World Vision

Ethical Principles for World Vision Evaluation and Research.

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Global Knowledge Management

Research design and implementation constitute fundamental components of our decision making, program and project design, monitoring, and evaluation processes.In this document, we incorporate ethical considerations that must be honored in all research initiatives where WV is involved. First, we highlight ethical principles that apply to all human subjects. Then, we offer specific considerations regarding ethical principles for research involving children and young people. Finally, we introduce the WV Global Center Ethics Committee as part of our institutional commitment to ensure ethical research through a third party review process. The main principle guiding our ethical considerations is our commitment to avoid any negative impact our research initiatives could have on the well-being of people involved in the research processas human subjects.

General Ethical Principles

The following ethical principles should be applied to all research initiatives where WV is involved. These principles apply to all human subjects, including research inquirieswhere the most vulnerable populations participate.

1) Protection of participants from harm by minimizing risks

Appropriate measures to minimize and mitigate risks must be taken. Risk reduction measures should minimizeharm to all aspects of well-being resulting from study procedures or study topics.

Do:

1. Assess potential risks and discomforts associated with each intervention, procedure or topic
2. Estimate the probability that a given harm may occur and its severity
3. Explain measures that will be taken to prevent and minimize potential risks and discomforts

Type of Risks	Risk Reduction Measures

• Physical
• Psychological
• Legal
• Social
• Economic
• Invasion of Privacy
• Breach of confidentiality
	• Sound Study Design[1] - study objectives can reliably be answered by the study design
	  ○ Taking into account local research context
	  ○ Based on relevant literature or best practices
	• Use of alternative procedures that are less risky
	• Use of precautionary procedures to decrease the probability that harm will occur
	• Institute safeguards to deal with harms if they occur
	  ○ Example: monitoring participants to promptly detect harm and modifying study procedures accordingly
	• Consult Subject Matter Experts in areas you do not have expertise
	• Train and support staff so they are safe and effective

Risk Contextual Factors	
• Time • Target population • Culture	

[1]Please see World Vision's Research Guidelines for generally accepted standards for conducting scientifically sound research

• Probability • Severity • Duration	○ Some research grants may require all involved staff to complete a certified human research subjects training ○ Follow WV child protection policies

2) ***Achievement of a balance between the risks assumed by the participants and the benefits to participants and to society***

Since it is not possible to eliminate all possible risks, the key is to minimize them so that the benefits of the research outweigh any potential negative effects.

Do:

1. Describe the direct benefits to the participants and the potential societal benefits that may be expected from the research or evaluation.
2. Compare these benefits to the risks and consider if the risk benefit ratio is reasonable.

Examples of Benefits	• Health-related, psychosocial, or other value to the individual participant • Acquisition of generalizable knowledge • Acquisition of programme specific knowledge to improve decision making and outcomes • Resulting knowledge useful for community advocacy • Benefit may be to the individual, society, the organization or a combination

Not a Benefits	• Compensation for participation in research when impacting livelihoods

The overarching standard is that the data gathered should directly benefit participants by building the evidence base of or improving World Vision programmes or policies.

Consider the risks of not doing the research or evaluation.

3) ***Fair and equitable participant selection***

Most populations are not homogeneous and participation should provide for equality of opportunity for all regardless of age, situation, ethnicity, gender, abilities, class, caste or other factors.

Populations who face social barriers may have very different experiences from the majority. Learning from these populations is important to developing more successful and beneficial programmes.

Do	Do Not
• Create selection processes and methods that challenge to correct, not reinforce, patterns of discrimination and exclusion. • Include populations who face social barriers: ○ Women, indigenous populations, working children, persons with disabilities, rural communities etc.	• Use populations of conveniences for your sample • Allow opportunities for coercion in the selection procedures ○ Is there an authoritative relationship between the recruiter and the potential participant, such as

• Define clear inclusion and exclusion criteria. • Establish your sample size before starting	teacher/student, physician/patient, or chief/subject? • Permit negative consequences for those who choose not to participate

4) *Appropriate safeguards to protect the rights and welfare of vulnerable subjects/populations*

Most Vulnerable populations are at the heart of World Visions work. While learning about their experiences and situations is important,additional protection must be put in place to protect them frompotential harm.

Who are vulnerable populations?	WV definition of Most Vulnerable Children
• children and minors • pregnant women • mentally and physically ill • prisoners • disabled persons • economically disadvantaged persons • educationally disadvantaged persons	• abusive or exploitative relationships • extreme deprivation • serious discrimination • vulnerability to negative impact from a catastrophe or disaster
Why do they need special protections?	
Vulnerable populations are considered to be those less able to protect themselves and their interests relative to other persons in a given setting or situation due to their status in society or relationship with authority. Such individuals have diminished autonomy and can more easily be coerced into participation.	

Population	Key Points to Consider
Children and minors (also see Annex 1Ethical Principles for Evaluation and Research with Children and Young People)	• capacity to consent/assent: ○ ability to understand the choices presented, to appreciate the implications of choosing one alternative or another, and to make and communicate a decision • pressure to participate • discovery and disclosure of sensitive information • child abuse reporting
Pregnant women	• risks and benefits to mother only, foetus only or both • previous research available assessing risks • possibility of participant becoming pregnant during the study
Mentally and physically ill	• capacity to consent • exclude or seek surrogate consent from a legally authorized representative
Prisoners	• pressure to participate
Disabled persons	• coercive incentives

Economically disadvantaged persons	• coercive incentives
	  ○ negative consequences for those who choose not to participate
	  ○ unreasonable advantages for participants

Educationally disadvantaged persons	• capacity to consent

5) *Ensure voluntary participation byobtaining and documenting free and informed consent*

Informed consent is a process of communication between a participant and a researcher/evaluator that results in the participant's voluntary agreement or refusal to participateafter fully understanding the methods, procedures, purpose, and the possible risks and benefits.

Components of ethical informed consent

• Uses language understandable to the subject
  ○ Consider the possibility that participants may not be functionally literate and use appropriate approaches for effective communication in such instances.
  ○ The information should be presented from the participants perspective and at a language level used for the general public (Grade 6 or 7) explaining all technical terms in plain language.
• Conducted under conditions that minimize coercion or undue influence.
• Describes purpose of the research, expected duration and procedures.
• Explains participants' rights to decline to participate and to withdraw from the research at any time
• Explains potential risks, discomfort or adverse effects.
• Explains any prospective benefits or outcomes and potential use of the information
• Explains limits of confidentiality and when confidentiality must be broken.
• Outlines incentives for participation.
• Provides an opportunity for participants to ask questions to elicit a better understanding of the study or procedures.
• Provides information about who participants can contact with further questions.

Not every research or evaluation project needs the process or documentation of informed consent. Consider the implications of having or not having before making the decision. The need for obtaining informed consent ought to be carefully thought out in the context of the specific project.

Waiver of Informed Consent Process If:	Waiver of Informed Consent Documentation If:
• The research involves no more than minimal risk to the subjects. • The waiver or alteration will not adversely affect the rights and welfare of the subjects. • The research could not practicably be carried out without the waiver or alteration. • Whenever appropriate, the subjects will be provided with additional pertinent information after participation.	• The main risks to the subject's participation relate to breach of confidentiality, and the consent document is the only record linking the subject with the research/evaluation. • Study participation presents minimal risk of harm and the research involves no procedures requiring consent outside the context of participation in a research study, for example: telephone survey about waste disposal

Evaluation and research that collects information from children must create supplementary procedures for gaining informed, voluntary assent from minors and consent from their parents or guardians.

6) *Protect the privacy of subjects and confidentiality of data and abide by local and international data governance laws*

- Think about data governance and sharing before research begins - develop clear guidelines and procedures for collecting, storing, using, and destroying study-related materials.
- Plan to limit access to and provide secure storage of the private information for a specified period of time and with a specific plan for its destruction at the end of that timeframe. These should be clearly outlined on the consent form and during the consent process.
- Are you collecting too much identifiable information (i.e., data that is "nice to know" versus what "you need to know")?
- Remove all direct identifiers as soon as possible
- Substitute codes for identifiers.
- Store code lists and data files in separate secure locations.
- Use accepted methods to protect against indirect identification, such as aggregate reporting or pseudonyms.
- Encrypt transmitted and stored data.
- Access and store data on computers without Internet connections.
- Limit access to identifiable data to certain staff members.
- When and how destroyed - Dispose of computer printouts, written notes and reports, and other records so that they cannot be found.
- Collect the least amount of personally identifying information needed to complete the project
- Security measures for any electronic and/or hard copy record(s) (e.g., password protection and locked filing cabinet storage; data encryption tools to secure data on laptops or other personal computers)
- Storing paper records in locked cabinets or assigning security codes to computerized records.
- Is data being transferred across regional, provincial, national, or international boundaries?
- Business Rules and controls for collecting personally identifiable information (link)
- Access and use of sponsorship data in StepWise (link)

Many countries have laws controlling who can collect data, what type of data can be collected and how this data can be transmitted across borders. It is the researcher's responsibility to know and abide by these laws and they must be understood prior to any Research proposal being developed. WV has a Data Governance group can provide more advice on these issues.

7) Seek review from WV GC Ethics Committee when necessary

As part of our commitment to ensure ethical research, World Vision has established a Global Centre Ethics Committee (EC). The Ethics Committees is designed to provide third party review in order to:

- minimizing conflicts of interest
- protect the welfare of research participants through attention to risks, benefits, and informed consent
- avoid exploitation of vulnerable individuals and populations

Research initiatives need to be reviewed by the GC Ethics Committee when the type of activity and donor regulations may require different forms of ethical supervision. The formation of a community advisory board to provide a forum for discussion of the research contents is one option to ensure that activities are locally understood and acceptable. A Community Advisory Board will most often be the necessary mechanism for World Vision's research activities. In some circumstances formal review by

both, the GC Ethics Committee and the local Ethical Review Boards may (detailed in red) be requiredwhen the type of activity and donor regulations require specific forms of ethical considerations. In some instances (detailed in yellow), further considerations must be discussed with the EC but a full submission might not be required. Elements detailed in green would not normally go to the EC, but if in doubt – ask! Contact GKM@wvi.org

There are certain types of research that WV never engages in. These are highlighted in black.

Where the research is being conducted in Partnership with an Academic Institution it would be expected that the research approach is first passed by the AIs ethics committee.

Even when the WV GC Ethics committee does not require a review, the country or region where the research will take place may require or recommend local review.

- Partnering with community leaders and stake holders may provide important insights about the local research context, including information about local customs, norms, and laws.
- Approval by local authorities or gatekeepers including the government, schools, health centres, or religious leaders may be required to enter the community or speak to certain populations.
- Involving community groups has the added advantage of giving investigators an opportunity to seek wider support and visible endorsement from locally respected figures.

Please see the Terms of Reference for theGlobal Centre Research Ethics Committee for details concerning: purpose, responsibilities, membership, meetings, schedule and administration.

Research WV will never engage in

- Procedures not normally required for patient care:
  - Non-invasive procedure involving imaging or microwaves
  - Anesthetics or sedation
  - Collection of blood samples using a syringe
- Evaluation of the safety and effectiveness of a mechanical device, drug or natural health product
- Collection of data through physically or clinically invasive procedures – including those known to pose considerable risks of harm (e.g., surgery, chemotherapy, radiation therapy)

World Vision GC Ethics Committee review is required when:

- Vulnerable population or individuals are participants
- Funder or Sponsor require review by a research ethics board
- Local policies require review by a research ethics board
- Significant deviation from routine clinical care or gathering of information in a clinical setting
- Breach of confidentiality could place participants at risk of legal liability, denial of insurance or other damage to financial standing, employability, or reputation
- Questions or procedures might cause participants psychological distress, discomfort or anxiety beyond what a reasonable person might expect in day to day interactions
- Questions that involve sensitive issues such as sexual orientation or practices, illegal behaviour, stigmatizing conditions or diagnoses, religious or cultural beliefs or practices
- A power relationship between the investigator and participants
- New process for which it would be difficult to estimate a balance of risk and benefit in advance

World Vision GC Ethics Committee review may be requiredwhen:
• New use of already approved drugs/medical devices • Designed to deceive or incompletely disclose the nature of the investigation to participants • Conflict of interest between an investigator and the sponsor/funder of the investigation • Secondary use of existing, personally identifiable data, documents, records or specimens originally collected for another purpose • Collection of data from voice, video, digital or image recordings

World Vision GC Ethics Committee review is NOT requiredwhen:
• "Minimal Risk" studies: the probability and magnitude of harm or discomfort anticipated in the proposed research or evaluation are not greater in and of themselves than those ordinarily encountered in daily life of the general population or during the performance of routine physical or psychological examinations or tests. • Secondary analysis of existing, not personally identifiable, data, documents, records or specimensoriginally collected for another purpose • Passive observation of public behaviour without collection of identifiers • Using Compendium of Child Well-being measurement tools • Tests, surveys, interviews, oral history, or focus groups that do NOT involve psychologically distressing topics or sensitive issues • Collection of data through non-invasive technical procedures routinely use in clinical or other settings: blood pressure, height, weight etc.

Appendix 1
Ethical Principles for Evaluation and Research with Children and Young People

As a child focused organisation, World Vision needs to ensure that we do not harm children and young people through our presence, programming or measurement. Given that children and young people are minors, the organisation needs to consider the ethics of including (and excluding) children in all types of evaluation and research initiatives, including direct survey methods, and the scope of such a survey.

The UN Convention on the Rights of the Child establishes the guiding principles and justification for gathering information from children:

- Children have rights to be listened to, to freely express their views on all matters that affect them, to freedom of expression, thought and association, and of access to information;
- Measures should be put in place to encourage and facilitate their participation in accordance with their age and maturity;
- Participation should promote the best interests of children and enhance their personal development;
- All children have equal rights to participation, without discrimination;
- All children have the right to be protected from manipulation, violence, abuse and exploitation.

As part of our mandate to advocate and protect the best interests of children, we must promote their participation in activities that concern them and give them a platform to express their own views. However, gathering information from and with children can raise ethical questions and concerns. It is critical that ethical principles are applied throughout the process. **Ensuring the best interest of every child is paramount and is an overarching principle for all engagement with children.** The best interests of children must be respected and protected as the top priority throughout the

entire process, from beginning to end. The following *10 ethical principles* have been adapted from Knowing Children, and must be followed in order to protect everyone involved.[2]

1. *Protect participants from harm*: This includes emotional, physical, and other forms of harm or distress. This principle requires the following steps:
   - Try to ensure that facilitators are not a threat to children through appropriate local background checks.
   - Discuss and take steps, prior to any child participation activity, to address any potential physical, social, emotional or other risks to facilitators[3] and participants. Attached here is a risk assessment tool that can guide this activity:

     Child Participation Risk Analysis Tool

   - Make arrangements for psychosocial supports to be in place as a possible option for participants who become distressed during an activity. This should involve mapping all psychosocial resources within the community including faith based leaders, counselors, psychologists or appropriate traditional healers.
   - As soon as participants show any form of distress, the activity should be paused and the individual(s) asked if they feel comfortable continuing. If not, the activity can either be stopped immediately or the individual(s) allowed to stop participating.

2. *Ensure safety of the facilitators*: Particular care must be taken when discussing illegal or sensitive issues, such as crimes against children; for example, there is sometimes a risk of potential threats from perpetrators. There should also be emotional support available within or available to the team for stress that facilitators may feel, especially as a result of discussing difficult issues for children that the team may not be able to resolve.

3. *All participation must be voluntary*: Voluntary participation means that every participant must give "informed consent." Informed consent means that people have explicitly agreed to participate in a process after being informed in ways that they can understand.

   For child participants (people under 18 years old; although in practice childhood and youth can extend above 18 years according to local cultural perspectives), it is necessary to get *both* the caregiver's and the child's consent. Informed consent should normally include signing an agreement to participate, unless that is culturally inappropriate, unsafe, not feasible, or would undermine the activity. In that case, verbal consent is required. The consent form should inform the participant about the confidentiality of any information shared. Something should be included about what might be done if the child discloses information about personal experience of abuse.[4]

4. *Respect cultural traditions, knowledge, and customs*: The facilitators should always respect and follow local codes of dress and behaviour, use the local language and age appropriate techniques, and be sensitive to differences among participants. Approval and support from local authorities including

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[2]*The Right to be Properly Researched: How to do Rights based, Scientific Research with Children* (2009), Knowing Children, Black on White Publications.

[3]*Facilitators* refers to staff, volunteers or partners who are working directly with children in a child participation activity; for example—researchers, interviewers, child club leaders, etc.

[4]Ennew, Judith and Plateau, Dominique Pierre. *How to research the physical and emotional punishment of children* (2004), Save the Children, p. 187.

government, schools, health centres, or religious leaders in addition to formal legal requirement of consent from caregivers may be required.

5. *Establish as much equality as possible*: Facilitators should always strive to sit, speak and act in ways that are child-friendly and that minimise power inequalities with participants as much as possible.

6. *Avoid raising unrealistic expectations*: The facilitators should not make any promises to children that they cannot keep, and should follow through on all commitments made to participants. This includes a broad range of possible commitments, such as promising to return and see a child to saying that we will implement a project in their community.

7. *Reciprocity*: Any compensation to participants (such as refreshments) should be agreed upon in advance. Avoid giving money because it can result in raised expectations, lead to tension and jealousy in the community, and bias participants' contributions (especially in research).

8. *Respect privacy*: Facilitators should not probe for information if it is clear that a participant would not want to answer. Also, facilitators should always ask for permission to use stories, pictures, or other information.

9. *Ensure confidentiality*: Data must be stored in a safe place where it cannot be accessed by unauthorised people. The facilitators should protect the identity of all participants by changing their names or not collecting names at all. Participants should not be named in reports or be traceable by anyone without explicit permission. As far as possible, share research results with participants before making them public and seek their consent to plans for distributing publications or communicating information. Confidentiality can be breached to provide immediate protection to a child.

10. *Develop and agree on behaviour protocols*: Facilitators should agree on behaviour protocols which cover appropriate and inappropriate behaviour. The WV International of National Office Child Protection Behaviour Protocols should be considered and adapted as appropriate.

Please see *Preventing and Responding to Distress In Child Participation Activities and Consultation with Children* for more information on equipping World Vision field staff to prevent and respond appropriately to distress when children are participating in World Vision activities. This document should be read along with the WVI Mental Health and Psychosocial Support DADDS, as well as the WVI Child Protection and WVI Child Participation Standards, which provide further guidance on other important considerations for meaningful and safe child participation.

References

Belmont Report - http://ohsr.od.nih.gov/guidelines/belmont.html
Declaration of Helsinki - http://ohsr.od.nih.gov/guidelines/helsinki.html

ARECCI Ethics Guidelines for Quality Improvement and Evaluation Projects developed by the Alberta Research Ethics Community Consensus Initiative (ARECCI) Network (2008).

ARECCI Ethics Screening Tool developed by the Alberta Research Ethics Community Consensus Initiative (ARECCI) Network (2005, revised 2008).

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The Right to be Properly Researched: How to do Rights based, Scientific Research with Children (2009), Knowing Children, Black on White Publications.

UNICEF, *Children Participating in Research, Monitoring And Evaluation (M&E) — Ethics and Your Responsibilities as a Manager,* Evaluation Technical Notes, UNICEF, New York, 2002.