

NCCR Evolving Language Human Research Ethics Roadmap

This document brings together the main principles of human research ethics, including research with indigenous populations, along with useful resources to understand them better and apply them.

Although it is good practice to respect all the principles listed here, this document is not binding. NCCR Evolving Language researchers are nevertheless bound to respect their University Ethics Guidelines.

For more information on the content below, please contact the TTF Ethics.

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References

I. Research Standards

1. Compliance with Swiss regulations

The NCCR Evolving Language conducts research with participants in compliance with Swiss regulation.

Resources:

- [Human Research Act](#)
- [Federal Act on Data Protection](#)
- [RESPECT Code of practice](#), 2
- [SAMS Handbook](#), p.21-27

2. Research abroad and international cooperation

High ethics standards should be applied when research is conducted abroad or in collaborations with researchers in foreign countries. Participants should not be exploited or endure unacceptable risk of harm because foreign regulations are less strict. See principles 4, 6 and 13 below.

3. Social value of research

Because research with participants often involves risk of harm for them – or at least requires them to voluntarily give some of their time – it should have social value through the generation of knowledge and potentially through the improvement in health or other social good.

To assess the value of a project, researchers need to:

- “Specify the beneficiaries of the research—who.
- Assess the importance of the research and its prospective value for each of the beneficiaries—what.
- Enhance the value of the research for each of the beneficiaries through dissemination of knowledge, product development, long-term research collaboration” Emmanuel et al. 2004.

Resources:

- [Emmanuel et al. 2004](#)
- [CIOMS](#), Guidelines 1

Misuse of research:

Research can have unintended problematic consequences or be used in unethical ways. To minimize that risk, consider the risk of misuse of your research while designing your project.

Resources:

- [EC Ethics in SSH](#) 8, pp. 21-22

4. Scientific validity of research

To produce social value, research needs to be conducted in compliance with high scientific standards.

This includes:

- Using scientifically sound methods
- No fabrication or falsification of data
- No plagiarism
- Publishing all results, positive as well as negative or inconclusive research or otherwise making them publicly available.
- Disclosing and mitigating conflicts of interest.
- “Ensuring that the research study is feasible within the social, political, and cultural context or with sustainable improvements in the local health-care and physical infrastructure” (Emmanuel et al. 2004).
- “Ensuring that the scientific design of the research realizes social value for the primary beneficiaries of the research” (Emmanuel et al. 2004).

Resources:

- [CIOMS](#), Guidelines 24, 25
- [SRA Guidelines](#), p.3, p.26-28
- [RESPECT Code of practice](#), 1
- [SAMS Handbook](#), p.29-35, p.88-89, p.99-118

5. Collaborative partnership

Research should be designed and conducted in partnership with the research population/community. Researchers need to (adapted from Emmanuel et al. 2004):

- Develop partnerships with researchers, makers of health policies, and the community.
- Involve partners in sharing responsibilities for assessing the value of research, planning, conducting, and overseeing research.
- Respect the community’s values, culture, traditions, and social practices. Researchers should have no intention to change them and minimize the risks of that happening.
- Develop the capacity for researchers, makers of health policies, and the community to become full and equal partners in the research enterprise.
- Ensure that there is a fair sharing of the benefits from the conduct and results of research. Communicating the scientific output of the study to participants is not sufficient since there might be none. Some benefit that is of value to the participants/community should be ensured so that they have a fair compensation for the risk they have taken. The benefit should be judged fair by a third party and not only by the participants or the community.

Resources:

- [CIOMS](#), Guideline 7-8
- [Emmanuel et al. 2004](#)

6. Review by an ethics committee

According to Swiss regulations, research on human diseases, on the structure and on the functions of the human body needs to be approved by a Cantonal Ethics Committee.

Many studies with human participants do not fall under that regulation. This is the case for most studies in the social sciences since they do not investigate diseases or the human body. For example, a study on the language of an indigenous population or one on the importance

of rhythm in speech would not fall under the regulation and would not require approval from a cantonal ethics committee. However, even if a study with participants does not fall under that regulation, it is good practice to have it reviewed by an institutional ethics committee (university or faculty) to test the scientific validity of the procedure and protect participants from harm. Ethics commissions can be helpful to improve a research protocol from an ethics point of view.

Resources:

- [CIOMS](#), Guideline 8
- [EC Ethics in SSH](#), 9-10, p.22-23
- [SAMS Handbook](#), p.58-62

7. Authorship

Researchers should follow the Guidelines of the [Vancouver Convention](#) guidelines.

These guidelines require that a researcher be considered an author if and only if s/he satisfies the four following criteria:

- “Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
- Drafting the work [(including supporting materials)] or revising it critically for important intellectual content; AND
- Final approval of the version to be published; AND
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.” (Vancouver Convention)

Researchers that have made other types of contribution to the paper can be thanked in the acknowledgements of the paper.

Resource:

- [Vancouver Convention](#)

II. Respect for participants and researchers

8. Risk of harm and benefits

Researchers need to assess the risk of harm to the participants and/or the study population prior to conducting their study and consider how to avoid it. The risk of harm needs to be balanced with the expected benefits for the individual or the concerned group and with the expected social and scientific value of the study.

To evaluate the potential harm of your research, keep in mind that the harm can be physical, emotional or economical.

In some cases, research can also involve risks of harm to the researchers. Those risks need to be evaluated as well and balanced with the expected scientific and social value of the

research.

Research in some countries can be dangerous for LGBTQIA+ researchers ([see map of sexual orientation laws](#)). When planning research in such countries, consider the possibility that a member of your team might be LGBTQIA+ and might not want to come out in their workplace. If you inform all your team members of the safety issues for LGBTQIA+ researchers, everyone can be informed without needing to disclose their sexual and gender identities.

Resources:

- [CIOMS](#) Guideline 4
- [EC Ethics in SSH](#), 2, p.4
- [SRA Guidelines](#) p.3,p.22-25
- [SAMS Handbook](#), p.49-56, p.77-83

Compensation:

Participants can be offered compensation for their participation in a study. However, the “compensation must not be so large as to induce potential participants to consent to participate in the research against their better judgment (“undue inducement”).” CIOMS Guideline 13

Resources:

- [CIOMS](#), Guideline 13
- [RESPECT Code of practice](#), 3
- [SRA Guidelines](#) p.8

Specific risks of harm depending on research sites:

“If you plan research in countries considered resource poor, provide details of benefit-sharing measures, such as responsiveness to local research needs and procedures to facilitate effective capacity-building. Please refer to the Global Code of Conduct in Resource Poor Settings for more information.

If your research site is located in an area that poses relatively high risks to you or your potential participants, provide clear strategies for keeping your research participants/informants, your research staff and yourself safe. A risk assessment needs to be made in which you should include details of safety measures you intend to take, including training for staff and insurance cover.” EC Ethics in SSH

Resources:

- [EC Ethics in SSH](#), 7, pp. 16-21
- [Global Code of Conduct in Resource Poor Settings](#)

9. Use of Placebo

“Placebo may be used as a comparator when there is no established effective intervention for the condition under study, or when placebo is added on to an established effective intervention.

When there is an established effective intervention, placebo may be used as a comparator

without providing the established effective intervention to participants only if:

- there are compelling scientific reasons for using placebo; and
- delaying or withholding the established effective intervention will result in no more than a minor increase above minimal risk to the participant and risks are minimized, including through the use of effective mitigation procedures” (CIOMS Guideline 5).

Resources:

- [CIOMS](#), Guideline 5
- [SAMS Handbook](#), p.54-55

10. Selection of participants

The selection of individuals and groups of participants depends on the scientific needs of the research but should be done with a view to fairness. This means that the risks and benefits of research should be equitably distributed among the different groups of people (nationality, gender, age, ability, etc.).

“Because categorical exclusion from research can result in or exacerbate health disparities, the exclusion of groups in need of special protection must be justified” (CIOMS Guideline 3).

When conducting social science research with indigenous communities, “select the study population to minimize the risks of the research and enhance other principles, especially collaborative partnership and social value” (Emmanuel et al.).

Resources:

- [CIOMS](#), Guidelines 3, 18, 19
- [Emmanuel et al. 2004](#)
- [EC Ethics in SSH](#), 3.5, p.11-12, 3.6, p.12
- [SAMS Handbook](#), p.37-47

11. Protection of vulnerable groups or individuals

If research is being conducted on vulnerable groups or individuals, specific measures need to be put in place to “safeguard the rights and welfare of these individuals and groups” (CIOMS Guideline 15).

Resources:

- [CIOMS](#), Guidelines 15, 16, 17
- [EC Ethics in SSH](#), 3.5, p.11-12, 3.6, p.12
- [SRA Guidelines](#) p.11-13
- [SAMS Handbook](#), p.37-47

12. Informed consent

Researchers should seek and obtain informed consent from participants before their engagement in the study.

Researchers have a duty to:

- When relevant, involve the research population or community “in establishing recruitment procedures and incentives” (Emmanuel et al. 2004).
- Obtain voluntary consent. Participants ought not to be threatened or constrained to

obtain consent.

- Provide participants with all relevant information (purpose of the research, duration, intended use of the results, benefits and risk of harm, access to the results). The format of the information should be culturally and linguistically appropriate.
- Obtain explicit consent. The form depends on the context of research and should be culturally and linguistically appropriate.
- Inform participants that they can withdraw their consent at any time without risk of retribution and ensure that this is the case.
- Avoid deception. Deception can only be used if there is no other way to have valid data because participants knowing about the research would skew the data and if the risk to participants is minimal. Participants should be informed about the real intent of the research as soon as deception is no longer necessary and should be given the option to withdraw their consent and have their data destroyed.
- Obtain consent from the legally authorised representative for children and vulnerable individuals. If the subject can give their assent, it should be obtained as well.
- “Implement supplementary community and familial consent procedures where culturally appropriate” (Emmanuel et al. 2004)
- Inform participants throughout the study and communicate the results to them once the study is completed.

Resources:

On consent in general:

- [CIOMS](#), Guidelines 9, 10, 16, 17
- [EC Ethics in SSH](#), principle 3.4, p.11, 4, p.13-14
- [SRA Guidelines](#), p.5-14
- [Emmanuel et al. 2004](#)
- [SAMS Handbook](#), 64-75, p.85-86

On deception and covert research:

- [EC Ethics in SSH](#), principle 3.1, p.6, 3.2, p.7

On internet research:

- [EC Ethics in SSH](#), principle 3.3, pp. 8-10
- [SRA Guidelines](#), p. 2,

13. Double use of organic material

When organic material is to be used for another purpose than the one researchers obtained consent for, further consent should be obtained. If a broad consent for unspecified future use has been obtained, the organic material can be further used without looking for explicit consent from the research participants. However, there needs to be a drop-out procedure and participants ought to be informed about it.

Resources:

- [CIOMS](#), Guidelines 11&12
- [SAMS Handbook](#), pp. 91-98

14. Confidentiality/data protection

Participants' data protection is both an important aspect of research ethics and a fundamental human right. Measures need to be taken to protect the privacy of participants and ensure the confidentiality of their information.

- Only anonymized data should be shared.
- Personal data should be deleted when it is no longer needed.
- In some cases, ensuring that data is anonymized and that participants cannot be identified can be insufficient. Measures might need to be taken so that the specific community or population of the study cannot be identified to protect them.
- Confidentiality can be raised in certain cases when there is evidence of criminal activity from or abuse of the subject.
- When non-anonymized data is to be used for another purpose than the one researchers obtained consent for, further consent should be obtained.
- Think about how you intend to use participants' data while developing the research protocol and consider asking participants their consent for reusing their data in the future during enrollment.

Resources:

- [CIOMS](#), Guidelines 12, 22
- [Emmanuel et al. 2004](#)
- [EC Ethics in SSH](#), 6, p. 15
- [SRA Guidelines](#), p. 2, p. 10, pp. 15-21
- [Federal Act on Data Protection](#)
- [GDPR](#)
- [On raising confidentiality to report a case to the authorities: EC Ethics in SSH 5, pp. 14-15](#)
- [SAMS Handbook](#), pp. 77-79, pp. 91-98

15. Research with indigenous communities

Research with indigenous communities can be delicate because of the difference in power between the researchers and the community and because of the impact that the researchers can have on the culture and the values of the community. When conducting research with indigenous communities:

- Obtain the community's approval for conducting research.
- Avoid participating in the wrong of postcolonialism and racism.
- Avoid missionary and political activism.
- Avoid intimate relationships with research participants.
- Reach an agreement with the community regarding intellectual property rights in advance.
- Avoid genetic testing of a community that could lead to discrimination within or of the community. (see [CIOMS](#) p.13 and cf. section 7 risk of harm and benefits)

Resources:

- [EC Ethics in SSH](#), 7, p.16-21
- [Emmanuel et al. 2004](#)

References

The main research ethics international guidelines:

- [Nuremberg code](#)
- [Declaration of Helsinki](#)
- [Belmont Report](#)
- [CIOMS guidelines](#)

On the history of research ethics declarations:

Rice, T. W. (2008). [The historical, ethical, and legal background of human-subjects research](#). *Respiratory care*, 53(10), 1325-1329.

Guidelines in social sciences and humanities:

- European Commission, [Ethics in Social Science and Humanities](#), 2018
- Social Research Association, [Research Ethics Guidance](#)
- The Institute for Employment Studies, [RESPECT Code of Practice for Socio-Economic Research](#)

Research with indigenous populations:

- Emanuel, E. J., Wendler, D., Killen, J., & Grady, C. (2004). [What makes clinical research in developing countries ethical? The benchmarks of ethical research](#). *The Journal of infectious diseases*, 189(5), 930-937.
- Government of Canada, [Research Involving the First Nations, Inuit and Métis Peoples of Canada](#)
- [CIOMS](#) guidelines

Research in Resource poor settings:

- Trust, Equitable Research Partnerships, [Global Code of Conduct in Resource Poor Settings](#)

Other:

Swiss Academy of Medical Sciences, [Research with human subjects, A manual for practitioners](#), 2015

[Vancouver Convention](#) Guidelines on Authorship