGeneration

- 3.1 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. This includes appropriate processes for complaints and remedies relating to violations of these Procedures.
- 3.2 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.

4. Office for Research, Evaluation Office and the Division of Data, Analytics, Planning and Monitoring and Regional Offices

Ensure Organizational Support for Ethical Evidence Generation Programmes

- 4.1 HQ, ROs, the Office of Research (OoR), the Evaluation Office, and the Division of Data, Analytics, Planning and Monitoring 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.
- 4.2 The Senior Advisor Ethics in Evidence Generation is responsible for providing advice, capacity building support and tools to facilitate ethical evidence generation on behalf of the Office of Research, DAPM and the Evaluation Office.

5. Audit function

Ensure compliance with this procedure

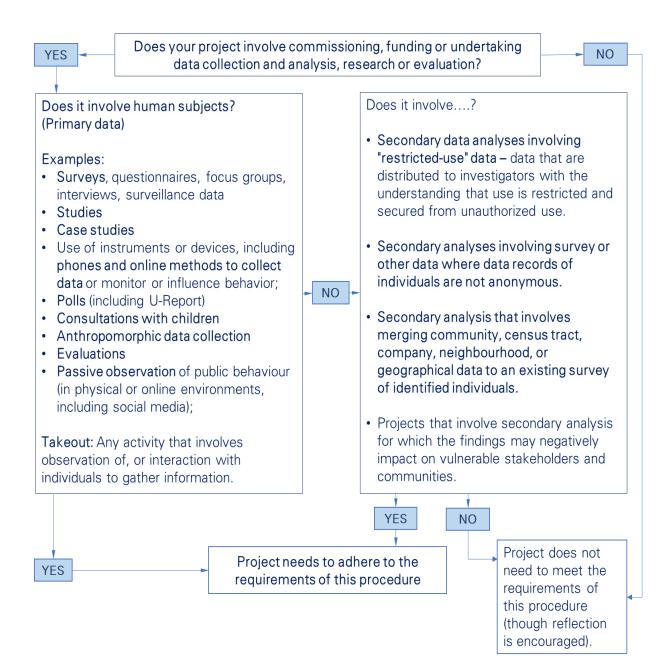
5.1 Compliance with this procedure may be subject to internal audits

6. Consultants, Contractors and Partners

Comply with this procedure

- 6.1 Consultants, contractors and partners should be aware of and agree to uphold the basic standards in the UNICEF Procedure. Where partners are involved in field work they will be required to also undertake ethics training.
- 6.2 The UNICEF pledge of ethical behavior should be discussed and wherever reasonable signed by consultants, contractors and partners.
- 6.3 All contractors and consultants must be aware of and adhere to <u>UNICEF's policy of zero tolerance</u> for sexual harassment, abuse and exploitation and discrimination.
- 6.4 Contractors responsible for drafting findings are responsible for ensuring that all reports- inception, mid-term and final- include reflection on ethics, risks and mitigation measures.

INSTRUCTION 2: DOES THIS UNICEF ETHICS PROCEDURE APPLY TO MY DATA PROJECT?



INSTRUCTION 3: CRITERIA FOR ETHICAL REVIEW

Implementation Detail

Where required by legislation or partner institutional policies, evidence generation must go through ethical review (even if not required by this Procedure). Where this is not the case, all proposals involving research, evaluation or data collection and analysis covered by this procedure, and meeting one or more of the following criteria, must also go through a relevant external ethical review board or panel:

Criteria for Ethical Review Board/ Panel:

- 1. Evidence generation that involves **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:
 - 1.1 Involves children as participants, researchers and data collectors;
 - 1.2 Specifically targets persons with an illness, disability or mental health issue as participants;
 - 1.3 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;
 - 1.4 **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).
- 2. Evidence generation involving primary data collection that has the **potential to result in direct harm to the participant** (through physical or psychological tests, measures or lines of questioning). This includes evidence generation activities that:
 - 2.1 Specifically explore issues related to violence, abuse or trauma;
 - 2.2 Provides health-based assessment, diagnoses and treatments as part of the programme
 - 2.3 Could **potentially result in discrimination** against individuals or cohorts of marginalized or disadvantaged groups
- 3. Evidence generation that has the **potential to compromise the privacy of subjects** and the **confidentiality of data** including:
 - 3.1 Data analysis of restricted access or non-anonymized data of individuals;
 - 3.2 Data analysis that will result in the classification of individuals that could result in direct or indirect discrimination ⁵
 - 3.3 **The measurement and collection of health-related data**, including assessments, diagnoses and the collection of biological samples;
 - 3.4 Issues noted in D below.
- 4. 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:
 - 4.1 Gender roles
 - 4.2 Violence

⁵ When analyzing large datasets, privacy and confidentiality considerations should not only be considered in relation to personally identifiable information but also to demographically identifiable information. Data analysis may result in data that while not personally identifying an individual may still enable them to be tracked or classified according to ethnicity, class, gender, age, health, location, occupation or other demographic data (known as demographically identifiable data – DII). This in turn, could result in discrimination against the individual

- 4.3 Abuse
- 4.4 Prostitution
- 4.5 Female Genital Mutilation
- 4.6 Political views
- 4.7 HIV/AIDS
- 4.8 Reproductive, sexual and mental health
- 4.9 Other information that may be perceived as private or sensitive within the social context
- 4.10 Opinions for which fear may exist of public disclosure resulting in limitations to future freedoms and access to services.⁶
- 4.11 Body Image
- 5. Evidence generation that involves non-universal distribution of resources (i.e. Randomized Control Trials involving the provision of cash transfers, or other goods and services, to one group and not to another group).
- 6. Evidence generation utilizing new/emerging/novel technologies or innovations for data collection or processing (directly or through third parties), inclusive of predictive or other "black box" analytics.

Routine programme monitoring and data collection exercises do not need to go through an external review board. However, the principles, considerations and requirements of these Procedures still apply.

⁶ This list is indicative rather than exhaustive.

INSTRUCTION 4: WHICH ETHICAL REVIEW MECHANISM TO USE

Implementation Detail

- 1. An external ethical review should be undertaken in the first instance by a **national ethical review board** or an **institutional review board of a contracting organization** if this is required by law or, in accordance with institutional requirements.
- 2. 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 procedures⁷ (for example, a local university-based or a private ethics review board⁸) 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 <u>three appropriately qualified or experienced</u> <u>members⁹</u> who are external to the originating unit, office or division.¹⁰
- 4. Where necessary and appropriate, alternative ethical review processes can be instigated:
- In consultation with the Senior Advisor, Ethics in Evidence Generation, alternate ethical review processes can be established. Criteria for alternate processes could include the frequency and breadth of the data collection^{11.} (e.g U-Report Ethics Focal Points)

See diagram below for pictorial representation:

For a compilation of health-related ethics review committees in countries globally see https://healthresearchweb.org/en/regulation and ethics review of research
UNICEE currently has an LTA with a private othics review heard. Details can be found:

⁸ UNICEF currently has an LTA with a private ethics review board. Details can be found: <u>https://unicef.sharepoint.com/sites/OoR-EEG/SitePages/Resources-and-Templates.aspx</u>

⁹ 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.

This can include academics/researchers, relevant members of civil society and UNICEF staff who are external to the originating unit, office or division.

¹¹ U-Report is an example of an alternate approach to ethical review that involves appointing a staff member (from a non programme team) as an ethical reviewer for each country, regional and divisional office who must review the ethical implications of the polls and sign off prior to implementation of any single poll.

Does your contracting organization have a recognized institutional ERB process that it is Institutional ERB: required to submit its **University ERB** ethics approval to? Sector/Industry Board ERB Hospital IRB Are you required under legislation to submit your proposal to a national ERB? National ERB Are you required by funders to submit your proposal to a particular Pre-existing UNICEF institutional/national ERB? Regional/Country office external review boards (if they meet the standards outlined in this procedure) Do you have access to a or, if not present: recognized national/institutional ERB, Establish local ethical review panel (3 that has the technical external persons). A private ethics expertise and rigour to review board (see LTA details at: undertake an ethical review https://bit.lv/2YQYshD) process that is consistent with these procedures? or other process in agreement with If none of the above apply Senior Advisor – Ethics in Evidence Generation (e.g. U-Report Ethics Focal Point Programme)

INSTRUCTION 5: CONTENT OF A PROTECTION PROTOCOL

Implementation Detail

- 1. Protection protocols must be in place prior to commencement of ethics review to ensure that participants and their communities are protected throughout the entire evidence generation process. This would include but not be limited to ensuring;
 - 1.1 any necessary privacy provisions are in place during recruitment of participants,
 - 1.2 the utilization or creation of safe environments for data collection,
 - 1.3 measures to safeguard against abusive or incompetent researchers/evaluators/enumerators,
 - 1.4 measures to respond to any safety concerns or grievances,
 - 1.5 measures adopted to minimize stress/distress (All programmes must design and utilize appropriate methods, practices and data collection environments¹² that minimize stress),
 - 1.6 measures to ensure that the evidence generation does not interfere with employment, education and other important social and economic activities.
 - 1.7 clear referral processes to relevant/local support services both during and after the evidence generation activity if necessary, and finally,
 - 1.8 clear processes for addressing evidence of abuse (with clear identification and reflection on any local mandatory reporting of abuse legislation).

For an example of a protection protocol see: <u>Template 1</u> <u>Template 2</u>

¹² 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.

INSTRUCTION 6: DOCUMENTATION OF ETHICS IN RESEARCH, EVALUATION AND DATA COLLECTION AND ANALYSIS INVOLVING HUMAN SUBJECTS OR SENSITIVE SECONDARY DATA.

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.

Research Proposal

- Identify any conflicts of interest
- Justify why it is being done (inclusions and exclusions)
- •Note any potential harms and benefits
- •Note the methods or practices to be adopted to ensure no harm and minimize stress
- •Highlight the presence and development of protection protocols (and any relevant details)
- •Note ethical issues related to dissemination and the mechanisms or approaches to be adopted to address or mitigate against these issues
- •Identify the likely nature of informed consent
- •Identify the likely mechanism to protect privacy of participants
- •Identify the means to secure storage of data
- •Identify and justify the likely nature of any payment of compensation.

Data Collection and Analysis

•UNICEF staff, contractor or partner must design and provide participants with an informed consent (IC) form provided in a format that is consistent with the capabilities (including literacy) of participants.

•The IC must provide information regarding:

- •The nature and purpose of the activity , including contact details for further information
- Information regarding voluntary and negotiable nature of the process and any payment or compensation
- Protection of privacy in data collection and storage
- •Any follow-up to the programme or project
- •Relevant dissemination processes
- •Any approval for future anonymised use of data.

Mid Term Report (if produced)

 Any unanticipated harms that arose and mitigation strategies adopted
Any unanticipated privacy and confidentiality issues and mitigation strategies adopted
Any unanticipated changes to

payment and compensation and justification

Final Report or Data Publication. In Ethics Section (include relevant sections from those listed below) identify:

Any conflicts of interest

- •Any potential future or actual harms and benefits
- Protection protocols utilized and any relevant issues
- •Mechanisms or approaches adopted to address or mitigate any ethical issues relating to dissemination and any relevant issues
- •How informed consent was obtained and any relevant issues
- •Measures taken to protect privacy of participants and relevant issues
- •Nature of storage of data
- •Payment and compensation provided and justification and any relevant issues
- •Any potential conflicts of interest arising from the programme involving staff, contractors or funding bodies.

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 I: 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. If assent is given, informed consent must still be obtained from the subject's parents or guardian or a responsible adult.

Categorical Privacy - indicates privacy issues arising from association with a particularl category (e.g. postcode) which may inadvertently lead to discrimination even where individuals are not personally identifiable. This may occur consequent to the use of predictive algorithms.

Confidentiality – Confidentiality is the process of and the obligation to protect 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.

Data breach means a breach of security leading to the accidental or unauthorized destruction, loss, alteration, disclosure, access, or unplanned loss of availability of data that is unencrypted or can be decrypted.

Evaluation¹³ – Evaluation is a systematic and objective effort to determine the relevance, appropriateness, effectiveness, efficiency, impact and sustainability of development and humanitarian 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.

Ethics - the right or agreed principles and values that govern the behaviour of an individual within the specific, culturally defined context within which work is commissioned or undertaken.¹⁴

Ethical evidence generation – Ethical evidence generation follows widely-held guidelines about the right or agreed principles and values that govern the behaviour of an individual within the specific, culturally defined context in which evidence generation is undertaken. Ethical evidence generation is reflective and explicitly considers its impact on both participants and the broader community throughout the evidence cycle from planning through to dissemination and monitoring and evaluation.

Evidence generation activities – For the purpose of this procedure, research, evaluation, data collection and analysis are collectively referred to as evidence generation activities. This is inclusive of <u>any data</u> collection resulting from online and offline consultations, polls and online surveys.

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.

¹³ UNICEF (2014) Taxonomy for Research, Evaluation and Studies. <u>https://unicef.sharepoint.com/teams/OoR/SitePages/Research%20Taxonomy.aspx</u>

¹⁴ Derived from UNEG (2020) UNEG Ethical Guidelines for Evaluation, NY.

Human Subject - a living individual from whom data is collected for evidence generation through intervention or interaction with the individual.

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.¹⁵

Institutional Review Boards (IRBs) or Ethical Review Boards (ERBs) or Committees – A specifically constituted review body established or designated by an institution¹⁶ 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, evaluation 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; seek to maximize the safety of subjects. In this procedure, IRBs will be covered by the term Ethical Review Boards.

Non-Disclosure Agreement – Within UNICEF, a non-disclosure agreement or NDA is a supplemental agreement to a supply contract. It involves additional data protection provisions to the standard Terms and Conditions contained in a UNICEF contract template.

Personal Data - Personal data means any information relating to an identified or identifiable individual ('data subject'). An identifiable individual is one who can be identified, directly or indirectly, in particular by reference to i) an identifier such as a name, an identification number, audiovisual materials, location data, an online 9 identifier, ii) one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of the individual or iii) assessments of the status and/or specific needs, such as in the context of assistance programmes. The definition of what constitutes personal data is contextual and expanding particularly due to enhancements in technology and methods for identifying individuals.

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

Research¹⁷ – The systematic process of collecting and analyzing data and information in order to generate new knowledge, answer a specific question or 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.

¹⁵ Levine, R.J. (1988) *Ethics and Regulations of Clinical Research*, Yale University Press, New Haven.

¹⁶ This could include a private organization.

¹⁷ UNICEF (2014) Taxonomy for Research, Evaluation and Studies, https://unicef.sharepoint.com/teams/OoR/SitePages/Research%20Taxonomy.aspx

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

Vulnerable cohorts and persons – groups and/or individuals, who, by virtue of their capacities, demographics, personal identification or affiliation, opinions, beliefs or circumstances may have less agency or may be at greater risk of harm within their current context.

ANNEX II: KEY DOCUMENTS AND TEMPLATES

Core Management Processes

- UNICEF Research Policy
- UNICEF Evaluation Policy
- UNICEF Procedure for Quality Assurance in Research
- UNEG Norms and Standards for Evaluation
- Agora Introduction to Ethics in Evidence Generation Online Training.
- For guidance on ethical monitoring and evaluation in Humanitarian contexts see <u>Ethical Standards for</u> Data Collection and Analysis in Humanitarian Settings
- Berman, Gabrielle, Hart, Jason; O'Mathúna, Dónal; Mattellone, Erica; Potts, Alina; O'Kane, Clare; Shusterman, Jeremy; Tanner, Thomas (2016). <u>What We Know about Ethical Research Involving</u> <u>Children in Humanitarian Settings: An overview of principles, the literature and case studies</u>, Innocenti Working Papers no. 2016 18, Florence, Italy: UNICEF Office of Research – Innocenti.IASC (2017)
- The Commitments to Accountability to Affected Populations
- UNICEF Evaluation Office (2002) Evaluation Technical note No. 1, Children participating in research, monitoring and evaluation — ethics and your responsibilities as a manager

Harms and Benefits

- <u>UNICEF's Policy on Conduct Promoting the Protection and Safeguarding of Children (CF-EXD-2016-006)</u>
- <u>Standards of Conduct for International Civil Service</u>
- UNICEF (2020) Personal Data Protection Policy
- UNICEF Child Safeguarding Personnel Standards
- UNICEF's policy of zero tolerance for sexual harassment, abuse and exploitation and discrimination
- Procedure for Managing Risks of Sexual Exploitation and Abuse in Implementing Partnerships (CSO's)
- <u>Reporting Allegations of Sexual Exploitation and abuse</u>.
- Protection Protocol Template
- Global Pulse Risks, Harms and Benefits Risk Assessment Tool
- Example of Guidelines for Handling Disclosure of child Abuse or neglect during Fieldwork
- Example Form for Mandatory Reporting of Abuse or Deliberate Neglect
- Reporting of Abuse Checklist for Data Collectors
- Prevention of Sexual Exploitation and Abuse: A Toolkit for UNICEF and Partners (incl. sample training agenda, TORs for investigators of SEA and other)
- <u>Guide to Ethically involving Local Professional Staff and Field Workers in Evidence Generation in Low</u> and/or Middle Income Settings
- Ethical Considerations Children and Use of Behvaioural Insights (Forthcoming)
- Ethical Consideration Children and Predictive Analytics (Forthcoming)

Informed Consent: Templates

- An example template for <u>Informed consent from parents or guardians</u> for children
- An example template to secure <u>assent from a child</u>

Privacy And Confidentiality:

- UNICEF (2020) Personal Data Protection Policy
- UNICEF Data Protection Impact Assessment (forthcoming)
- UNICEF (2021) Personal Data Breach Procedure (forthcoming)

- Ethical considerations for remote data collection in times of COVID-19 pandemic
- UNICEF Standard on Information Security Incident Management
- UNICEF Standard on Information Security: Access Control (outlines who can access UNICEF ICT infrastructure and host storage, when and for how long)
- <u>UNICEF Standard on Information Security Cryptography</u>
- UNICEF Standard on Information Security: Vendor Management
- NDA for contractor use of Government Partner Data
- <u>Class I System UNICEF Security Requirements</u>
- Class II System UNICEF Security Requirements

ANNEX III: PLEDGE OF ETHICAL CONDUCT IN EVIDENCE GENERATION

By signing this pledge, I hereby commit to discussing and applying the UNICEF Procedure on Ethics in Evidence Generation and to adopting the associated ethical behaviours.

Respect

I will engage with all stakeholders of an evidence generation in a way that honours their dignity, well-being, participation, personal agency and characteristics. Specifically, I will ensure:

- 1. **Informed consent processes for all participants to the evidence process**. This requires due consideration of how, whether and any risks of engaging/not engaging persons whose agency may be limited due to age, circumstance or personal capacities and capabilities.
- 2. Access and engagement with the evidence process by all relevant stakeholders- be they powerless or powerful, with due attention to factors that may impede access such as sex, gender, race, language, country of origin, LGBTQ status, age, background, religion, ethnicity and ability. This includes engagement in shaping/informing data needs and access to results.
- 3. **Meaningful engagement and fair treatment** of all relevant stakeholders at all stages of the evidence generation process.
- 4. Fair representation of different voices and perspectives in evidence products.
- 5. Equitable partnerships with communities acknowledging that communities have attributes and value that go beyond the mere sum of its members and may be impacted by evidence in ways that are distinct from individual impacts and recognizing and valuing the community's time and knowledge base and consulting consults all relevant/affected communities throughout this cycle.

Beneficence

I will strive to do good for people and planet while minimising harm arising from evidence generation as an intervention. Specifically, I will ensure:

- 6. **Explicit and on-going consideration of risks and benefits** from evidence generation processes, the products of such processes and longer-term consequences.
- 7. Maximum benefits at systemic (including environmental), organizational and programmatic levels.
- 8. Minimum harm. I will not proceed where harms cannot be mitigated.
- 9. **Evidence generation makes an overall positive contribution** to human and natural systems and the mission of the United Nations.

Justice

I will give consideration to who benefits and who carries the burden of evidence generation. Specifically, I will ensure:

- 10. Selection of Participants based on appropriate methods. Selection should not result in unjust distributions of the burdens and benefits of evidence processes on particular individuals or communities. Such considerations are required to avoid the injustice that arises from social, racial, sexual, and cultural biases institutionalized in society.
- 11. Relevance of the evidence generation process to those who will be participating.

Integrity

I will actively adhere to the moral values and professional standards of evidence generation practice as outlined in the UNICEF Procedure on Ethics in Evidence Generation and following the values of the United Nations. Specifically, I will be:

- 12. Honest and truthful in my communication and actions.
- 13. **Professional**, engaging in credible and trustworthy behaviour, alongside competence, commitment and ongoing reflective practice.
- 14. Independent, impartial and incorruptible.

Accountability

I will be answerable for all decisions made and actions taken, responsible for honoring commitments, without qualification or exception, and will report potential or actual harms observed. Specifically, I will be:

- 15. **Transparent regarding evaluation** purpose and actions taken, establishing trust and increasing answerability on performance to the public, particularly those populations affected by the evidence generation.
- 16. **Responsive** as questions or events arise, adapting plans as required and referring to appropriate channels where corruption, fraud, sexual exploitation or abuse or other misconduct or waste of resources is identified.
- 17. **Responsible** for meeting the evidence generation purpose and for actions taken, and for ensuring redress and recognition as needed.

I commit to playing my part in ensuring that evidence generation is conducted according to the Charter of the United Nations and the ethical requirements laid down above and contained within the UNICEF Procedure for Ethical Standards in Research, Evaluation, Data Collection and Analysis. Where this is not possible, I will report the situation to my supervisor, designated focal points or channels, and will actively seek an appropriate response.

(Signature and Date)

DOCUMENT MANAGEMENT INFORMATION PAGE

Document Title	UNICEF Procedure for Ethical Standards in Research,	
	Evaluation and Data Collection and Analysis (2021)	
Document Number	CF/PD/DRP/2015-001 v.2 March 2021	
Effective Date	April 2021	
Mandatory Review Date	April 2024	
Responsible Business Owner	Office of Research	
Responsible Manager	Senior Advisor – Ethics in Evidence Generation	
Document Summary	UNICEF's strategic agenda to harness the power of evidence to drive change for children makes ethical conduct in evidence generation ¹⁸ an organizational imperative. Ethical reflection and conduct as part of everyday evidence generation is necessary if we are to engage appropriately with all our stakeholders, including with the hardest to reach, the furthest from help and the most excluded.	
	Drawing on UNICEF global policy and the responsible data for children principles ¹⁹ , this procedure establishes minimum and binding standards for ethical evidence generation and analysis processes in UNICEF globally	
Regulatory content the Document Replaces	Update of previous UNICEF Procedure for Ethical Standards in Research, Evaluation and Data Collection and Analysis (2015)	
Topics Covered	Ethics, Data, Research, Evaluation, Safeguarding, Data Protection.	
Corporate Risk Area	Governance and Accountability, Misconduct, Wrongful and Negligent Behavior Towards Others, Information Management, Environmental and Social Sustainability, Organisation Resilience Management	
Reference / Links to Enabling Legislation and Background	Declaration of Helsinki (1964), The Belmont Report on Ethical Principles and Guidelines for the Protection of Human Subjects of Research (1979), The Convention on the Rights of the Child (1989) UNEG Ethical Guidelines for Evaluation (2020), IASC Commitments on Accountability to Affected People	
Links to Relevant Policy	Research PolicyEvaluation PolicyChild Safeguarding PolicyUNICEF (2020) Personal Data Protection PolicyUNICEF's policy of zero tolerance for sexual harassment, abuse and exploitation and discrimination	

¹⁸ "Evidence generation" refers to all research, evaluation and data collection and analysis activities.
¹⁹ www.rd4c.org

Links to Relevant Procedure	Procedure for Quality Assurance in Research Procedure for Managing Risks of Sexual Exploitation and Abuse in Implementing Partnerships (CSO's) UNICEF (2021) Personal Data Breach Procedure (forthcoming)
Links to Relevant Guidance	UNEG Norms and Standards for Evaluation Responsible Data for Children Principles Ethical Standards for Data Collection, Monitoring and Analysis in Humanitarian Settings What We Know about Ethical Research Involving Children in Humanitarian Settings: An overview of principles, the literature and case studies The Commitments to Accountability to Affected Populations Evaluation Technical note No. 1, Children participating in research, monitoring and evaluation — ethics and your responsibilities as a manager Standards of Conduct for International Civil Service UNICEF Child Safeguarding Personnel Standards Reporting Allegations of Sexual Exploitation and abuse Guide to Ethically involving Local Professional Staff and Field Workers in Evidence Generation in Low and/or Middle Income Settings Ethical considerations for remote data collection in times of COVID-19 pandemic UNICEF Standard on Information Security Incident Management UNICEF Standard on Information Security Cryptography UNICEF Standard on Information Security Vendor Management Class I System UNICEF Security Requirements Ethical Considerations Children and Use of Behvaioural Insights (Forthcoming) Ethical Consideration Children and Predictive Analytics (Forthcoming)
Links to Relevant Training Materials	Agora Introduction to Ethics in Evidence Generation Online Training.
Links to Other Knowledge & Information Resources	Example Form for Mandatory Reporting of Abuse or Deliberate Neglect Example of Guidelines for Handling Disclosure of child Abuse or neglect during Fieldwork Protection Protocol Template Global Pulse Risks, Harms and Benefits Risk Assessment Tool An example template for Informed consent from parents or guardians for children An example template to secure assent from a child

UNICEF and Partners UNICEF Data Protection	Dioitation and Abuse: A Toolkit for Impact Assessment (forthcoming) of Government Partner Data
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