AUSTRALIAN COUNCIL FOR INTERNATIONAL DEVELOPMENT

GUIDELINES

FOR ETHICAL RESEARCH AND EVALUATION IN DEVELOPMENT

February 2015

ABOUT ACFID

The Australian Council for International Development (ACFID) unites Australia's nongovernment aid and international development organisations to strengthen their collective impact against poverty.

VISION

- A world where gross inequality within societies and between nations is reversed and extreme poverty is eradicated.
- A world where human development is ecologically and socially sustainable for the benefit of current and future generations.
- A world where governments lead their societies in striving to protect and realise all people's human rights.

This vision will be achieved through the collective efforts of civil society, governments, business and all peoples who are concerned for the future of our collective humanity.

ROLES AND PURPOSE

ACFID's purpose is to provide leadership to the not-for-profit aid and development sector in Australia in achieving this vision and to fairly represent and promote the collective views and interests of our membership.

We advocate with our members for Australia to be a leading force in international human development and human rights. We are the primary vehicle for collaboration and collective action by NGOs in Australia. We foster good practice and capture this in sector standards and self- regulation. We foster peer support, learning and networking amongst NGOs, and all interested in human development and human rights.

EXECUTIVE SUMMARY

The Australian Council for International Development (ACFID) has developed the following guidelines through the contributions of, and consultation with, members and partners. The purpose of these guidelines is to assist ACFID members and their partners to understand and apply principles of ethical research conduct. They are intended as an educative tool to support and advance ethical research in theory and practice.

In particular, the guidelines provided here draw from the principles and obligations of the *ACFID Code of Conduct* and assist members to operationalise the *ACFID Principles for Ethical Research and Evaluation in Development*. The ACFID Principles and the guidelines provided in this document should inform all stages of research including design, planning, implementation, analysis, dissemination and use.

ACKNOWLEDGEMENTS

This guidance has been authored with and by individuals who were members of the ACFID University Network Committee and ACFID Ethical Research Working Group in 2013 and 2014.

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1. BACKGROUND

In all areas of their work, ACFID members, through their signatory status to the *ACFID Code of Conduct* (the ACFID Code), are encouraged 'to observe the highest ethical standards'.[1] Further, the Australian Government National Health & Medical Research Council (NHMRC) *National Statement on Ethical Conduct in Human Research* (2007 and updated in March 2014) (the National Statement) identifies a set of ethical guidelines to which all human research in Australia or conducted by Australian organisations is expected to adhere.[2] As such, in addition to understanding and supporting standards for development practice, a focus on research requires careful consideration of the ethical concerns and complications that can arise, particularly when conducting research for development and in developing countries.

In 2013, ACFID released *Principles for Ethical Research and Evaluation in Development* (the ACFID Principles) for ACFID members to adopt or adapt for their own use. The content in this document builds from these Principles and contains high-level guidance to assist with their application throughout the research process. Key considerations in this guidance include informed consent, privacy and confidentiality, cultural sensitivity, assessing risks and benefits, ethics review and in-country ethics approval.

2. PURPOSE

Ethical guidelines are not about a list of 'do's and don'ts', as the types of ethical considerations will vary depending on the research methods and context. Rather, guidelines are about assisting with recognising, understanding and resolving ethical issues that may arise throughout a research process. Guidelines also provide a framework to apply principles of ethical research so that research involving human participants can achieve its aims, while protecting the safety, rights, welfare and dignity of those involved (namely, the participants).[3] Such considerations are paramount as 'ensuring ethical research is a vital part of maintaining the legitimacy of research practice'.[4]

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[1] For a discussion of the ethical issues facing NGOs see Horton K & Roche, C (eds) (2010). *Ethical Questions and International NGOs: An exchange between Philosophers and NGOs*. Library of Ethics and Applied Philosophy 23, Springer: London.

[2] NHMRC (2007). *National Statement on Ethical Conduct in Human Research*, Canberra: Commonwealth of Australia.

[3] For a discussion on this point, also see Thomson, C (2012). *Why Ethics matters,* An Address to the Third Annual conference of the Australasian Ethics Network, Brisbane, 16 February 2012, University of Wollongong.

[4] May, T (2011). 'Social Research: Issues, methods and process', *Values and ethics in the research process*, Third Edition, Buckingham: Open University Press, p. 46.

The purpose of these guidelines is to assist ACFID members and their partners to understand and apply principles of ethical research conduct. They are intended as an educative tool to support and advance ethical research practice.

Given the diversity and range of research conducted by ACFID members, this document provides a starting point for advice and resources. The document is intended for researchers and practitioners within the ACFID membership to assist with planning, commissioning and conducting ethical research.

3. BASIS

Beyond the core texts in research ethics used to develop the *ACFID Principles*, this document draws from a range of professional codes and existing ethical guidelines for research and evaluation developed by community, aid and development non-government organisations with experience researching in cross-cultural contexts. This documentation is referenced in Annex 1 as recommended resources for ACFID members to draw on.

4. TYPES OF RESEARCH

Taking research to be 'an original investigation undertaken to gain knowledge, understanding and insight',[5] three broad types of applied research are likely to be undertaken by ACFID members and other development agencies.

- **Operational research**: conducted for the purpose of informing design or programming (e.g. situational analyses, retrospective analyses, action research)
- **Policy and advocacy research**: conducted to investigate issues related to the needs of target populations for the purpose of informing policy and advocacy positions and campaign activities
- **Market research**: to collect and analyse information to be used for marketing purposes (governed by private sector industry standards).

5. APPLICABILITY

In any of the three types of research described above, **where research involves human participants** and results in unpublished or published material, ethical considerations outlined in this document should be taken into account and addressed.

[5] NHMRC (2007). *Australian Code for the Responsible Conduct of Research*, Canberra: Commonwealth of Australia.

Research that involves human participants includes people's participation in surveys, interviews or focus groups, or being observed by researchers.

Where there are no human participants, for example a desktop review using existing material in the public domain, research is exempt from this guidance.

Evaluation is often considered a form of applied research involving information gathering from human participants and is commonly undertaken by development agencies. Evaluation is defined here as the 'systematic, objective assessment of an ongoing or completed project, program or policy'.[6] Evaluation is conducted for the purposes of learning and accountability and may be undertaken internally or externally (includes baseline surveys and impact assessments).

In practical terms, the differences between research and evaluation are often 'less important than the way in which the process is conducted – they both require information to be gathered systematically, thoroughly and carefully'.[7] Given that evaluation entails the use of methods and tools similar to other research processes, there is enough commonality in practice that they have been jointly addressed within this document.

As such, and consistent with the ACFID Principles, from this point onwards the term 'research' will be used to encompass both research and evaluation, and the term 'researchers' to also encompass 'evaluators'.

6. BUILDING A RESEARCH PROTOCOL OR PLAN

As a minimum and as a standard of good practice, all research should follow a defined research protocol or plan and any change in these plans will require renewed consideration and response to ethical implications.[8] The ACFID Principles are useful for thinking through the ethical considerations that will need be explained and acted upon throughout the research process, from the conception and design, to participant

[6] OECD-DAC (2010). *Quality Standards for Development Evaluation*, DAC Guidelines and Reference Series. Available at: http://www.oecd-ilibrary.org/development/dac-quality-standards-for-development-evaluation_9789264083905-en, accessed 21 November 2014, p. 6.

[7] Australian Institute of Family Studies (2013). *Evaluation and Innovation in Family Support Services*, 'Box 1: Evaluation and research – are they different?' November 2013. Available at: http://www.aifs.gov.au/cfca/pubs/factsheets/a145794/index.html, accessed 21 November 2014.

[8] ACFID Code of Conduct (Principle B.1.2) obliges members to 'set out a clear purpose and objectives for all aid and development activity including consideration of the timeframe, sustainability of the activity and its impacts beyond their involvement'.

selection, data collection, analysis and interpretation, through to dissemination of the results of the research.[9]

The sections that follow are set out to guide researchers through the steps necessary to build and implement a research protocol or plan that is mindful of ethical considerations. Further discussion of the specific considerations for research participants, responding to cultural context, assessing risk and relevant approval processes are discussed in turn. Below is a set of questions to help you get started.

Getting started

The following questions and references provide a starting point for researchers to begin thinking through what the ethical considerations are, identifying how the ACFID Principles may apply and to design research accordingly in a research protocol or plan. This is not an exhaustive list of relevant considerations as these will vary depending on the subject matter and type of research being conducted.[10]

When planning to conduct research, consider:

1. Is the research necessary and well justified? What are you looking to investigate and why is it important?
2. Is the research well planned? Does it connect to a particular program of work in your organisation? Do researchers have the relevant expertise to conduct the research?
3. What is the context in which the research will be conducted? How will this context influence the research design?
4. How is the methodology and analysis appropriate to the context and what is being investigated?
5. What are the potential harms and benefits for researchers and participants that could arise from the research?
6. What information about the research will be provided to the participants? How will free and informed consent be obtained and ensured throughout the research process?
7. Are there any other parties or partners involved in the research? What are their interests in the research? Who will benefit directly and indirectly from the

[9] See FHI 360 (2012). *Research Ethics Training Curriculum*, Second Edition. Available at: http://www.fhi360.org/sites/all/libraries/webpages/fhi-retc2/index.html, accessed 21 November 2014. FHI 360 maintains a comprehensive research ethics training curriculum that may be a helpful starting point in understanding research ethics.

[10] These questions have been adapted from Oxfam Australia (2009). *Oxfam Australia Research Ethics Guidelines* and Médecins Sans Frontières (2013), *Research Ethics Framework: Guidance document*. Full details are available in Annex 1 – 'Ethical Research and Evaluation Guidelines in Development'.

research?

8. How do you plan to protect confidentiality and anonymity? What will happen to the data? How will it be accessed and secured?
9. Have researchers received training, information and assistance related to addressing ethical issues?
10. How will the findings be disseminated and used? Will participants have access to validating and receiving the results of the research? What will happen when the research is complete?

7. CONSIDERATIONS FOR RESEARCH PARTICIPANTS

This section discusses considerations and processes related to participant rights and safety that will need to be addressed throughout the research process, including issues of privacy and confidentiality, as well as informed consent, with particular guidance for informed consent with children.

Privacy and confidentiality

Research participants should have the right to remain anonymous and to have their rights to privacy and confidentiality respected. In this sense, privacy and confidentiality refers to how much information a participant may wish to share and entrust with the researcher, as well as how the information they share is obtained, protected and stored. Researchers may give opportunities to participants to choose varying degrees of confidentiality, from anonymity to different forms of identification such as by number or age or sex. When working overseas and in developing countries, interpretations of 'privacy' may vary, and local meanings of the term should be taken into account. In particular, this may be the case in those countries with a strong focus on the collective rather than the individual.

It may also be respectful to ask participants how they would like to be represented in research products, their desire for an opportunity to comment on this representation, and who should have access to the knowledge generated.

Researchers should be aware that preserving anonymity requires that there be no link between the data (responses) and the source (the participant), and in some cases this might be impossible since characteristics of the participant may identify them. In such cases it may be possible for researchers to take care that information is sufficiently aggregated or with sufficient details changed so that no community, household or individual can be identified.

If there are any limits to confidentiality (for instance, mandatory disclosure of cases of abuse) then these limits should be made clear to participants during the consent

process. Privacy also requires that researchers take responsibility for data to be stored securely with access limited to designated, authorised people.[11]

Ethical questions regarding knowledge generation, ownership and related rights of participants should be considered, as should the potential value of the material for further research.

Informed consent

Informed consent is one of the basic minimum requirements that must be addressed to ensure that ethical research principles are upheld. Informed consent should be considered at the beginning and throughout the research process, especially in longer initiatives. Specific procedures and considerations should be observed in the case of particular groups such as children and young people, and people with disabilities and are described in the subsections below.

The core idea is that **a participant agreeing to take part in research should do so voluntarily, without coercion and with sufficient understanding of the research procedures, potential risks and potential benefits**. Informed consent serves to support this process. Such consent does not absolve the researcher from protecting participants.

Informed consent means that a participant is given clear information about the research, is able to choose not to participate, and is able to withdraw at any time and without consequence. Any limits to this right should be explained.

Informed consent is an ongoing process and must be renegotiable so that participant understanding and comfort is assured. Information provided to participants (either verbally or written) should include:

- ✓ Research aims and objectives
- ✓ Details of information that is being sought
- ✓ How responses will be recorded and used
- ✓ The degree to which participants will be consulted prior to publication
- ✓ How findings will be communicated to participants
- ✓ Potential benefits and consequences of participation, including potential risks
- ✓ Reimbursements or incentives (if any) that will be provided for participating in the study

[11] The Australian Code recommends retaining research data for five years. See NHMRC (2007). *Australian Code for the Responsible Conduct of Research*.

- ✓ The name of the organisation that is funding the research
- ✓ Contact details for someone independent of the research process for inquiries and complaints
- ✓ An explanation of the voluntary nature of the participant's involvement
- ✓ The name of the investigator.

Researchers should make an informed choice between written (signature, thumbprint or other personal mark) and verbal consent. In all cases, it is advisable that an informed consent script or form be completed to ensure that all elements of the informed consent process are adhered to, documented and clearly communicated.

Illiteracy, low literacy, fear, or suspicion of written consent is the basis for using verbal consent, or for having a witness present. In the case of verbal consent, the researcher may document that the consent procedure has been followed, noting whether permission has been granted.

Researchers and ethical reviewers should also closely consider the relevant cultural context[12] for the research and the potential for participants to be in a real or perceived 'dependent or unequal' relationship with the researchers.[13] Some considerations to take into account are:

- Permission to seek consent from the participant may be needed from formal and/or informal gatekeepers as well as individuals.
- Opportunity may need to be provided for potential participants to ask questions and to discuss participation with someone who is able to support them in making their decisions.
- Visual aids may be necessary to explain the research in certain settings.
- On-going communication and confirmation of consent may be required during the research to ensure that the concept of consent is understood, particularly towards the end of the research process.
- The researcher should avoid setting unrealistic expectations about the potential benefits and outcomes of the research.

[12] A useful text related to evaluating programs involving Aboriginal and Torres Strait Islanders is: Williams, E, Guenther, J & Arnott, A (2011). *Beyond informed consent: how is it possible to ethically evaluate Indigenous programs*, Paper presented to the NARU Public Seminar Series, Darwin, 23 November 2011, pp. 1–11. Available at: http://naru.anu.edu.au/__documents/seminars/2011/paper_williams_2011.pdf, accessed 21 November 2014.

[13] In many cases, the National Statement guidance on participants in dependent or unequal relationships may be relevant, particularly where developed country researchers are leading research.

- Communicating the findings of the research to participants needs to be ensured, and the ways in which this will happen also needs to be communicated to participants during the consent process.
- Careful, culturally appropriate decisions need to be made on the nature of any recompense to participants or a community for participation, ensuring that any recompense is not perceived as an undue inducement. For instance, benefits in the form of building participant knowledge or capacity through providing training or other support could be considered.
- According to the National Statement, an accessible, local contact should be available to participants, including someone independent of the process to handle any complaints.[14]

Informed consent for children and young people

Before including a child or young person[15] in research, researchers must firstly ensure that participation is not contrary to that child's or young person's best interest, and maintain alignment with any relevant Child Protection Policy and the UN Convention of the Rights of the Child (1989).[16]

Informed consent raises particular challenges when research involves children and young people,[17] arising from four main concerns:

1. Children's or young people's capacity to understand what the research involves, and therefore whether their consent to participate is sufficient
2. Possible coercion of children or young people by parents, peers, researchers or others to participate
3. Potential for conflicting values and interests of parents, guardians or primary caregivers and children
4. During a research process, possible disclosure by a child of information that raises child protection concerns (e.g. information indicating that they are currently at risk of or are experiencing violence, exploitation or abuse), obliging researchers to report such circumstances.

The following guidance is provided to help addresses these concerns.

[14] For ACFID members, a suitable complaints process may be aligned with those developed as a part of their compliance with the Code of Conduct.
[15] Under the age of 18 is considered a child, and 19–24 is considered a young person.
[16] See UNICEF (1989) Convention on the Rights of the Child, www.unicef.org/crc/, accessed 21 November 2014.
[17] A useful paper discussing the problems arising in informed consent in exploratory research with young children is Flewitt, Rosie (2005). 'Conducting research with young children: some ethical considerations', *Early Child Development and Care*, 175(6), pp. 553–565. The paper looks at negotiating initial and ongoing consent, questions of anonymity when collecting and reporting on visual data, confidentiality, and including respondents in research validation and outcomes.

Clarify the approach to informed consent in research design. All children and young people should be engaged in discussion about the research purpose, and information must be provided in a way that is appropriate to their age, competencies, context and evolving capacities.[18] Research designs should specify how researchers will judge the child's capacity to consent to participation in research, and how the research will be presented in a child-friendly manner to address children's right to understand the parameters of their participation. Participant consent for use of images should be included where relevant.

Sufficiency of consent. A child's or young person's consent is sufficient only if he or she demonstrates sufficient maturity to understand the relevant information and to give consent. Often, additional consent is required from parents (or guardian or primary caregiver) whereby a child agrees to participate, however the parents provide consent. In this case, care must be exerted to ensure that participating in the research really is and continues to be in the child's best interests. At all times, children and young people have the right to cease participating in research activities if they choose and opportunity for this should always be provided (and any limits to this explained). This relates to the principle of respect in consideration of the dignity of the individual participant, their capability and right to make decisions about matters that affect them and the researchers' responsibility to uphold 'children's right to dissent, that is to refuse participation and to withdraw at any time and to prioritise this over their parents' or others' wish for them to participate'.[19]

Local law. There may be local laws that govern at what age children are able to provide consent; such laws should be consulted and compliance ensured.

Child protection. Researchers should be aware of relevant child protection laws, policies and procedures of each institution from which participants are recruited (i.e. schools, community groups) and should be familiar with in-country child protection referral mechanisms and child protection focal points. They should also be well equipped to handle a disclosure (in terms of training and skills) and should have a reporting or referral plan in place to be able to respond. As part of the consent process, participants (and/or parent/ guardian/primary caregiver) should be advised before

[18] Further recommended reading is available through the Ethical Research Involving Children (ERIC) project noted in Annex 1 – Resources and Supporting Documentation. For specific guidelines regarding informed consent involving children and youth, see Ethical Research Involving Children (ERIC) (2013). *Ethical Guidance: Informed Consent*. Available at: http://childethics.com/wp-content/uploads/2013/10/ERIC-compendium-Ethical-Guidance-Informed-consent-section-only.pdf, accessed 21 November 2014.

[19] ibid, p. 56.

research commences that, should any information they provide indicate that they are at risk of abuse or exploitation, researchers will need to follow relevant procedures.[20]

Informed consent for people with a disability

People with a disability[21] are entitled to full and equitable participation in research as outlined in the UN Convention on the Rights of Persons with Disabilities. This includes people with a cognitive impairment, intellectual disability or a mental illness. Many people with disability will have full capacity to participate in research and should not be deemed to be of high risk solely due to their disability. The impact of a disability is often dependent on environmental barriers; hence researchers should be cognisant to ensure that research processes are inclusive of people with disability and that their specific participation limitations are addressed.

The following guidance is provided to address potential participation limitations.[22]

Clarify the approach to informed consent in the research design. Researchers need to clearly describe in their research design how they will determine a person's capacity to consent to the research, who will make this decision, and the criteria on which it is based. Ideally, the broader research focus should be clearly aligned with development objectives established by people with disability and/or disabled people's organisations.

Approach to securing informed consent. People with disability should have risks, confidentiality and the purpose of the study outlined with the clear option to withdraw from research at any point (or with any limits to this fully explained). The consent process should include information on potential benefits that the research may have to people with disability. Informed consent to participation in research should be sought either from:

- The participant or
- The person's guardian or other person or organisation authorised by law.

[20] Further requirements pertain to Principle B.3.4 of the ACFID Code of Conduct 'Protection of Children'.

[21] Consistent with the UN Convention on the Rights of Persons with Disabilities and a rights based model of disability, this guidance employs the term 'people with a disability'. For further discussion on terminology see: CBM (2012). *Inclusion Made Easy: A quick program guide to disability in development*. CBM. Available at: http://www.cbm.org/article/downloads/78851/CBM_Inclusion_Made_Easy_-_complete_guide.pdf, accessed 21 November 2014.

[22] Additional valuable information related to informed consent for people with disabilities can be found in Dalton & McVilly (2004). 'Ethics Guidelines for International Multicenter Research Involving People with Intellectual Disabilities', *Journal in Policy and Practice in Intellectual Disabilities*. 1(2), pp. 57–70. Available at: http://iassid.org/pdf/ethics-guidelines.pdf, accessed 21 November 2014.

Whether a person has the capacity to consent depends on the nature of their condition, including fluctuations in the condition, and the complexity of the research. Ideally, consent should also be witnessed by a person who has the capacity to fully comprehend the potential benefits and risks of the research, who is independent from the research team and, where possible, knows the participant and is familiar with his or her condition. Where potential participants are especially vulnerable, consideration should be given to the appointment of a participant advocate. **However, at all times,** participant resistance, discomfort or refusal to participate must be respected regardless of the views and opinions of others in the consent process.

Appropriate methods of communication. Where appropriate, background information and consent forms and actual research tools should be provided in varying formats such as plain language, pictorial/visual cues, large print, Braille and/or audio, based on individual preference.

8. CULTURALLY SENSITIVE RESEARCH DESIGN AND APPRECIATION OF CONTEXT

This section encourages researchers to think about how a given piece of research should reflect the context in which the research takes place. Research cannot be assumed to have beneficial outcomes for host communities or relevant research participants. To design research that aligns with the ethical principles of respect, beneficence, research merit and integrity, and justice, requires a firm grounding in the relevant local cultural values, norms[23] and the local historical and political context. For any given context, a first step is to identify key cultural values and customs and analyse how these impact on meaningful adherence and interpretation to ethical research principles.[24] This process requires critical reflection on researchers' own cultural values, how these influence proposed questions and design, and challenging them with alternative perspectives at all stages of the research.

Models to support ethical research should be explored, many of which increase reliance on participatory, collaborative processes and concepts of partnership and reciprocity.

Examples of models and approaches that could be employed include:

- Involvement of participants in framing research and research questions and/or other steps such as deciding data collection methods, analysis methods or validation, seeking alignment with cultural norms.
- Explicit attention to offering specific skills training or other forms of support in return for participation in research, building on the concept of reciprocity and mutual value.
- Well-designed processes for how research findings are communicated to participants including methods to actively engage participants with the findings and their implications.
- Establishment of institutional arrangements with on-going involvement of participants to ensure integrity of the research initiative. For example, involvement of an independent research reviewer at nominated stages to identify ethical issues that may arise, and consequent adaptations to the approach.

[23] For instance, development of ethical guidelines for research with Aboriginal and Torres Strait Islanders identified six cultural values as underpinning ethical conduct: Reciprocity, Respect, Equality, Responsibility, Survival and protection, Spirit and integrity.

[24] For more on this point, see Honan, E, Obaidul HM, Alhamdan, B, Phommalangsy, P & Lingard, B (2012). 'Ethical issues in cross-cultural research', *International Journal of Research & Method in Education.* 36(4).

- Community/participant control over the research process itself, with the local people leading and implementing the research.
- Involvement of local co-researchers (not from the relevant community/locality) who carry relevant cultural values and insight. This approach may also provide other benefits through supporting local research capacity building. In such cases, researchers have the responsibility to ensure that local co-researchers undertake the research in an ethically appropriate manner.

Gender should be a key concern since norms and laws in many countries require specific research design considerations. This involves reflecting on the implications of the research for male and female participants and being respectful of gender and sexual identities.[25] Consideration should also be given to the intersection of gender with other factors that shape a person's circumstances and interests, including age, ethnicity, (dis)ability or religion. While gender categories are helpful in identifying commonalities among members, individuals are diverse and the interests and needs of people who share the same gender will vary. Attention to such intersections is important because these can magnify disadvantage, risks and barriers to participation, as well as change the potential benefits of the research. Such intersections require specific consideration, particularly if the research aims to be representative or to target very poor or marginalised groups.

Gender-sensitive research is encouraged as it takes into account and values the implications of gender on individual circumstances including their roles, responsibilities, power relations, perspectives and priorities, as well as legal status and rights.[26] A gender-sensitive approach can also support empowerment[27] through consideration of:

- The *immediate* effects of the research (such as women's time and their ability to meet their gendered roles and responsibilities), and on the security of research participants, particularly where the research involves participants who are vulnerable or marginalised
- The *longer-term* effects, for example, on the awareness of or implications for human rights and legal protections; capacity to voice needs and priorities; or on

[25] For further discussion see Gune, E & Manuel, S (2007). *Doing Research on Sexuality in Africa: Ethical Dilemmas and the Positioning of the Researcher*. OSSREA Bulletin. Available at: http://www.arsrc.org/downloads/features/manuelgune.pdf, accessed 21 November 2014.
[26] For a helpful summary on this point see Leduc, Brigitte (2009). *Guidelines for Gender Sensitive Research*. ICIMOD. Available at: http://www.icimod.org/?q=1286, accessed 21 November 2014.
[27] For further discussion and examples of gender-sensitive research characteristics see UN-INSTRAW. *Gender Research: A How-to Guide*, and for discussion of a participatory approach see Gurung, Min Bdr & Leduc, B (2009). *Guidelines for a Gender Sensitive Participatory Approach.* ICIMOD. Available at: http://www.icimod.org/?q=1286, accessed 21 November 2014.

wider community views about the capacities and contributions of a particular group.

9. APPROPRIATE REVIEW AND APPROVAL PROCESSES

Assessing risk is an important step towards identifying an ethical review and approval process that is 'fit-for-purpose' for a given piece of research, and identifying processes to minimise and manage risk. The following sections contain advice relevant to understanding this process.

Assessing, minimising and managing risk

Assessing the ethical acceptability of risks means including considerations of the following elements, using available evidence and a transparent process.

- Identify the risks and kinds of harm that may occur throughout the research (see 'Beneficence' in the *ACFID Principles* for an articulation of possible types of harm) and assess their likelihood and severity
- Identify who (participants and/or others) the risks or harm may affect and how
- Establish approaches for minimising, managing and monitoring the risks
- Identify the potential benefits and who is likely to receive them
- Weigh up and discuss whether the benefits of the research exceed the potential harm.

Research is often considered of 'negligible risk' where any foreseeable risk is no more than inconvenience, and 'low risk' where the only foreseeable risk is discomfort. In these cases, a reduced or internal assessment of ethical issues may be considered rather than a formal ethical review and approval. Such cases might apply to evaluation or research processes that address non-sensitive issues or topics, do not involve vulnerable groups, and use minimal participant time. Further, such an internal assessment might be considered for well established evaluation methods and where the aim or purpose of the research is to improve the implementation of an established intervention or program (quality assurance).

In all other cases, some form of formal ethical review is needed, described further below, and researchers have an ongoing responsibility to minimise risks to participants by re-assessing the need for the research (or who is best placed to lead or conduct such research), or the research aims or methods or both. Researchers also have a responsibility to include mechanisms or a process to respond to and monitor predicted and potential harm.

Ethical review

Human Research Ethics Committees (HREC) are established to review and evaluate research protocols to ensure that a given piece of research has adequately addressed the principles of ethical research conduct and, in turn, safeguards both researchers and research participants. An ethical review process can offer helpful insights related to the ethical considerations of a research project that should be taken into account and addressed before proceeding.[28]

Each HREC is different and researchers may not have direct access to an HREC unless partnered with an institution, such as a university, that maintains and registers such Committees in line with the National Statement. Some organisations may accept proposals for review by external organisations however, often with an associated fee.[29]

Regardless of an organisation's access to an HREC, it is ultimately the researcher's responsibility to document and demonstrate how a research project will address principles for ethical research.

Establishing an advisory or peer review group of individuals with expertise in the research area and/or methodology is a useful process for advice on how to address ethical issues throughout the research. However, such a group should not be considered as a replacement for a review offered through an HREC; rather, it can be a helpful support mechanism.

When is ethical review required?

In many cases of quality assurance and evaluation,[30] a program will require careful oversight and planning but an ethical review is not necessary. This includes situations where:

- Data is routinely collected (or ongoing) using well established operating procedures and/or existing protocols (such as those applied to evaluation processes noted earlier). As with the above section on assessing, minimising and managing risk, at all times consideration must be given as to whether the

[28] A helpful paper outlining the different stages of an ethics review and examples (including evaluation) for identifying whether the research requires ethics review is Scott, D (2013). *Demystifying Ethical Review*. Australian Institute of Family Studies, February 2013. Available at: https://www3.aifs.gov.au/cfca/publications/demystifying-ethical-review, accessed 21 November 2014.
[29] The NHMRC maintains a list of registered Human Research Ethics Committees and the contact details for their host organisations in Australia.
[30] This guidance has been drawn from the following documents, with full details noted in Annex 1 – 'Resources and Supporting Documentation': NHMRC (2014). *Ethical considerations in quality assurance and evaluation activities*, Médecins Sans Frontières (MSF) (2013). *Research Ethics Framework: Guidance Document*, and Marie Stopes International (MSI) (2013) *Ethics Checklist*.

proposed evaluation or quality assurance activity poses any risks for participants beyond those routinely experienced in the environment where the activity is being conducted
- Data is being collected and analysed for the sole purpose of maintaining standards or identifying areas for improvement where work is being conducted
- Data cannot not be linked to individuals (see Privacy and Confidentiality section of this document and the related ACFID Principle 'Respect for Human Beings').

Ethical reviews should be considered where:

- The potential harm and risk to those involved in the research (researchers and participants) is not 'low' or 'negligible', as discussed in section on assessing, minimising and managing risk
- Research is exploratory in nature and gathers information beyond that routinely collected
- Research potentially impinges on the privacy and confidentiality of those involved in the research
- Research involves the secondary use of data collected from an evaluation activity for purposes other than those described to partners and participants and the intended use of the data goes beyond program improvement
- Research involves a comparison of cohort, randomisation, use of control groups or placebos
- Targeted or additional analysis of data collected from an evaluation activity that involves minority or vulnerable groups and the intended use of the data goes beyond program improvement.

In-country ethical approval

Researchers should ensure that they are aware of, and follow, any national ethics processes, any relevant ethical review processes through local institutions, and comply with local laws.[31] In addition, research conducted in other countries by researchers from Australian institutions must comply with the Australian Code for the Responsible Conduct of Research and National Statement.[32] Where no national ethical approval process is available, it is expected that principles for ethical conduct, such as those articulated in the *ACFID Principles*, as well as how they are applied through the guidelines articulated here, will still need to be applied.

[31] ACFID Code of Conduct (Principle D.2.1) obliges members to 'ensure that their organisations have in place compliance systems and processes to ensure that their legal obligations are being met in each jurisdiction where work is carried out', p.26.
[32] *Australian Code for the Responsible Conduct of Research* (2007), p 8.1.

ANNEX 1: RESOURCES AND SUPPORTING DOCUMENTATION

Australian National Guidelines

Australian Institute of Aboriginal and Torres Strait Islander Studies (AIATSIS) (2011). *Guidelines for Ethical Research in Australian Indigenous Studies*, Canberra: Australian Institute of Aboriginal and Torres Strait Islander Studies.

- The AIATSIS Guidelines outline standards of ethical research and human rights for research with Indigenous peoples. They are primarily intended for research sponsored by AIATSIS, but inform much research in this area in Australia. The Guidelines consist of 14 principles accompanied by guidance about how the principle should be applied. The guidelines contain particularly helpful information about how to respect traditional knowledge and local culture in the research process.

NHMRC (2007). *National Statement on Ethical Conduct in Human Research*, Canberra: Commonwealth of Australia.

- The National Statement (NS) is a set of ethical guidelines, developed by the Australian Government, and applicable to all human research in Australia or conducted by Australian organisations. The NS 'Chapter 4.8: People in Other Countries' emphasises that research conducted overseas by researchers from Australian institutions must comply with the NS. Research design and conduct should acknowledge local cultural values and Australian HRECs should only approve research if participants are accorded no less respect and protection than the NS requires.

NHMRC (2007). *Australian Code for the Responsible Conduct of Research*, Canberra: Commonwealth of Australia.

- Also known as 'The Code', this document is intended to guide Australian institutions and researchers in responsible research practice. The Code promotes integrity in research and explains what is expected of researchers by the community where the research is conducted. The Code also offers advice on how to manage complaints, allegations and misconduct for researchers, administrators and the community.

NHMRC (2014). *Ethical Considerations in Quality Assurance and Evaluation Activities*, Canberra: Commonwealth of Australia.

- As quality assurance and evaluation activities often use similar methods or approaches as those in a research study, this document aims to clarify the level of ethical oversight required for these activities. Consideration must be given as to whether research participants are exposed to risk, burden, inconvenience or a breach of their privacy.

NHMRC (2003). *Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research*, Canberra: Commonwealth of Australia.

- These guidelines are, in addition to the National Statement, the authoritative national government statement on research involving Aboriginal and Torres Strait Islander Peoples. The guidelines provide assistance to researchers in the conception, design and conduct of research, as well as HRECs, and articulate the meaning to Aboriginal and Torres Strait Islander Peoples of the six values that underpin these guidelines.

International Guidelines

Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO) (2008). *International Ethical Guidelines for Epidemiological Studies*, Geneva: CIOMS.

- Focused specifically on epidemiological studies, the document outlines international guidance for the conduct of medical and health related research, noting appropriate approaches to working with/in particular populations or situations (for example, regarding informed consent).

United Nations (UN) (19 October 2005). *Universal Declaration on Bioethics and Human Rights*, New York: UN.

- The principles in this Declaration articulate, in Article 21, that ethical review should occur both in the host country and the country in which the funder is located; that transnational health research should be responsive to the needs of host countries; and that when negotiating a research agreement, terms for collaboration and agreement on benefits of research should be established with equal participation.

Guidance from other professional bodies

Australasian Evaluation Society Inc, (2013). *Guidelines for the Ethical Conduct of Evaluations*. Available at: http://www.aes.asn.au/join-the-aes/membership-ethical-guidelines.html, accessed 21 November 2014.

- These guidelines refer specifically to three stages of the evaluation process: commissioning and preparing, conducting, and reporting of results. The guidelines contain clear advice related to principles that should be adhered to throughout each of the three stages.

OECD-DAC (2010). *Quality Standards for Development Evaluation*, DAC Guidelines and Reference Series. Available at: http://www.oecd-ilibrary.org/development/dac-quality-standards-for-development-evaluation_9789264083905-en, accessed 21 November 2014.

- This document was prepared by the Network on Development Evaluation, a subsidiary body of the Development Assistance Committee (DAC) at the Organisation for Economic Co-operation and Development (OECD). They were drafted and tested through an international consultation process across donors and partners. The standards are written following the steps in an evaluation process as well as providing overarching considerations for the evaluation process, including ethics.

United Kingdom Evaluation Society (2013). *Guidelines for Good Practice in Evaluation*. Ware, UK: United Kingdom Evaluation Society. Available at: https://www.evaluation.org.uk/assets/UKES%20Guidelines%20for%20Good%20Practice%20January%202013.pdf, accessed 21 November 2014.

- The guidelines identify and list the core considerations for ethical practice in evaluation for individual evaluators, commissioners, self-evaluators and evaluation participants.

Ethical research and evaluation guidelines in development

Chronic Poverty Research Centre (2001). *Chronic Poverty Research Centre Methods Toolbox*. Available at: http://www.chronicpoverty.org/page/toolbox, accessed 21 November 2014.

- This document includes an introduction focused on ethics in poverty research,

followed by a page of practice guidelines, and several pages of specific guidance on particular vulnerable groups (e.g. children and people with a disability).

Marie Stopes International (MSI) (2013). *MSI Ethics Checklist* and *MSI Informed Consent Guidelines*. London, UK: MSI. Available at: http://mariestopes.org/data-research/ethics-review-committee, accessed 21 November 2014.

- The MSI checklist contains a helpful list of criteria in the form of questions used to assist MSI research, monitoring and the evaluation of staff in determining whether a given activity requires an ethical review. The consent guidelines contain helpful guidance for staff in drafting an informed consent form and to administer informed consent during the research process.

Médecins Sans Frontières (MSF) (2013). *Research Ethics Framework: Guidance Document.* MSF. Available at: http://fieldresearch.msf.org/msf/, accessed 21 November 2014.

- The framework contains a useful list of considerations for occasions in which MSF research does and does not go through an ethical review. It also contains an in-depth checklist of ethical issues that need to be considered in a research plan from design to implementation and the use of research findings. This includes particular attention to issues that may arise as a result of a collaborative or community partnership.

Nuffield Council on Bioethics (2002). *The ethics of research related to healthcare in developing countries*, report prepared by a Working Party of the Nuffield Council on Bioethics. Available at: http://nuffieldbioethics.org/project/research-developing-countries/, accessed 21 November 2014.

- The report has a particular focus on the development and understanding of local expertise in healthcare research. It contains in-depth guidance for researchers related to obtaining informed consent (Chapter 6). The report also takes into account the issue of exploitation when conducting or funding research in developing countries.

Save the Children International (2012). *Evaluation Handbook*, London, UK: Save the Children. Available at: http://resourcecentre.savethechildren.se/content/library/documents/evaluation-handb

ook, accessed 21 November 2014.

- This document is specific to child rights-focused evaluations; however, it is a helpful reference guide for individuals working in country offices. The Handbook identifies the key steps in the evaluation process alongside relevant child protection and ethical issues that must be considered.

Guidance for specific issues and groups

Humanitarian settings

Curry D, Waldman R & Caplan A (2014). *An Ethical Framework for the development and review of health research proposals involving humanitarian contexts*, Enhanced Learning and Research for Humanitarian Action, Project Final Report. Available at: http://www.elrha.org/uploads/FINAL%20R2HC%20Ethical%20Framework_Final%20Report_24%20January%202014.pdf, accessed 21 November 2014.

- The framework discusses key ethical issues and proposes key research questions and tools related to developing research protocols in humanitarian crises and complex emergencies. It contains a useful summary of background literature and guidance for the content of the framework.

Disability

Centre for Disability Research and Policy (2014). *Monitoring Manual and Menu for CBR and other community-based disability inclusive development programs*, Version 1, April 2014, University of Sydney. Available at: http://sydney.edu.au/health-sciences/cdrp/projects/cbr-monitoring.shtml, accessed 21 November 2014.

- This document contains seven principles for monitoring programs to ensure adequate and ethical data collection. This includes examples of how information gathered through monitoring can be used to improve program outcomes and helpful steps for monitoring activities to ensure that they meet the seven principles for disability inclusion. These steps may be relevant and applicable to disability inclusive research.

Dalton & McVilly (2004). 'Ethics Guidelines for International Multicenter Research Involving People with Intellectual Disabilities', *Journal in Policy and Practice in Intellectual Disabilities*. 1(2), pp. 57–70. Available at: http://iassid.org/pdf/ethics-guidelines.pdf, accessed 21 November 2014.

- While focused specifically on intellectual disabilities, the guidelines contain

concise advice for those who fund and conduct research with people with a disability in a cross-cultural context. Helpful advice is provided for research design, research conduct and informed consent.

Farmer, M & Macleod, F (2011). *Involving Disabled People in Social Research*, Guidance by the Office for Disability Issues, Office for Disability Issues HM Government. Available at: http://odi.dwp.gov.uk/docs/res/research/involving-disabled-people-in-social-research.pdf, accessed 21 November 2014.

- This document contains useful advice and examples of how to involve people with a disability in the research process, from study design, commissioning and tendering, through to dissemination of results. It also contains practical points for consideration when choosing an appropriate research method.

HIV/AIDS

UNAIDS (2000). *Ethical considerations in HIV preventive vaccine research*. UNAIDS guidance document, third reprint April 2004, Geneva: UN. Available at: http://data.unaids.org/publications/IRC-pub01/jc072-ethicalcons_en.pdf, accessed 21 November 2014.

- The document contains clear guidance related to addressing ethical considerations in HIV prevention and vaccine research. In particular, the document addresses the ethical issues of conducting such research internationally, nationally and locally as well as with vulnerable populations. For example, see Guidance Points: 3 Capacity building, 4 Research protocols and study populations, 7 Vulnerable populations, 12 Informed consent, and 13 Informed consent – special measures.

Domestic Violence/Violence against Women

Ellsberg, M, & Heise, L (2005). *Researching violence against women: a practical guide for researchers and activists*, Washington DC: World Health Organization and Program for Appropriate Technology in Health. Available at: http://www.who.int/reproductivehealth/publications/violence/9241546476/en/, accessed 21 November 2014.

- This manual offers comprehensive guidance in researching violence against women. It focuses on conceptualising violence against women as a health and development issue, addresses ethical considerations in researching violence against women, and provides practical guidance in all stages of the research

process, moving from research to action.

Jewkes, R, Dartnall, E & Sikweyiya, Y (2012). *Ethical and Safety Recommendations for Research on Perpetration of Sexual Violence*. Pretoria, South Africa: Sexual Violence Research Initiative, Medical Research Council. Available at: http://www.svri.org/, accessed 21 November 2014.

- This document details recommendations for research that involves those who have, and those who have not, committed instances of sexual violence. The guidelines assume that the work will be conducted with men, but the principles outlined are applicable to research with women who may also perpetrate sexual violence. The guidelines outline the relevant considerations and ethical issues, along with examples of questioning and responses to issues that may arise throughout the research process.

Partners for Prevention (2013). Replicating the UN Multi-country Study on Men and Violence: understanding why some men use violence against women and how we can prevent it, Ethical and Safety Guidelines for Research on Gender Based Violence. Bangkok, Thailand: Partners for Prevention. Available at: http://www.partners4prevention.org, accessed 21 November 2014.

- These guidelines relate to research conducted both with survivors and perpetrators of violence. It also outlines how the wellbeing of both the research participants and the research team should be addressed.

WHO Department of Gender, Women and Health (2001). *Putting women first: Ethical and safety recommendations for research on domestic violence against women*. Geneva: World Health Organization. Available at: http://www.who.int/gender/violence/womenfirtseng.pdf, accessed 21 November 2014.

- This paper outlines the recommendations developed by the World Health Organization regarding the distinct risks, ethical and safety issues associated with planning and conducting domestic violence research. The document discusses the safety and wellbeing for both the research participants and those conducting the research. They are designed for use for investigators, project co-ordinators and others implementing research focused on domestic violence, and also by those initiating or reviewing such research (e.g. donors, research ethical committees).

Zimmerman, C, & Watts, C (2003). *WHO ethical and safety recommendations for interviewing trafficked women*. Geneva: World Health Organization. Available at: http://www.who.int/gender/documents/women_and_girls/9789242595499/en/,

accessed 21 November 2014.

- These recommendations were developed to build on the WHO *Putting women first* guidance. It is primarily intended for use by researchers, media and service providers unfamiliar with the situation of trafficked women. The recommendations do not explicitly discuss the distinct risks and obligations of interviewing female minors. The document also contains a set of 10 basic standards for interviewing women who are in or have left a trafficking situation.

Children and Youth

Australian Research Alliance for Children and Youth (ARACY) and the New South Wales (NSW) Commission for Children and Young People (2009). *Involving children and young people in research: a compendium of papers and reflections from a think tank*, the ARACY and the NSW Commission for Children and Young People, 11 November 2008. Available at: http://www.kids.nsw.gov.au/uploads/documents/InvolvingChildrenandYoungPeopleinResearch.pdf, accessed 21 November 2014.

- This is a discussion paper offering useful guidance and ideas for children and youth participatory research. Topics raised and useful examples are provided in relation to research approaches and methodologies, ethics and consent issues and the implications and recommendations for practice.

Morrow, V (2009). *The Ethics of Social Research with Children and Families in Young Lives: Practical Experiences*, Published by Young Lives in August 2009. Available at: www.younglives.org.uk, accessed 21 November 2014.

- This paper outlines the approach taken to research ethics within Young Lives, a long-term study of childhood poverty in four developing countries. It describes some of the practical difficulties that Young Lives faced, and emphasises the importance of understanding local contexts in undertaking research with children and families in environments that are dynamic, economically, environmentally and politically.

Powell, MA, Fitzgerald, R, Taylor, NJ, & Graham, A (2012). *International Literature Review: Ethical Issues in Undertaking Research with Children and Young People* (for the Childwatch International Research Network). Lismore: Southern Cross University, Centre for Children and Young People / Dunedin: University of Otago, Centre for Research on Children and Families. Available at: http://childethics.com/, accessed 21 November 2014.

- The Ethical Research Involving Children (ERIC) Project website is led by the

Centre for Children and Young People at Southern Cross University on behalf of project partners UNICEF's Office of Research, Innocenti; the Childwatch International Research Network; the Centre for Children and Young People at Southern Cross University, Australia; and the Children's Issues Centre at the University of Otago, New Zealand.

- The ERIC website contains useful guidance, case studies, training resources, journal articles and a forum for discussing ethical issues associated with conducting with children. A helpful literature review summarising issues and considerations when undertaking research with children and young people is:

Additional references

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Thomson, C (2012). *Why Ethics matters,* An Address to the Third Annual conference of the Australasian Ethics Network, Brisbane, 16 February 2012, University Of Wollongong.

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- Motivation Australia
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- Salesian Missions
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ACFID

14 Napier Close

Deakin ACT 2600

Private Bag 3

Deakin ACT 2600

Australia

P +61 2 6285 1816

F +61 2 6285 1720

E main@acfid.asn.au

www.acfid.asn.au