CGIAR RESEARCH ETHICS CODE

Approved by the CGIAR System Board as a CGIAR Policy with effect from 3 November 2020
(Decision Reference SB/M17/EDP12)

CGIAR's Core Ethical Values

Integrity | Dignity and Respect | Sustainability |Excellence and Innovation | Partnership[1]

Integrity

We are honest, tell the truth, keep promises, pursue objective scientific research, admit mistakes, earn trust, and always act professionally by being accountable and transparent

Dignity and Respect

We value and embrace diversity and inclusion, treat all stakeholders with respect and dignity, promote equity, avoid all forms of discrimination, and promote human rights

Sustainability

We plan responsibly for the long term, and are committed to environmental, social and economic food security, safety and global prosperity

Excellence and Innovation

We strive for excellence by maintaining high standards of scientific rigor, actively encouraging innovation and creativity, and pursuing our passion for learning and discovery

Partnership

We value the diverse voices of our internal and external stakeholders, and seek all forms of engagement, collaboration and teamwork

[1] These Core Ethical Values are extracted from the CGIAR Ethics Framework endorsed by the System Management Board on 3 October 2019.

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1. Purpose

1.1 CGIAR entities have a shared mission: *Ending hunger by 2030 – through science to transform food, land and water systems in a climate crisis*. To deliver on this common mission, CGIAR has adopted a unified system of governance for all CGIAR legal entities, to provide forward-looking and aligned strategic direction and oversight for bold cross-disciplinary research.

1.2 CGIAR strives to conduct its operations according to the highest ethical standards and create an environment that promotes CGIAR's Core Ethical Values of integrity, dignity and respect, sustainability, excellence and innovation, and partnership.[2]

1.3 Those involved in CGIAR research activities have a significant obligation and responsibility to embody CGIAR's Core Ethical Values. Their adherence to working in accordance with best practice ethical standards is fundamental to ensuring broad public trust and confidence in CGIAR operations.

1.4 The purpose of this Research Ethics Code ("this Code") is to ensure that clear, achievable and relevant standards of ethical conduct apply to all CGIAR Research. [2]

1.5 This Code may be complemented by additional policies where appropriate, provided that these are consistent with this Code.

2 Scope

This Code applies to the following persons (collectively referred to as "Researchers"):

i) all individuals employed or otherwise contracted by a CGIAR entity (for example, staff, consultants, secondees, students, visiting fellows and scholars) who are involved in research activities of any kind; as well as

ii) individuals employed or contracted by CGIAR partners who are involved in CGIAR research programs or projects or whose research is otherwise funded by a CGIAR entity.

3 General standards

3.1 Scientific quality and integrity

3.1.1 Researchers must strive to conduct high-quality research that has clear developmental and practical value in relation to the CGIAR mission. They must develop studies and research programs that are built on adequate prior knowledge and are scientifically sound, undertaking scientific activities only within the boundaries of their

[2] As defined by the CGIAR System Framework and the Charter of the CGIAR System Organization, as amended from time to time. On the date of approval of this Code, "CGIAR Research" is defined as "*the research carried out by the Centers and the CGIAR System Partners in support of the CGIAR Strategy and Results Framework*".

competence, based on their education, training or work experience. Researchers must adhere to the highest possible technical standards that apply to their field of work.

3.1.2 Researchers must strive for the highest reliability in the quality of research, including the design, methodology, analysis and use of resources. They must do their utmost to ensure factual accuracy of data and research results and must not engage in research misconduct (falsification, fabrication, plagiarism, suppression or purposeful misinterpretation of data or research results). They shall keep good records of scientific activities, such as data collection, research design and correspondence with collaborators or journals and shall adhere to the CGIAR Open Access and Data Management Policy in the management of data.

3.1.3 Researchers shall promote the open exchange of ideas, research methods, data and results, and their discussion, scrutiny and debate, subject to any considerations of confidentiality and third-party rights. They shall ensure that their methodologies and findings are open for discussion and peer review. Researchers are independent and impartial in their communication with other Researchers and open and honest to the public.

3.1.4 Research managers must ensure that Researchers under their supervision have the necessary resources to conduct scientific activities in line with required standards and ensure that the right capabilities and competences are assigned to research activities. Researchers must ensure that they have the necessary skills and resources to carry out research themselves or through collaboration with specialists in relevant fields. They recognize the need for ongoing education in order to remain competent and they utilize the appropriate scientific, professional, technical and managerial resources needed to ensure competence in their work-related activities.

3.2 Reporting and dissemination of research results

3.2.1 In accordance with the CGIAR Principles on the Management of Intellectual Assets, CGIAR regards the results of its research and development activities as international public goods. CGIAR is committed to the widespread diffusion and use of research results to achieve the maximum possible access, scale, scope of impact and sharing of benefits to advantage the poor, and particularly farmers, in developing countries. To facilitate this, Researchers must ensure the prompt publication and dissemination of research results by the most appropriate means, subject to intellectual property, privacy, confidentiality and contractual considerations. The management of research data must be done in accordance with the CGIAR Open Access and Data Management Policy, the CGIAR Open Access and Data Management Implementation Guidelines and the CGIAR Principles on the Management of Intellectual Assets.

3.2.2 **Responsibility for research findings**

a) Researchers must ensure that reporting results serve, and do not compromise, the initial goals and purpose of their research. Researchers must take particular care to state all relevant qualifications on the findings and interpretation of their research. Researchers must also disclose underlying assumptions, theories, methods, measures, and research designs that might bear upon findings and interpretations of their work. In presenting their work, Researchers must report their findings fully and not omit relevant data.

b) Consistent with the spirit of full disclosure of methods and analyses, once findings are publicly shared, Researchers shall permit their open assessment and verification by other responsible Researchers with appropriate safeguards, and where applicable, protect the anonymity of research participants.

c) If Researchers discover significant errors in their publication or presentation of data, they must take reasonable steps to correct such errors in a correction, a retraction, published errata or other public fora as appropriate.

3.2.3 **Authorship credit**

a) Researchers must take responsibility and credit, including authorship credit, only for work they have actually performed or to which they have contributed. They must ensure that principal authorship and other publication credits are based on the proportional scientific or professional contributions of the individuals involved, regardless of their status. Decisions on publication and authorship must be agreed jointly and communicated to all members of the research team.

b) Researchers must fully credit the contributions of research partners, including non-professional partners such as farmers. Credits include co-authorship, which is strongly encouraged, and being named in acknowledgements. Authorship will not be allocated to honorary or guest authors (and those that do not fulfil criteria of authorship).

3.2.4 **Respect for intellectual property and confidentiality**[3]

a) Researchers must honor patents, copyrights and all other forms of intellectual property. Researchers must follow the terms of specific applicable licenses to the intellectual property accessed and used. Researchers must not use unpublished data, methods or results without permission from the intellectual property owner.

b) Researchers must clearly acknowledge all sources used in their research and obtain permission from any individuals if a significant amount of their work has been used in a publication. In their publications, presentations, training, practice and service, all

[3] For further guidance on the management of intellectual assets and intellectual property rights please refer to the CGIAR Principles on the Management of Intellectual Assets and the Implementation Guidelines for the CGIAR Intellectual Assets Principles on the Management of Intellectual Assets.

Researchers must provide acknowledgment of, and reference to, the use of the work of others, even if the work is not quoted verbatim or paraphrased.

c) Researchers must provide fair, prompt and rigorous evaluations and respect confidentiality when reviewing the work of others. In all circumstances, Researchers must not use or otherwise seek to gain from information or material received in a confidential context (such as knowledge obtained from reviewing a manuscript, serving on a proposal review panel or reviewing budgetary information), unless they have authorization to do so, or until that information is otherwise made publicly available.

3.2.5 Funder acknowledgement

All funders and sponsors of research must be acknowledged in accordance with the CGIAR Funder Acknowledgement Guidelines as well as any applicable instructions or terms provided by such funders and/or sponsors.

3.2.6 Accountability and transparency

a) Researchers must ensure that any research undertaken complies with the agreements, terms and conditions relating to their project and facilitate systematic and transparent tracking of outputs and impacts as per established procedures for performance management.

b) Research managers and supporting operational units (such as finance, procurement and partnerships units) must adhere to appropriate, accountable and transparent use of funding for research by ensuring compliance with the procedures that are in effect for the planning, monitoring, reporting, evaluation and impact assessment of CGIAR projects (including projects conducted by CGIAR alone and with partners).

3.3 Conflict of interest

3.3.1 Conflict of interest: concept

a) A conflict of interest arises in a situation where there are reasonable grounds to believe that a Researcher's:

   i. direct or indirect personal interest, including that of a closely associated third party such as a family member, in a matter; or

   ii. duty owing to another organization outside the CGIAR System

present a risk that a Researcher's professional judgment will, may or may be perceived to be unduly influenced.

b) A conflict of interest may be actual (it exists), potential (it might develop into one) or perceived (it may be considered to exist by others).

c) Conflicts of interest may arise as a result of a Researcher's association with an organization external to the CGIAR System, or closely associated third parties (such as family members and/or professional associates) whose interests may conceivably conflict with those of one or more of the CGIAR entities on a given issue.

d) In many situations, conflicts of interest will relate to financial interests, or the potential for personal or professional advantage, but they may also arise by virtue of the potential a given situation or relationship presents for the undue exercise of influence.

e) In situations where Researchers are required to address a conflict of objectives, they must be particularly vigilant when taking decisions, ensuring they are made with full objectivity and transparency. In taking such decisions, Researchers must take into account a range of factors and potential outcomes in determining the appropriate course of action to take, mindful of trade-offs that may need to be made in the process.

3.3.2 **Declaring conflicts of interest**

a) The onus is on each Researcher to self-identify actual, potential or perceived conflicts of interest, since only he/she has the detailed knowledge to do so.

b) Researchers must identify and declare conflicts of interest as and when they arise, in accordance with established operating procedures.

c) Researchers should actively seek advice from others to assist them in determining whether an actual, potential or perceived conflict of interest might exist. Advice channels may include the CGIAR Chief Ethics Counsel, fellow Researchers, ethics focal points, legal counsel or focal points of a CGIAR entity. Researchers should remain open to indications of potential conflicts of interest from other individuals.

3.3.3 **Managing conflicts of interest**

a) Once identified, a conflict of interest must be managed appropriately, in accordance with established operating procedures.

b) In determining the course of action to follow, the materiality of the interest and the likelihood that it will impair the objective and impartial exercise of judgment required of Researchers must be duly assessed.

3.4 Working with research and development partners

3.4.1 In delivering scientific innovations to achieve its mission, CGIAR Researchers collaborate with development partners, national agricultural research and extension services and the private sector to achieve impact at scale. CGIAR's Core Ethical Values reflect the importance of these partnerships by highlighting the value of the diverse voices of stakeholders and commitment to all forms of engagement, collaboration and teamwork. There is therefore an ethical obligation on the part of Researchers to treat their partners with respect, as equals in the joint activity and with sensitivity to the cultural norms and values of partner countries.

3.4.2 CGIAR's Core Ethical Values must be clearly articulated to research and development partners, emphasizing CGIAR's commitment to valuing and embracing diversity and inclusion, treating all stakeholders with respect and dignity, promoting equity, avoiding all forms of discrimination and promoting human rights. Where Researchers encounter apparent discrepancies between the expectations of partners and the CGIAR mission and the Core Ethical Values, they are encouraged to engage in dialogue with partners with the view to overcome any discrepancies and to seek external expert advice when necessary.

3.4.3 Researchers must ensure transparency with regard to the objectives of the partnership, expectations related to the outputs and outcomes, and communication about research progress and uptake of research during the partnership. Researchers must engage in open dialogue with partners regarding their aspirations for collaboration and strive to ensure that CGIAR research delivers on the goals agreed with partners.

3.4.4 In relation to the outputs of partnerships, CGIAR Researchers must ensure that all participants of any collaboration, including local and external scientists and non-research specialists, have access to research results (for example, in the form of data and publications) and are appropriately credited, either through authorship, contribution or formal acknowledgement, as per the provisions in section 3.2.3.

4 Specific standards

4.1 Research involving human subjects

4.1.1 The provisions in this section apply to research involving people as subjects in research, whether in the form of surveys, interviews, focus group discussions, participant observations, multi-stakeholder dialogues or participatory action and learning. For a full definition and examples, please refer to Annex III. The procedures for approval of research involving human subjects shall be established as part of System-wide policies and services within the CGIAR Research Ethics Code.

4.1.2 Researchers must ensure that all their research complies with international standards of ethical treatment and protection of human subjects, including the three core principles of respect for persons, beneficence and justice, as stated and explained in the Belmont Report. All research plans must be implemented in compliance with national laws regarding research involving human subjects, including laws and regulations on personal data or personally identifiable information ("PII") (see section 4.1.8 below), and in accordance with relevant policies on personal data protection. [4]

4.1.3 In all its research activities, CGIAR must treat human participants with dignity and respect and have procedures in place to (i) obtain prior informed consent to ascertain that research is voluntary; (ii) protect the privacy of the individual or household, as

[4] Such policies are under development.

applicable; and (iii) protect participants from any risk to which they may be exposed while participating in CGIAR research.

4.1.4 Researchers must make a non-arbitrary, systematic and fair assessment of the possible harms and benefits of their research. This must include physical, psychological, legal, social and economic harm and benefits accruing to individuals, families and communities.

4.1.5 **Selection of research participants**

a) The selection of participants shall be made on the basis of the objectives of the study, rather than on non-research interests. When the experimental design of research involving human subjects includes various groups, adequate selection methods and other specific technical standards relevant to the study must be used to obtain an impartial allocation of the participants in each group. Special attention must be paid to ensuring diverse representation from subject groups, including participation from women, men and minority groups where possible and consistent with the objectives of the study.

b) Research may require the involvement of marginalized or vulnerable people. Researchers shall not exclude vulnerable groups from studies based on the complications involved, but rather take measures to protect vulnerable individuals and groups adequately. For this, Researchers must ensure that research plans minimize the possibility of coercion, undue influence or manipulation, and maximize the likelihood of valid informed consent.

4.1.6 Researchers must not offer excessive or inappropriate financial or other inducements to obtain the participation of research participants, particularly when it might coerce participation. Researchers may provide compensation to the extent that resources are available and appropriate.

4.1.7 **Prior informed consent**

a) Voluntary participation is a precondition for involving human subjects in research. Researchers must therefore obtain informed consent from participants by obtaining permission before data collection and/or an intervention (refer to Annex III).

b) Researchers must uphold the right of research participants to consent to, withdraw from, or refuse to take part in research. Participants must be made aware that their participation is voluntary and that they can withdraw at any time. No coercion or undue inducements shall be given by Researchers or by those in authority acting for Researchers. In undertaking research with vulnerable people, [5] Researchers must take care to ensure that the voluntary nature of the research is understood, and that consent is not coerced.

[5] For example, illiterate farmers, children or youth, migrant populations or displaced persons. For a full definition, please refer to Annex I.

c) The standard informed consent process includes provision of information about the research project and receipt, from each subject, of consent (written or verbal) to participate in a research project. Before undertaking research activities, Researchers must ensure that research participants are fully informed about the nature, purpose, methods and intended possible uses of the research; [6] what their participation in the research entails; and any benefits, harm or risks to them and others induced by the research. Please refer to Annex III for more details on the process of obtaining prior informed consent.

d) Researchers must also obtain informed consent from any person involved prior to recording audio, video or taking photographs and obtain permission to use the recorded materials (please refer to Annex III for a template), unless these activities involve naturalistic observations in public places and it is not reasonably anticipated that the recording will be used in a manner that could cause personal identification or harm.

4.1.8 **Confidentiality and personal data protection**

a) Research data must be handled in a way that protects the wellbeing of people by not harming their safety, dignity or privacy. As far as research data involves PII, Researchers must comply with relevant policies on personal data protection. [7]

b) CGIAR must protect the privacy of individuals and maintain the confidentiality of PII which, alone or collected together, can lead to the identification of a particular person or household, such as:

- a name and surname
- a home address
- an email address
- phone or mobile number and the advertising identifier of a phone
- an identification card number, social security number or similar ID
- location data including the location data function on a mobile phone
- geospatial coordinates of personal or household assets, including homesteads and fields owned and/or managed or used by subjects
- an Internet Protocol ("IP") address or a cookie ID
- any other identifier that allows for the identification of a person or a small group of persons, including people's images or voices
- nationality, religious beliefs or any other personal identifier, when collected together with any of the above.

[6] In some behavioral experiments it may be necessary for the true nature of the experiment to not be disclosed to participants. In such cases, after data collection is completed, the Researchers are required to provide the true objectives and details of the study and must request permission from the human subjects to use the data for research.

[7] Such policies are under development.

c) PII must not be released or made public in any manner as it is regarded as confidential by laws and regulations of most countries. All data must be adequately protected during storage to prevent losses and to ensure that the identity of participants cannot be traced to the source by Researchers analyzing the data. All PII (including records of interviews and informed consent forms) must be kept in a secure archive.

d) When research requires maintaining PII in databases or record systems, Researchers must delete any variables that identify a particular person or household before the information is made publicly available. If PII is entered into databases or records systems available to persons without the prior consent of the relevant parties, Researchers must protect anonymity by not including personal identifiers or by employing other techniques that mask or control the disclosure of individual identities.[8] PII data collected by CGIAR must not be shared with third parties without explicit permission from participants.

e) Researchers must comply with the standards for managing, storing and sharing research data outlined in the CGIAR Open Access and Data Management Policy and the CGIAR Open Access and Data Management Implementation Guidelines. All non-confidential research data collected by researchers shall be made open according to the CGIAR Open Access and Data Management Policy.

4.1.9 **Protection from risks**

a) Researchers working with local communities or other stakeholders must be vigilant of the potential risks posed by research undertaken and any potential negative responses or unintended effects. CGIAR Researchers shall collaborate with local organizations with extensive experience and sound records in identifying and mitigating possible risks in a way that is culturally appropriate in a given context. Efforts are made to consult and collaborate with local women's and minority groups to assist in identifying potential gender and diversity considerations in managing risks.

b) Researchers must take all possible steps to ensure the safety and security of themselves, partners, research participants and other persons affected by their research. When conducting research, Researchers must not encourage activities or behave in ways that are unhealthy or life-threatening to research participants or others. Similarly, they must avoid activities that may affect the reputation of those involved in research. Researchers must suspend research immediately if they perceive that its continuation could be damaging to anyone involved.

c) If any group affected by research activities challenges the research team's right to be in the community, attempts to prevent the research from being conducted, or threatens violence, Researchers shall withdraw from the location and seek the assistance of partner institutions with the authority to resolve the dispute and discuss remedial options with communities. Communities or individuals at risk must be aware

[8] For tools and procedures for managing confidential research data see, for example, the International Livestock Research Institute (ILRI) Policy Procedure on Disclosure of Confidential Research Data.

of whom to contact, and have their details, to discuss any issues that arise regarding their research.

4.2 Research involving animals

4.2.1 Respect for animals must form the foundation for all decisions regarding animal care and use for scientific purposes for CGIAR and its Researchers. CGIAR must aim to engender this same culture in collaboration with partners.

4.2.2 Animal ethics must serve as a moral and legal framework that is applied to evaluate whether proposed actions involving the use of animals should be performed. The consideration of animal ethics is required for any scientific procedure involving animals, observational studies where an animal's behavior or habitat may be affected or any other interactions with animals. It is unethical for Researchers to conduct unnecessary or poorly designed animal experiments, even if the impact on animals is low.

4.2.3 Any new or ongoing research or teaching activity using animals must receive animal ethics approval. This applies to all vertebrate and some invertebrate species, including cephalopods and decapod crustaceans, and any bird, reptile or mammal past the mid-point of gestation/incubation. Routine veterinary or agricultural practices do not need ethics approval. When evaluating environmental impacts (see section 4.4) this list of species should be broadened further to include all invertebrate species that are of importance, such as pollinators or any locally endangered species.

4.2.4 **The 3Rs: Replace, reduce and refine the use of animals in research**

a) The fundamental principle guiding research and training involving animals is that animals can, and should, be used in research or teaching which may benefit humans, animals or the environment, provided there is no acceptable non-animal alternative. This must apply to animals in laboratory, farm and field settings where evaluation of the necessity of the activity and the appropriateness of the design is carried out prior to and during the use of animals in experiments or teaching. This may involve some evaluations being conducted after previous approvals have been granted.

b) When animals are used for scientific purposes, the internationally established principles of replacement, reduction and refinement (the three Rs) [9] should be taken into account:

- **Replacement** requires that wherever possible, techniques that totally or partially replace the use of animals for scientific purposes must be sought.
- **Reduction** refers to the use of methods that enable Researchers to obtain comparable levels of information from fewer animals or to obtain more information from the same number of animals.
- **Refinement** refers to the use of methods that prevent, alleviate or minimize pain, suffering, distress or lasting harm and/or enhance welfare for the animals used.

[9] Russell and Burch (1959).

Refinement includes the appropriate selection of relevant species with a lesser degree of structural and functional complexity in their nervous systems and a lesser apparent capacity for experiences that derive from this complexity.

c) When considering the 3Rs, and the ethical use of animals in research and training activities, CGIAR recognizes that this includes animal acquisition, transport, husbandry, enrichment, preventative care (including pain relief) and end-of-study plans. End-of-study plans can range from re-homing to reuse or euthanasia and the consideration of the humane end point – the clear, predictable and irreversible criteria that allow for early termination of a procedure before an animal experiences harm that is not authorized or scientifically justified. An example of this is euthanasia as soon as an animal has been determined to be infected in a disease infection study, rather than waiting for the disease to cause suffering or mortality in the animal.

d) Acclimation of animals to research settings is a critical part of **refinement** and involves a consideration of the dietary, behavioral, social and environmental needs of a species.

e) Coordination between projects is encouraged as part of **reduction** processes. For example, saving tissue from animals at the end of a trial for another experiment will save further animals from being used.

f) An assessment of the welfare impacts of, and cumulative effects on, an animal's lifetime experience must be conducted when designing experiments. Frequent mild procedures will create a cumulative burden on animals. Experimental designs that increase the welfare impact on fewer individual animals is not appropriate when aiming to **reduce** animal numbers (for example, doubling the number of surgical procedures one animal undergoes so that another does not need to be used fails to consider the impact of the cumulative burden).

g) Good animal welfare and effective application of the 3Rs is contingent on technical ability and expertise. Therefore, only qualified personnel are authorized to handle and supervise the handling of animals in experiments or teaching. These ethical concepts apply to domesticated and wild animals.

4.2.5 **Animal welfare and care**

a) As well as the ethical considerations of research, the welfare of animals must be considered. While related, these are two different concepts. Animal welfare is *the physical and mental state of an animal in relation to the conditions in which it lives and dies.* [10] Animal welfare is based on the principle that an animal should be treated in a way that meets its biological, behavioral and affective state needs, all which contribute to a good quality of life for the animal. With regard to research quality, compromised welfare can also result in greater variability of data; inappropriate or 'wrong' biological/clinical responses; data that cannot be reproduced/is incomplete; increased financial costs; and data that cannot be applied to other situations.

[10] World Organization for Animal Health (OIE), *Terrestrial Animal Health Code*, 2015.

b) It is recommended that the Five Domains framework be used when assessing an animal's needs and welfare. [11] The Five Domains framework comprehensively describes the essential components of an animal's quality of life: nutrition, environment, health, behavior and mental state. It builds on the important aspects of the well-known Five Freedoms, [12] while addressing some of their limitations. For example, while the Five Freedoms describe an absence of negative experiences, they do not describe the positive experiences that are needed for an animal to have a life worth living.

c) For the welfare of animals, including fish, under the care of any CGIAR research team it is required that:

- animals are sourced, bred, transported, used and disposed of with procedures that are in line with international and national regulations, policies and best practice
- temperature, humidity and ventilation be controlled at the appropriate levels and monitored regularly
- lighting be appropriate to support normal physiological function and a system for monitoring noise and vibration be put in place
- housing and space allow for the normal physiological and behavioral needs of animals
- animals receive quality feed that will support their normal growth and development (deviation from this may be appropriate if it is a nutritional or related study)
- animals receive daily care from qualified personnel
- specifically, for fish, water quality parameters and life support systems be appropriate to the animal species.

d) For research involving or affecting wild animals, awareness of the unique welfare and husbandry needs of individual wildlife species is required and must be adhered to. CGIAR Researchers must comply with the rules and requirements of agencies that have jurisdiction over wildlife.

<u>Recognition of sentience</u>:

e) CGIAR Researchers must recognize that animals have rights and an intrinsic sentient value which must be respected, especially the capacity to sense and express pain, suffering, distress, lasting harm, and even conscious natural behavior. Therefore, animals used in research and training must be treated humanely, with proper respect and care.

[11] Mellor D. & Beausoleil N. Extending the 'Five Domains' model for animal welfare assessment to incorporate positive welfare states. *Animal Welfare*, 24 (3), 241-253. 2015

[12] Webster J. Assessment of animal welfare: the five freedoms. *Animal Welfare: A Cool Eye Towards Eden.* Blackwell Science: Oxford, UK, 10-14. 1994

4.2.6 **Implementing standards, guidelines and best practice**

a) CGIAR recognizes that in some countries, national regulations, standards and guidelines on animal welfare may be lacking. There may be disparities between two countries (for example, between cross-border study sites, or between donor and implementation countries). The World Organization for Animal Health (OIE) Guiding Principles for Animal Welfare, including Chapter 7.8 Use of Animals in Research and Education, can be a useful guide to establish and apply minimum standards.

b) All CGIAR animal research activities and animal care must strive for best practice. Best practice animal care includes guaranteeing appropriate species-specific enclosures, feed, water, temperatures, ventilation, lighting and enrichment for animals involved in research (see section 4.2.5). It also includes appropriate animal handling, veterinary care and pain relief. CGIAR recognizes that in cases of research using privately owned animals (for example, farm livestock), the management practices of owners may not meet the best practice standards adhered to by CGIAR Researchers. In these circumstances, the research activity itself must still adhere to best practice standards and guidelines. Monitoring, reporting and developing competencies are all essential components of animal ethics in research.

Monitoring:

c) Animals must be monitored and assessed at all stages of a project for signs of pain and distress, including deviations from normal behavior. Monitoring is essential to identify unexpected impacts and intervene quickly, to detect planned endpoints as early as possible and to ensure that experimental plans remain on track. Appropriate monitoring protocols and mechanisms for feedback to the approving body must be developed and adhered to.

d) Many species used in CGIAR research, including fish, are prey species. This means that they have subtle pain signals and strong fear responses. Both of these must be considered when adapting animals to research settings, managing animals during the research process and handling animals in field studies.

Reporting and continuous learning:

e) Animal welfare and ethics are continually changing as more research becomes available on how to best care for animals in research and non-research settings. CGIAR commits to the value of learning to improve both animal care and research practice. Annual and end-of-project reporting must be conducted to facilitate this. To be most useful, these should include information such as a summary of the project progress to date, the total and current number of animals used and whether or not the project is meeting its objectives. End-of-project summaries and evaluations for completed projects should include animal care considerations.

Competency and standard operating procedures:

f) All people involved in the care and use of animals in a research project must be either competent in the procedure they perform, or under the direct supervision of a person who is competent to perform the procedure. In order to ensure competency, standard operating procedures for these common activities are needed. This applies to monitoring and husbandry practices at all stages and sites of animal care and use. This also applies to collaborators from partner organizations.

4.3 Research involving modern biotechnology

4.3.1 Use of biotechnology

a) CGIAR engages in plant, animal and fish breeding using next-generation breeding techniques to develop varieties that increase resilience to climate change and tolerance or resistance to diseases and pests, and to provide better and more diverse nutrition and sustainable livelihoods. CGIAR recognizes that the utilization of modern agricultural technologies is essential to provide increased genetic gains and innovative breeding products to users. The responsible application of new breeding methods can contribute to increased effectiveness and faster plant and animal breeding that benefit societies. CGIAR studies, develops, deploys and monitors these technologies, as well as the products developed through them, in partnership with national research programs that guide variety improvements.

b) Modern biotechnology methods are in constant development and currently include genetic engineering, genome editing and novel plant breeding techniques that are used to develop enhanced traits that may not be part of the species gene pool. [13] They are also used to achieve greater efficiency relative to more traditional breeding techniques. In contrast to genetic engineering, genome editing and novel breeding techniques specifically edit DNA at precise, targeted genomic locations, similar to the process that occurs in conventional breeding, resulting in desirable genotypic and phenotypic changes without the introduction of foreign genetic material.

c) CGIAR is committed to developing products that are safe for humans, animals and the environment. In doing so, Researchers must undertake appropriate safety assessments of all new products introduced into CGIAR breeding programs. CGIAR facilitates the development of multiple products using modern biotechnology methods with nutritionally enhanced and agriculturally important traits that have provided economic and environmental value to many producers around the world. These products have contributed to food security, climate resilience, and reducing adverse environmental impacts, while also complementing other agricultural innovations.

d) CGIAR has a mandate to deliver plant and livestock improvements with the most benefits to partner countries and to facilitate capacity development to allow for the proper handling of genetic material. The Core Ethical Values of CGIAR apply to the

[13] Definitions of these methods can be found in Annex I.

process of transferring new plant varieties to partners and any necessary capacity development.

4.3.2 **Sovereignty and safety**

a) CGIAR recognizes and respects the sovereignty of individual nations to determine if, when and how innovative products will be used and provides the requisite technical support, as requested.

b) CGIAR works with partners to develop an integrated set of solutions for food and agriculture and supports establishing proper decision-making processes. CGIAR Researchers must adhere to international and local rules and standards throughout the development life cycle. When developing products using modern biotechnology, Researchers must provide evidence-based information to inform decisions by stakeholders within the boundaries of their explicit roles and scientific competencies.

The role of CGIAR in product development:

a) Delivery of improved varieties developed using novel biotechnology must be done through a process that includes an assessment of the socio-economic impacts of the introduction of novel traits, product development, safety assessments of introduced material and novel traits, the process of obtaining regulatory clearance and the deployment of new products to farmers.

b) CGIAR's focus is on the research and development stages. However, to fulfill the mandate of providing access to improved agricultural crop varieties to farmers, CGIAR is committed to providing helpful transparent information and data on newly developed products. CGIAR also contributes to developing and supporting the appropriate quality assurance and stewardship practices required by partners who are responsible for obtaining regulatory clearance and product deployment.

c) CGIAR must support the stewardship practices that apply to regulated, confined field trials during the development of new plant varieties. During product development, CGIAR Researchers must adopt principles and management practices for the responsible stewardship of agricultural biotechnologies, such as those established by Excellence Through Stewardship, a global nonprofit organization that provides best practices for agricultural biotechnology. CGIAR partners that take up CGIAR innovations must be provided with relevant documents, capacity development and other types of scientific support to enable national partners to succeed in navigating the regulatory phase.

Policies and protocols:

d) CGIAR must advocate responsible development and use of conventional and innovative technologies. CGIAR recognizes that safety assessments and protocols are required to protect human and animal health and the environment.

e) During the development and safety assessment of agricultural products using new technologies, CGIAR must abide by the regulations of host countries, international

food safety standards, the guidelines developed by the Codex Alimentarius Commission and the provisions of the Cartagena Biosafety Protocol. When working with national partners, CGIAR Researchers must assess the safety of products on a case-by-case basis and in compliance with national regulations and international best practices.

Public dialogue:

f) CGIAR recognizes that as with all innovations, civil society has many questions about products developed using novel biotechnology methods. Consistent with its mission, CGIAR will listen with respect to viewpoints on plant, animal and fish improvements and contribute to informed debates with the appropriate expertise and evidence-based information.

g) CGIAR encourages discussion of the ethical and social implications of scientific developments in biotechnology.

h) CGIAR Researchers deliver innovation, capacity development, policy dialogue and outreach activities related to biosafety issues. Furthermore, CGIAR develops scientific inputs on these issues for national and regional stakeholders, while actively participating in national and global dialogues on biosafety issues with governments, civil society organizations, the media and policy dialogue forums.

4.3.3 Access to novel biotechnology products developed by CGIAR

a) CGIAR supports equitable access to affordable, sustainable, high quality and appropriate agricultural modern biotechnologies for all.

Intellectual property rights:

b) In line with its role to develop, use and share international public goods, CGIAR works with partners to secure access to operate with novel technologies in target countries, as well as to ensure equity in the benefits derived from them. For guidance on the sound management of intellectual assets and intellectual property rights, Researchers must refer to the CGIAR Principles on the Management of Intellectual Property Assets and the CGIAR Implementation Guidelines for the CGIAR Principles on the Management of Intellectual Assets.

Socio-economic impacts from the use of modern technologies:

c) CGIAR partners with national institutions to develop varieties with new traits based on the identified needs of countries and regions. CGIAR projects involving the use of novel biotechnology include socio-economic analyses to elucidate potential impacts across society and identify the main adopters of new varieties or technologies (these may include, for example, small-scale farmers or environmental benefits).

4.4 Environmental impacts of research

a) Researchers must strive to promote social good and environmental sustainability and prevent or mitigate social and environmental harm through research, capacity development and advocacy. CGIAR research aims to increase the positive environmental impact it generates and continuously reduce its environmental footprint. Researchers must ensure the integration of nationally and internationally recognized sustainability practices into their research and internal operations.

b) Researchers must ensure that their research respects ecosystems, biodiversity and natural resources when designing and conducting research. They must take the necessary steps to ensure that any adverse effects of research are reduced to the greatest extent possible. Researchers must set up research protocols that avoid or reduce potential harm to their study sites and studied ecosystems. [14]

c) Identification, monitoring and reporting on environmental risks must be undertaken as part of risk assessments in proposed research at the design and approval stages. [15] The process for this must be built into the CGIAR Performance and Results Management System.

d) All research activities must comply with the applicable environmental laws and regulations of host countries. Research must be guided by the relevant international frameworks, codes of conduct and international conventions as they relate to the management and protection of the natural environment, including but not limited to:

- the Stockholm Convention on Persistent Organic Pollutants
- the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade
- the International Code of Conduct on the Distribution and Use of Pesticides
- the Guidelines on Good Practice for Ground Application of Pesticides
- the Convention on Biological Diversity and its Cartagena Protocol on Biosafety and the Nagoya Protocol
- the Ramsar Convention on Wetlands.

e) Where sentient animals are involved, Researchers must consider both environmental and animal welfare impacts. Sentient animals include all mammals, birds, reptiles and fish, as well as cephalopods and decapod crustaceans. When research may alter the habitat and/or behavior of animals, animal ethics approval may also be required (see section 4.2). Wild species have very reactive fear responses, so the risk of behavioral

[14] Examples of activities with possible impacts on the environment and biodiversity include land clearing for cropping trials, introducing irrigation, fertilizer trials or changing environmental flows, all of which can affect biodiversity, nutrient depletion and water quality, among others.

[15] The Center for International Forestry Research (CIFOR) Environmental and Social Management System (ESMS) and the CIFOR Project Appraisals and Risk Assessment Checklist provide examples of provisions that can be used for carrying out risk assessments. The International Water Management Institute (IWMI) Risk Mitigation Declaration for Possible Impacts on the Environment and Biodiversity is another resource that includes an Environmental Mitigation and Monitoring Plan (EMMP), based on United States Agency for International Development (USAID) procedures.

disturbances from the presence of Researchers is a genuine one. Activities that may indirectly impact wildlife include the introduction of chemicals into the environment, changing habitats and lighting and noise disturbances. Even in situations where animals are not considered to be at risk of impact, these impacts must be considered as they may generate unexpected consequences and would thus be important to include as part of the risk assessment process.

4.5 Participatory research

4.5.1 Where participatory approaches are adopted, Researchers must strive to involve farmers, communities and other stakeholders in the design, management, implementation, analysis and application of research to ensure that local needs and priorities are met. In such circumstances, Researchers must support communities through capacity building, farmer information exchange or other appropriate methods with the aim of ensuring quality research results for wider adoption.

4.5.2 **Refraining from creating unrealistic expectations**

a) In their engagement with communities and individuals, Researchers must take care not to create unrealistic expectations among people who participate in research, either in terms of immediate material or non-material benefits or longer-term positive impacts. This is particularly the case when the interaction is framed as 'action research', which involves a joint process of learning between CGIAR Researchers and a group of people that specifically aims to achieve a social transformation for that group.

4.5.3 **Respect for cultural norms and traditions**

a) Researchers must respect the values, culture and traditions of the communities they engage with. They must strive to have a sound understanding of the local context prior to interaction with communities and comply with any customs, protocols and local laws. Researchers must be sensitive to the values and cultures of the groups being studied and how this may affect research participants' understanding of the purpose and nature of research. Researchers have a responsibility not to impose external values, standards or cultural norms onto communities.

b) Researchers do engage in research that challenges certain norms, including gender inequities or patterns of decision-making and authority that reinforce poverty or social exclusion, but they must do so in ways that are grounded in an understanding of the local context and that respond to the goals and priorities that local groups deem legitimate.

4.5.4 **Research involving traditional knowledge and technologies**

a) Local communities and indigenous people who exchange traditional knowledge and technologies with CGIAR must be made fully aware of the research plan that utilizes this knowledge and technologies, and any dissemination plans that include this knowledge and/or technologies.

b) Acknowledgement, confidentiality and anonymity must be discussed and adopted as situations require to ensure that the CGIAR commitment to produce international public goods is not impeded while respecting the ownership of information or technology. This principle includes the recognition that indigenous people have prior proprietary rights and cultural responsibilities for the environment that they have traditionally inhabited or accessed and that they may wish to keep some information confidential.

4.6 Access to genetic resources

4.6.1 As per Article 3 of the CGIAR Principles on the Management of Intellectual Assets, CGIAR must recognize the indispensable role of farmers, indigenous communities, agricultural professionals and scientists in conserving and improving genetic resources.

4.6.2 Researchers must observe the principles of the Convention on Biological Diversity (CBD) and its Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (Nagoya Protocol). Researchers must ensure that they follow national policies, laws and regulations on access and benefit-sharing when accessing and using genetic resources and their associated traditional knowledge.

4.6.3 When accessing genetic resources and associated traditional knowledge, Researchers must comply with processes and standards for obtaining prior informed consent as established in applicable national and subnational policies and laws, including those implementing the CBD, its Nagoya Protocol and the International Treaty on Plant Genetic Resources for Food and Agriculture. The Guidelines on the Nagoya Protocol for CGIAR Research Centers provide guidance on complying with national access and benefit sharing (ABS) laws when accessing biological and genetic resources, including obtaining prior informed consent and arriving to mutually agreed terms.

4.6.4 In countries where there are no implementing measures in place, Researchers must proactively seek out ways to fulfil the spirit of these international agreements, and to the extent possible, work with the partner organizations in those countries, the national focal points on ABS and the competent national authorities.

4.6.5 For further guidance on fulfilling obligations when seeking to access and use traditional knowledge associated with genetic resources, Researchers should refer to the Guidelines on the Nagoya Protocol for CGIAR Research Centers.

5 Implementation

5.1 Arrangements for implementation

5.1.1 This Code will be publicly available on the CGIAR website.

5.1.2 Implementation arrangements for the Code will be developed in a companion document. Together, the Code and the companion document on implementation will constitute CGIAR's Policy on Research Ethics.

5.1.3 Researchers who require guidance on the interpretation or implementation of this Code may request the advice of the CGIAR Chief Ethics Counsel, ethics focal points, legal counsel or focal points of a CGIAR Entity.

5.2 Reporting possible ethical misconduct

5.2.1 Individuals who suspect, or may be aware of, possible violations of this Code have a responsibility to immediately bring them to the attention of CGIAR in accordance with the applicable policies and procedures relating to whistleblowing.

5.2.2 CGIAR must not tolerate retaliation against anyone who in good faith raises a concern or reports misconduct. However, knowingly reporting false information is contrary to this Code, and individuals who do so may be sanctioned accordingly.

5.3 Addressing and managing ethical misconduct

5.3.1 Ethical misconduct must be managed appropriately, in accordance with established operating procedures, to ensure due follow-up action, as relevant and necessary.

5.3.2 The assessment of potential ethical misconduct must reflect due process and will be strictly conducted on a confidential basis. Any remedial actions must be determined on a case-by-case basis, in accordance with the respective applicable procedures.

5.4 Periodic review

5.4.1 The effectiveness of this Code will be reviewed periodically, and not less frequently than every three years.

Annex I – Definitions

Animal welfare
The physical and mental state of an animal in relation to the conditions in which it lives and dies.

Assent
Permission given to participate in a research study where the individual is not able to legally consent. Such individuals can include minors and persons with diminished cognitive capacity. They may also dissent, which means they do not agree. Working with children or adults not capable of giving consent requires the consent of the parent or legal guardian and the assent of the subject.

Benefit
Something that promotes the wellbeing of an individual or group, or the public generally. A benefit for an individual in the context of CGIAR may include access to genetic resources, technology, water, land and other resources that improve their livelihoods, food security, climate resilience and economic and environmental sustainability. Payment for participation in a study is not considered a benefit of the study and often there is no guaranteed benefit of participation.

Beneficence
The principle that governs Researchers which ensures that the research maximizes benefits and minimizes harm to participants. This principle ensures that Researchers have the welfare of the research participant as a goal of any research.

Confidentiality and personal data protection
The treatment of information, including personal data, that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others without permission in ways that are inconsistent with the understanding of the original disclosure.

Consent
The voluntary agreement of a person or group, based on adequate knowledge and understanding of relevant material, to participate in research. Informed consent is one possible result of informed choice, the other possibility is refusal. Oral consent may be used for persons who cannot read or feel uncomfortable signing forms for cultural reasons. In this case, a written text describing what will be told to subjects when oral consent is necessary should be provided. Consent may only be given by individuals who have reached the legal age of consent (typically 18 years old).

Cumulative burden
The impact that repeated procedures, including handling, restraint and recovery time, may have on an animal. Cumulative burden should be assessed in relation to an animal's lifetime experience. The lifetime experience of an animal includes all aspects of health, welfare and care, along with the impact of all scientific procedures.

Genetic engineering
Genetic changes resulting from the application of modern biotechnology as defined in the Cartagena Protocol on Biosafety.

Genome editing
The use of molecular biology techniques to facilitate precise, efficient and targeted modifications at genomic loci. These techniques include zinc-finger nucleases (ZFNs), transcription activator-like effector nucleases (TALENs) and type II clustered regularly interspaced short palindromic repeat (CRISPR)/CRISPR-associated protein 9 (Cas9).

Harm
Adverse effects to the interest or welfare of an individual, a group, or the public generally. Harm extends to physical harm, discomfort, anxiety, pain and psychological disturbance and includes placing a person at social disadvantage.

Humane end point
The clear, predictable and irreversible criteria that allow the early termination of a procedure before an animal experiences harm that is not authorized or scientifically justified.

Human subject
A living individual or a group of living individuals about whom a Researcher obtains either (1) data through intervention or interaction with the individual, or (2) identifiable private information.

Intervention
Physical procedures through which data are gathered and/or manipulations of the human subject or the human subject's environment that are performed for research purposes.

Justice
The assurance that there is equal sharing of the burdens and benefits of research.

Novel plant breeding techniques
Methods that allow for the development of new plant varieties with desired traits, by modifying the DNA of seed and plant cells. They are called 'new' because these techniques have only been developed in the last decade and have evolved rapidly in recent years.

Personal data/personally identifiable information (PII)
Any information relating to any identified or identifiable natural person. An identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to any identifier such as a name, an identification number, location data, an online identifier, or to one or more factors specific to the physical, psychological, genetic, mental, economic, cultural or social identity of that natural person.

Research
Any original investigation undertaken in order to gain knowledge and understanding. For example, a systematic study, including research for development, testing and evaluation, designed to develop or contribute to generalizable knowledge. "CGIAR Research" is defined

as "research carried out by the Centers and the CGIAR System Partners in support of the CGIAR Strategy and Results Framework".

Research manager
The main Researcher overseeing or conducting the research process.

Risk
An event or circumstance that may affect the achievement of objectives. A risk has a cause and effect.

Sentience
The awareness and cognitive ability necessary to experience feelings.

Traditional knowledge
Knowledge on the conservation and use of agricultural biodiversity that people have developed over time in a given community, based on experience and as a result of local culture and environmental conditions. Traditional knowledge is a dynamic; it evolves as it is transferred through generations.

Vulnerable people
Individuals with limited capacity to protect their own interests. They may have inadequate power, intelligence, education, resources, strength or the required attributes to protect their own interests. Examples include illiterate farmers, unemployed or impoverished people, migrants, refugees, children and young people, the elderly, ethnic minorities and women in a traditional patriarchal society.

3Rs
The three principles that aim to improve the ethics of animal experimental design: replacement, reduction and refinement.

Annex II – International treaties and conventions guiding the CGIAR Research Ethics Code

1. Basel Declaration Society. 2010. *Basel Declaration*. Zurich, Switzerland: Basel Declaration Society. Accessed 1 September 2020. https://www.basel-declaration.org/basel-declaration-en/assets/File/Declaration/Declaration_en_Z%C3%BCrich.pdf

2. [CIOMS/WHO] Council for International Organizations of Medical Sciences in collaboration with the World Health Organization. 1993. *International Guidelines for Biomedical Research Involving Human Subjects.* Geneva, Switzerland: CIOMS/WHO. Accessed 1 September 2020. http://www.codex.uu.se/texts/international.html#background

3. Convention on Biological Diversity Secretariat. n.d. *Convention on Biological Diversity*. Montreal, Canada: Convention on Biological Diversity Secretariat. Accessed 1 September 2020. https://www.cbd.int/ and:

    a. Convention on Biological Diversity Secretariat. n.d. *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization* (2014). Montreal, Canada: Convention on Biological Diversity Secretariat. Accessed 1 September 2020. https://www.cbd.int/abs/

    b. Convention on Biological Diversity Secretariat. 2020. *The Cartagena Protocol on Biosafety to the Convention on Biological Diversity* (2000). Montreal, Canada: Convention on Biological Diversity Secretariat. Accessed 1 September 2020. https://bch.cbd.int/protocol

    c. Convention on Biological Diversity Secretariat. 2019. *Mo' otz Kuxtal Voluntary Guidelines.* Montreal, Canada: Convention on Biological Diversity Secretariat. Accessed 1 September 2020. https://www.cbd.int/doc/publications/8j-cbd-mootz-kuxtal-en.pdf

4. [FAO] Food and Agriculture Organization of the United Nations. 2020. *International Treaty on Plant Genetic Resources for Food and Agriculture* (2001). Rome, Italy: FAO. Accessed 1 September 2020. http://www.fao.org/plant-treaty/en/

5. [FAO] Food and Agriculture Organization of the United Nations. 2003. *International Code of Conduct on the Distribution and Use of Pesticides.* Rome, Italy: FAO. Accessed 1 September 2020. http://www.fao.org/3/y4544e/y4544e00.htm

6. [FAO] Food and Agriculture Organization of the United Nations. 2001. *Guidelines on Good Practice for Ground Application of Pesticides.* Rome, Italy: FAO. Accessed 1 September 2020. http://www.fao.org/3/y2767e/y2767e00.htm

7. [HHS] United States Department of Health and Human Services. 2016. *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (1979). Washington D.C., United States: HSS. Accessed 1 September 2020. https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html

8. [ISE] International Society of Ethnobiology. 2020. *The International Society of Ethnobiology Code of Ethics* (2006). Gainesville, United States: ISE. Accessed 1 September 2020. http://ethnobiology.net/code-of-ethics/

9. [IUCN] International Union for Conservation of Nature and Natural Resources. 2020. *The IUCN Red List of Threatened Species*. Cambridge, United Kingdom: IUCN Global Species Programme Red List Unit. Accessed 1 September 2020. https://www.iucnredlist.org/

10. [NIH] National Institutes of Health, United States Department of Health and Human Services. n.d. *The Code of Nuremberg* (1947). Bethesda, United States: NIH. Accessed 1 September 2020. https://history.nih.gov/display/history/Nuremburg+Code

11. Ramsar Convention Secretariat. 2010. *The Ramsar Convention on Wetlands.* Gland, Switzerland: Ramsar Convention Secretariat. Accessed 1 September 2020. https://www.ramsar.org/sites/default/files/documents/pdf/lib/hbk4-18.pdf

12. Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade Secretariat. 2010. *Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade* (1998). Châtelaine, Switzerland: Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade Secretariat. Accessed 1 September 2020. http://www.pic.int/

13. Stockholm Convention on Persistent Organic Pollutants Secretariat. 2019. *Stockholm Convention on Persistent Organic Pollutants* (2001). Châtelaine, Switzerland: Stockholm Convention on Persistent Organic Pollutants Secretariat. Accessed 1 September 2020. www.pops.int

14. [UN] United Nations. n.d. *The Universal Declaration of Human Rights* (1948). New York, United States: UN. Accessed 1 September 2020. http://www.un.org/en/universal-declaration-human-rights/index.html

15. [UN] United Nations. 2008. *UN Declaration on the Rights of Indigenous Peoples*. New York, United States: UN. Accessed 1 September 2020. https://www.un.org/esa/socdev/unpfii/documents/DRIPS_en.pdf

16. [UNICEF] United Nations Children's Fund. 2013. *UNICEF Ethical Research Involving Children*. Florence, Italy: UNICEF. Accessed 1 September 2020. https://www.unicef-irc.org/publications/706-ethical-research-involving-children.html

17. [WCRI] World Conferences on Research Integrity. 2020. *The Singapore Statement on Research Integrity* (2010). Accessed 1 September 2020. https://wcrif.org/guidance/singapore-statement

18. [WMA] World Medical Association. 2020. *The World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects* (1964). Ferney-Voltaire, France: WMA. Accessed 1 September 2020. https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects

Annex III – Research involving human subjects

Research involving human subjects is defined as research undertaken about or on a living individual or a group of living individuals. It includes:

- gathering data about humans
- using methods such as interviews, focus groups, questionnaires, ethnographies and participant observations
- intervening with human subjects through experiments and manipulation of people or peoples' environments
- observing or recording private behavior, including behavior that individuals have a reasonable expectation would not ordinarily be observed or recorded
- obtaining personally identifiable information (PII) on individuals, such as school records, names and/or domiciles, income, or identifiable information collected by another Researcher or organization
- conducting studies on nutrition or similar topics through interacting or collecting any type of samples or data from human subjects
- influencing change or modification of current habits for the purpose of research.

Prior informed consent [16]

The language and documentation of prior informed consent, particularly the explanation of the research activity, its purpose, its duration, any experimental procedures, the risks, the benefits and any alternatives, must be presented in a manner that is understandable to the population asked to participate. Participants must be provided with the opportunity to ask questions about the research. They need to be assured that their anonymity and confidentiality will be safeguarded, unless they explicitly agree to be identified.

The process of seeking consent must be context-specific, taking into consideration individual or community needs. Among other considerations, Researchers shall consider power structures within communities and households to determine whether informed consent is required from community leaders and/or household heads.

Evidence of a completed prior informed consent process must be obtained in written form or through verbal consent in specific circumstances when written consent cannot be provided. In the case of visually impaired people or persons with limited ability to read and write, verbal consent must be obtained and documented. In such cases, the following must be observed:

i. Researchers must keep a record with sound evidence of the reason for the need to waive written consent. This could include evidence that the participants or their community express a preference for verbal consent versus written consent (such as a letter from a village leader or a community representative).
ii. The waiver will not affect the rights and welfare of the research participants.

[16] Source: The International Maize and Wheat Improvement Center (CIMMYT) Ethics in Research Policy.

iii. Researchers must ensure that more than one Researcher is present who can attest to, and sign to verify, consent. In the absence of this, a witness from the community can attest to, and sign to verify, consent.
iv. Research activities must not present more than minimal risks and involve procedures for which consent would not normally be obtained outside of the research context.

Research managers must ensure that individuals in charge of obtaining consent undergo specialized training on procedures for taking prospective participants through an informed consent process.

Where a proposed participant is a minor aged 13 to 17 years who is possessed of sufficient understanding to grant informed consent but is precluded from granting such consent solely on the grounds of age, Researchers must obtain assent from the minor, in addition to permission from a parent or guardian.

In the case of children aged 12 years or younger, consent from a parent or guardian must be obtained. Although in many instances the consent of the mother is sought, there are settings or situations where the consent of the household head is required prior to securing that of the child's mother, if she is not the household head.

No informed consent can include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the Researchers, the sponsor, the institution or its agents from liability for negligence.

Participant Information Sheet requirements

Human subjects involved in any CGIAR research activity must have a clear understanding of the research purpose, their role, associated risks and other implications before giving their prior informed consent to participate. Such understanding is achieved by conveying in the local language (or when applicable, dialect) the following information with a Participant Information Sheet (PIS):

- the aims of the study and the methods to be used
- the institutional affiliations
- the contact information of the Researcher(s)
- the reason or method of selection of a participant
- the geographical scope of the study
- the type of information that will be discussed and collected
- how the results will be reported and shared
- the treatment to be given to personal data
- the anticipated benefits for participants, their community and society
- the anticipated risks and possible inconvenience for participants
- the time it will take to participate in the study
- foreseen compensation, if any

- the right to abstain from participating in, and to withdraw from the study at any time, without reprisals
- any additional element of informed consent, as may be required by the nature of the project.

Informed Consent Form [17]

While consent forms may differ according to the project, they are required to include at least the following or similar statements:

- I have read and understood the Participant Information Sheet (PIS).
- I have been given the opportunity to ask questions and have had them answered to my satisfaction.
- I agree to take part in this project.
- I understand that my participation is voluntary and that I am free to withdraw at any time without giving a reason.
- A statement that asks the participant to consent to procedures for handling any personal data collected (including, for example, statements on confidentiality and anonymization).
- A statement that asks the participant to consent to proposals for data storage, archiving, sharing and re-use for future research.
- A statement that asks the participant to consent to any planned audio or visual recording, including photos (if relevant).

Image/Video/Audio Release Form [18]

For Researchers to use image, video or audio recordings obtained as part of research activities, they must obtain written consent from persons being recorded. A sample statement is provided below.

By signing this form, I confirm consent to photographs/videos/audio taken which show me

on (date): _____ at (location) _____

I grant (CGIAR entity) _____ and project partners the right to use images on websites or printed material, for non-commercial purposes only.

_____

Name Age (if above 18 years)

[17] Source: The International Rice Research Institute (IRRI) Informed Consent Guidelines.

[18] Source: The International Water Management Institute (IWMI) IRB Guidelines for Audio, Video or Digital Recordings.

_____

Contact information (email, phone, or town/address)

_____

Signature Date

IF SUBJECT IS UNDER 18 YEARS OF AGE:

I confirm that I am the legal guardian of the child named above and therefore may grant permission for this subject release on behalf of the child:

_____

Name of Legal Guardian / Relationship to Child / Date / Signature of Guardian

WITNESS:

_____

Name of Witness / Organization Affiliation / Date / Witness Signature