CIMMYT
International Maize and Wheat Improvement Center

Policy

# Ethics in Research

**Policy number: DDG-POL-04-2019**

**November 2019**

## General Objective:

CIMMYT is committed to the highest standards in research. This Policy sets out standards to ensure compliance with ethical requirements in research when involving Human Subjects. It implies that we (i) obtain informed consent, (ii) treat Human Subjects with dignity and respect; (iii) have procedures in place to protect them from any risk while participating in CIMMYT or CIMMYT-related research, and (iv) involve a competent Research Ethics Committee (REC) to review, approve and supervise activities that include complex or sensitive interaction with Human Subjects, or where national legislation or the funder may require REC involvement.

Separate CIMMYT policies apply to:

- CIMMYT's Reseach Data and Information Products Policy, describing management and dissemination of research data and other information products [link];
- CIMMYT's Code of Conduct, describing principles at the CIMMYT workplace [link].

## Scope:

This Policy applies to all CIMMYT employees, consultants, seconded staff, students, visiting scientists, other visitors and to all CIMMYT Partners that use funds managed or administered by CIMMYT, whether they originate from CGIAR Research Programs, projects, or any other source.

## Policies:

1. In all its research activities, CIMMYT treats Human Subjects with dignity and respect and has procedures in place to (i) obtain prior informed consent, (ii) implement privacy protection principles; and (iii) protect participants from any risk to which they may be exposed while participating in a CIMMYT research or communication activity.

2. CIMMYT Ethical standards seek to include international conventions, local legislation, and best practices. If a discrepancy arises between this Policy and the requirements of any law or funder, the higher standard prevails as applicable during the relevant performance.

3. Infringement of this Policy may lead to disciplinary action.

## Prior informed consent:

4. Potential participants in any CIMMYT research activity must have a clear understanding of its 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) at least, the following information:
   - 4.1. The aims of the study and the methods to be used;
   - 4.2. The institutional affiliations;
   - 4.3. The contact information of the researcher(s) and CIMMYT's Compliance Officer;
   - 4.4. The geographical scope of the study;
   - 4.5. The kind of information that will be discussed and collected;
   - 4.6. How the results will be reported and shared;
   - 4.7. The treatment to be given to personal data;
   - 4.8. The anticipated benefits for participants;
   - 4.9. The anticipated risks for participants;
   - 4.10. The time it will take for participating in the study;
   - 4.11. The right to abstain from participating in, and to withdraw from the study at any time, without reprisals;
   - 4.12. Any additional element of informed consent, as may be required by the nature of the project.

5. CIMMYT follows the standards of the Indigenous and Tribal Peoples Convention and country-specific regulations and approvals when dealing with individuals from indigenous communities and tribes. When dealing with another type of communities, CIMMYT may still evaluate the need to obtain permission from the community elder or persons acknowledged as representatives or guardians, according to the customs of such community.

6. In addition to the youth themselves, parental consent is obtained when a proposed participant is younger than eighteen (18), and sought in cases where the locally-established, lower age of majority is less than eighteen (18).

## Protection from risks

7. CIMMYT takes measures to ensure no harm comes to individuals, families, or communities from CIMMYT research activities.

8. CIMMYT specifically identifies the risk of harm to children and incorporates reasonable risk mitigation measures into the Research Protocols, considering criteria set in the Safeguarding of Children and Adults at Risk Policy [link].

9. Research activities that may have an impact on participants privacy, security, nutrition, health; may damage their income, standing, employability, or reputation, or exposes them to any other foreseeable risk, are to be reviewed by a Research Ethics Committee ("REC") to ensure appropriate remedial actions are taken. The research activity will be rejected if such remedial action is found to be inadequate.

10. CIMMYT will conduct regular audits to verify compliance with prior informed consent and privacy protection standards.

## Privacy protection

11. CIMMYT protects the privacy of individuals and maintains the confidentiality of information which alone or collected together can lead to the identification of a particular person or household ('Personal Information'), such as:
    - 11.1. A name and surname;
    - 11.2. A home address;
    - 11.3. An email address;
    - 11.4. Phone or mobile number; the advertising identifier of a phone;
    - 11.5. An identification card number, social security number or similar ID;
    - 11.6. Location data including the location data function on a mobile phone;
    - 11.7. Geospatial coordinates of personal or household assets, including homesteads and fields owned and/or managed or used by subjects;
    - 11.8. An Internet Protocol (IP) address or a cookie ID;
    - 11.9. Any other identifier that allows identifying a person or a small group of persons; and
    - 11.10. Nationality, religious beliefs, or any other personal identifier, when collected together with any of the above.

12. If private or personal data is being collected, it is not released or made public in any manner. Any reference to personal data in publications or any public disclosure is made after the data is aggregated, anonymized and/or codified (in an encrypted or processed form) so to not reveal the identity of any individual.

13. Personal data and household data ("Personal Information"), including codes that may identify raw data, is treated as Proprietary and Confidential Information, which means (i) it is protected against loss or alteration, (ii) securely stored under lock and key, and in databases or files that are confidential or require restricted access, and (iii) using confidentiality protocols that include the designation of the staff responsible for managing and guarding the raw data ("Trustee of the Information") and the individuals authorized to access the Personal Information.

14. CIMMYT only distributes, transfers or shares Personal Information with third parties when prior informed consent of the owner has been obtained.

## Research Ethics Committees (REC) that oversee Human Subjects Research

15. CIMMYT uses clearance from a REC, to approve and supervise Human Subject Research in the following cases:
    - 15.1. When activities involve complex or sensitive interaction with Human Subjects;
    - 15.2. When clearance is required based on national legislation;
    - 15.3. When clearance is required based on Funder requirements;
    - 15.4. When clearance is required to publish in peer-reviewed journal articles.

16. CIMMYT uses its Internal Research Ethics Committee (IREC), composed of three (3) CIMMYT scientific staff members, one CIMMYT legal staff member and an external member drawn from a pool of experts with different expertise within Human Subject Research, to approve and supervise Human Subject Research in the cases 15.1, 15.3 and 15.4 above. CIMMYT uses an External Research Ethics Committee (EREC) in case 15.2 above, or when (i) a Funder explicitly requires it, or (ii) the subject matter goes beyond the competency of its IREC.

17. Complex or Sensitive Human Subjects Research for which IREC approval must be obtained include:
    17.1. Collection or use of Human Subjects Personal Information (when data is not anonymized);
    17.2. Collection or use of data from Human Subjects that may have an impact in the Human Subject(s)'s privacy, security, nutrition or health;
    17.3. Any collection or use of data that places the Human Subjects at risk of criminal or civil liability or damages their standing, employability, or reputation;
    17.4. Any collection of body tissue, including but not limited to blood samples; or
    17.5. Any research involving minors under the age of 18;
    17.6. Any research involving indigenous communities or tribes.

18. The IREC bases approval and supervision on a Research Protocol that describes procedures in place (i) to protect Human Subjects from any risk or discomfort they may be exposed while participating in a study and (ii) to address any legal requirements to conduct research in a given community, including:
    18.1. How consent is obtained and documented;
    18.2. Specific program design and operation procedures for obtaining parental or guardian consent and involvement when research includes minor participants, including when participation is limited to taking of pictures or videos;
    18.3. Consistency with local communities uses and practices, including the languages or dialects spoken, the social, cultural, religious and spiritual values, and their institutions;
    18.4. Measures to protect the privacy of Humans subjects and prevent undue disclosure of Personal Information; and
    18.5. The complexity or sensitivity of the topics to be addressed in the study and when collecting private data from individuals.

19. CIMMYT's Research Leader is responsible for preparing the Research Protocol and oversees compliance with this Policy while conducting Human Subjects Research led by CIMMYT. When the project is led by a research partner, CIMMYT agrees with the Partner how to handle the necessary clearances for the research.

20. Once clearance is given to a Human Subjects Research Protocol, any substantial changes (for example, asking a different set of questions, conducting research with a diverse population, or changing consent procedures) will require a new clearance. For that purpose, the CIMMYT Research Leader must apply for an amendment of REC clearance, according to the Policies and Procedures.

21. Once clearance is given to a Human Subjects Research Protocol, the associated research is subject to oversight by REC. The level of oversight depends on the sensitivity of the research and follows established best-practices.

22. CIMMYT's Internal Research Ethics Committees reviews and endorses standard protocols that can be used to obtain informed consent, ensure protection from risks and privacy protection for interaction with Human Subjects that are less complex and not sensitive and hence do not require individual REC approval and supervision (see Annex I).

# Policy Interpretation:

Disputes arising under this Policy will be resolved by the Internal Research Ethics Committee, who also documents any disputes. General Counsel may be asked to give advice. If in doubt, the CIMMYT Legal Department can confirm whether research requires REC clearance based on the type of interaction with Human Subjects or local/national law.

# Annex I – Definitions

### Human Subjects Research

Human Subjects Research is defined as research that is undertaken about or on a (living) human or a group of (living) humans, i.e., where humans are the subject of the research, individually or as part of a group.

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 manipulations of subjects or subjects' environments;
- Observing or recording private behavior, including behavior that individuals have a reasonable expectation will not be observed and recorded;
- Obtaining private identifiable information collected about or provided by individuals, such as a school record, 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 research.

### Interaction with Human Subjects that do not require individual REC approval and supervision, unless specifically asked by the funder, local/national law, or by a publisher for peer-reviewed journal articles:

- When using strictly factual information and the objective of the research is not studying the people providing the data/responses.
- Research, where considerations to protect the privacy of individuals are duly addressed as part of the Research Protocol or project planningincluding for activities that consist of:
    - surveying or interviewing humans about something other than themselves or their communities, for example, interviewing farmers about farming practices used;
    - research conducted in established, commonly accepted educational settings involving standard educational or training practices;
    - Training and workshops that are given as part of research dissemination and scaling up practices;
    - Taking of pictures or videos that do not involve minors, indigenous communities or tribes;
    - Testing of agricultural technology when the sole use of such technology does not represent any risk for the people involved.
- Research involving the use of survey or interview procedures regarding public behavior.

- Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement).
- Research involving observations of public behavior.
- Research involving the collection or study of existing data, documents, records, if these sources are publicly available.
- Research involving the collection or study of existing data, documents, records, if the information is recorded by the researcher in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
- Interviews of elected or appointed public officials or candidates for public office.
- Taste and food quality evaluation and consumer acceptance studies, if wholesome foods without additives are consumed.
- Taste and food quality evaluation and consumer acceptance studies if food is consumed that contains a food ingredient or agricultural chemical or environmental contaminant at or below the level and for use found to be safe according to the norms in the country where the study takes place.

## IRB, CUHS, and REC

"IRB" stands for *Institutional Review Board* in US legislation, a generic term for the board inside a research institution that reviews Human Subjects Research. Often the IRB is known as the *Committee on the Use of Human Subjects in Research* ("CUHS") or *Research Ethics Committee* ("REC"), depending on the country or region where the institution or entity operates.

The goal of the IRB/CUHS/REC is to make sure that research protocols prepared by scientists comply with minimum ethical requirements, such as:

(i) obtaining the informed consent from the Human Subjects to conduct any research that requires it, before any further interaction with the Human Subjects takes place;
(ii) Human Subjects are treated with dignity and respect.

When dealing with Human Subjects, there are procedures in place to protect them from any risk to which they may be exposed to because of their participation in the study (embarrassment, discomfort, danger from exposure of their identities, right to privacy, etc.), and to ensure their right to privacy is protected, when applicable. All references in this Policy to the internal review body for Human Subjects Research will be made to "REC."