Democratic Republic of Congo

MINISTRY OF HEALTH

GUIDELINES FOR THE ETHICAL REVIEW OF RESEARCH INVOLVING HUMAN SUBJECTS IN DR CONGO

In collaboration with :

With funding from:

GUIDELINES FOR THE ETHICAL REVIEW OF RESEARCH INVOLVING HUMAN SUBJECTS IN DR CONGO

Contents

Preface

Guidelines for the ethical review of research involving human subjects in the Democratic Republic of Congo were lacking given the amount of studies that are conducted in this country that involve the direct or indirect observation or manipulation of human subjects . 'human.

We had the honor of supervising the validation workshop for this reference instrument jointly drafted by a Technical Committee made up of experts:

– from the Interdisciplinary Center of Bioethics for Francophone Africa of the School of Health Kinshasa Public;

– the African Human Trypanosomiasis Platform;

– the Ministries of Health, of Higher and University Education and of Scientific Research.

It was on this occasion that we were able to grasp the depth of these 37 guidelines which are summarized in five points, namely:

a) General considerations on research ethics
b) Composition and operation of an Ethics Committee,
c) Guidance for informed consent, d)
Guidelines for the processing of biological samples, e)
Guidelines for investigators and sponsors.

These guidelines will enlighten investigators, members of ethics committees, pharmaceutical companies, sponsors and other partners as well as the general public in the protection of human beings who participate in research in the Democratic Republic. of Congo.

The Ministry of Public Health of the Democratic Republic, in collaboration with other state institutions of the country, will offer the support it can so that these lines, which do not replace the laws and regulations of the country on public health research and the protection of human rights, but are complementary to them, are used wisely.

This tool for education, orientation, control and reinforcement of the integrity of research involving human beings should be popularized and applied by all the partners involved in the prevention, care, support and biomedical, behavioral and humanities research.

I salute the active participation of colleagues from other departments who have helped to produce this first version of the guidelines, which is open to constructive criticism which will enable the technical team of writers who put them together to improve them and to amend them in future editions.

For the Ministry of Public Health

Dr Pierre LOKADI OPETHA
General secretary
Secrétaire Général

Acronyms and abbreviations

BPC	**Good Clinical Practices**
THIS	**Ethics committee**
CER	**Research Ethics Committee**
Cf.	**Confer**
THERE	**Independent Committee**
CIOMS	**Council for International Organisation of Medical Services**
CSDT	**Safety Data Monitoring Committee**
CV	**Curriculum Vitae**
DSMB	**Data Safety Management Board**
GCP	**Good Clinical Practice**
I	**International Conference on Harmonisation**
IP	**Principal Investigator**
OMS	**World Health Organization**
PI	**Principal Investigator**
RDC	**Democratic Republic of Congo**

Preamble

Considering that the Democratic Republic of Congo is a signatory to the various international legal instruments relating to international human rights law;

Mindful of the importance attached by the Constitution of the Republic Democratic Republic of Congo of February 18, 2006 to biomedical research involving the human subject in its article 202 – point 36 – letter m;

Considering that in the Charter of the United Nations, the peoples of the United Nations reaffirmed their faith in fundamental human rights, in the dignity and worth of the human person, in the equal rights of men and women, and declared their determination to promote social progress and better standards of life in larger freedom;

Concerned about the legal void in terms of research involving the human subject in our country;

Considering the need to integrate the recommendations of the international community in relation to research involving the human subject in the Congolese internal legal order;

To address this obvious legal vacuum in order to allow good practices in research involving the human subject; And while waiting for the legislator to legislate on the matter;

It is urgent and imperative to develop guidelines that will guide any Researcher, Sponsor, and Principal Investigator to properly conduct and conduct research involving the human subject in the DRC.

1. General considerations on research ethics

Guideline 1: Ethical and scientific rationale for biomedical research involving human subjects

The ethical justification of biomedical research involving human subjects lies in the prospect of discovering new ways to improve the health of each. Such research can only be ethically justifiable; if she is driven in a manner that respects and protects research subjects; and which is fair and morally acceptable in the communities where the research is carried out.

Researchers and sponsors should ensure that proposed studies involving human subjects conform to generally accepted scientific principles and are based on an adequate and demonstrated knowledge of the scientific literature relevant.

The possibility of obtaining information that would be impossible to collect by others means, the scientific validity of the research, and the competence of the researchers and other research personnel must be the essential characteristics of any ethically justified research involving human subjects. Additionally, the methods employed must be appropriate to the research objectives and the discipline.

Researchers and sponsors must also ensure that any person participating to conduct research work is qualified by virtue of his training and his experience to perform their role competently. These considerations should be duly reflected in the research protocol submitted for evaluation and authorization to ethics committees as well as scientific committees or authorities competent national authorities.

Guideline 2: The reference principles

These guidelines are rooted primarily in the Declaration of Helsinki taking into account its successive updates including that of 2008, and secondarily WHO Guidelines for Good Clinical Practices (1995), Tripartite Guidelines for the Harmonization of Good Clinical Practice (ICH) of 2006 as well as other reference documents on the ethics of research.

With respect to the act of "conducting research involving subjects humans", the three ethical principles mentioned here are:

- Respect for people and their autonomy
- Beneficence or non-maleficence
- Justice

Respect for the person involves two ethical considerations fundamentals, namely:

a) Respect for autonomy, which requires that everyone be capable of discernment as to his personal choices is treated with respect for this option self-determination;

b) The protection of persons whose autonomy is restricted or limited, who requires that dependent or vulnerable people be protected against harm or abuse.

Provisions must therefore be made to protect the rights and welfare vulnerable people.

The principle of justice therefore requires us to treat people in a way appropriate and to design the research in such a way that its risks and benefits are shared equitably among research participants
The above three principles should be manifested through procedures and guidelines that the researcher must follow.

Guideline 3: Understand and respect local culture

Researchers have an obligation to understand and respect the culture of local populations, in particular the relationships between individuals, the beliefs religious, philosophical and attachment to the land.

Guideline 4: Procedure for undertaking research

The steps to follow to undertake research involving the human subject are the following :

1 time step: Development of a memorandum of understanding between the sponsor/Principal Investigator and the partner research institutions (various programs, the university, the hospital, the analysis laboratory etc.),

2 th step: Application for authorization and Registration of the study with the Ministry concerned at the same time as the submission of the protocol to the ethics committee for opinion.

3 th step: Transmission of the opinion of the ethics committee by its president to the investigator principal within 15 days following the meeting of the ethics committee with a copy for information to the Minister who decides.

a) In the event of a favorable opinion from the ethics committee, the ministry decides on the granting or no permission to descend on land.

b) In the event of a reasoned unfavorable opinion from the ethics committee, the ministry does not authorize carrying out this study.

c) The promoter may resubmit his protocol to the ethics committee once he has modified the elements which had motivated the unfavorable opinion.

4 th step: The principal investigator or his delegate with the authorization of the Ministry concerned and with the favorable opinion of the ethics committee, contacts the community, in particular through local administrative authorities and leaders opinion on the approved research project. At this stage, the researcher must interact with the community by considering its rights and obligations as well as rights and obligations of research participants.

Guideline 5: Role of an ethics committee

Any research proposal involving human subjects must be submitted for evaluation of its scientific validity and its ethical acceptability to the committee of ethics. This committee must be independent of the research team and approved by the Ministry of Health or Research. The investigator must obtain their approval before starting the search.

An ethics committee can exercise its function at the institutional, local, regional or national. An ethics committee may receive funds directed at the expense of operation, with predetermined tariffs (not exceeding 2% on the costs of research, having excluded the cost of investment), public and which do not allow

create a situation of dependence vis-à-vis the investigators for its
ethical and scientific evaluation activities of the protocols (this payment does not oblige him to give approval or authorization for a protocol if the ethical standards are not not respected).

The ethics committee guarantees the protection of the rights of research subjects, their safety and to some extent their well-being. Scientific evaluation and ethical evaluation cannot be dissociated. Unfounded research scientifically involving human beings as subjects is ipso facto unethical because it may expose them to risk or inconvenience without justification; even in the absence of risk of bodily harm, the time lost by the subjects and researchers to non-productive activities constitutes a loss of valuable resources.

Normally, ethics committees should be able to assess aspects scientific and ethical aspects of the proposed research (in the case of studies with specificities, for example in paediatrics, they will be able to call on experts independent of the research group in this field).
An ethics committee can be set up under the aegis of national health authorities or local authorities, national (or centralized) medical research councils or other representative bodies at national level.

The basic responsibilities of an ethics committee include the following:

- Ensure that all proposed interventions, in particular the administration of drugs and vaccines or the use of medical devices or processes under development, are safe enough to be applied to Human being;
- Ensure that the proposed research is scientifically valid or that another competent expert body has ensured this itself;
- Ensure that all other ethical questions raised by a protocol be satisfactorily resolved in terms of both principle and practice;
- ensure that the information transmitted to the research subjects via the leaflet of information and consent are fair and understandable by the latter

(if necessary, a witness must be used to better explain), that the investigators in the research centers transmit all the information well (especially for vulnerable populations who cannot read).

- Ensure that the patient is properly informed of the potential risks and its right to refuse without prejudice to his care or to interrupt his participation.
- Review the qualifications of researchers, including their knowledge of principles applicable to research practice, as well as the material state of the research site in order to ensure the proper conduct of the trial (via CVs, documents giving the inventory or if necessary during site visits);
- Keep track of decisions and take action to track progress ongoing research projects.

2. Composition and operation of an Ethics Committee

Guideline 6: Composition of an ethics committee

An ethics committee must be composed of doctors, scientists and representatives of other categories such as nurses, lawyers, ethicists and religious, as well as non-professionals able to represent the cultural and moral values of the community and to enforce the rights of subjects. Men and women must sit there.

A certain number of the members of these committees could be renewed periodically in order to reconcile, on the one hand, experience and, on the other, a fresh perspective. To guarantee the independence of a committee vis-à-vis the investigators or promoters and avoid any conflict of interest, any member of the committee having interests special or particular, direct or indirect, in a proposal must exclude itself from evaluation of this proposal.

Like all other operating standards, these terms must be defined in writing in EC procedures.

Guideline 7: Procedures for appointing members of an Ethics Committee

The procedures for appointing the members of an Ethics Committee must include the following points:

- Selection criteria
- Mandate's duration ;
- Reappointment policy;
- Disqualification procedure;
- Resignation procedure;
- Replacement procedure.

Like all other operating standards, these terms must be defined in writing in EC procedures. These procedures will also define the specific roles and tasks of the various functions (president, secretary, etc.).

Guideline 8: Conditions for appointing members of an Ethics Committee

A description of the conditions of appointment must be prepared and must include in particular the following points :

- All members must accept that their full name, profession and affiliation are made public;
- All members must sign a confidentiality agreement regarding the deliberations meetings, files submitted, information concerning participants in research and other related data; in addition, all staff administrator of the EC must sign a similar confidentiality agreement.

Guideline 9: Functions of members of an ethics committee

Works councils must clearly define the functions necessary for the smooth running of ethical evaluation. The different functions within the works council (e.g. president, secretary), the requirements linked to each function, the terms and conditions of access to a function as well as the duties and responsibilities associated with it (e.g. agenda, minutes, notification of decisions) must be the subject of a procedure.

Guideline 10: Quorum Requirements

ECs should establish specific quorum requirements for study a case and make a decision. These requirements should include the points following:

- Minimum number of members required to achieve quorum (e.g. more than half of the members);
- Professional qualifications required (e.g. doctor, lawyer, statistician, staff paramedic, lay) and distribution of these requirements within the quorum; no quorum must not be exclusively composed of members of the same profession or of the same sex; the quorum must include at least one member whose primary area of expertise is non-scientific and at least one member independent of the institution or research site.

Guideline 11: Independent Consultants

ECs may use, or list, independent consultants likely to bring specific expertise to the EC in the review of protocols proposed research. These consultants may be specialists in ethics, law or specialist in a disease or medical field (for example, pediatrics), a particular methodology (for example, in social sciences or public health), or be representatives of communities, patients or interest groups particular. Methods for appointing independent consultants must be established.

Guideline 12: Training of EC members

Works Council members must receive basic training and have access to continuing education on the ethical and scientific aspects of research biomedical. The conditions of appointment must indicate the provisions foreseen to provide EC members with initial training on the work of the EC as well as the possibilities offered in order to strengthen their expertise in carrying out a ethical evaluation. These provisions should also include the requirements or expectations regarding the basic training and continuing education of EC members.

This training can be carried out within the framework of cooperation with other Works Councils, locally, in the country or region but also on other occasions favorable to basic training and continuous training of EC members.

Guideline 13: Submission of a dossier

ECs are responsible for establishing well-defined procedures for submitting a request for review of a biomedical research project. Those procedures, as well as any standard forms established, must be public and available to applicants. It would be desirable that, to facilitate the task researchers, these procedures and forms are harmonized between all CEs active in the country.

13.1 Submission

A request for ethics review of a biomedical research project must be submitted by the principal investigator, who must be a researcher qualified, responsible for the ethical and scientific conduct of research.

13.2 Application Requirements

The procedures for submitting a research project must be clearly described in an evaluation request procedure. These requirements should include the following points :

13.2.1 Name(s) and address(es) of EC secretary or member(s) to whom the application file must be submitted;

13.2.2 Application form(s), made available by the EC, and listing the documentation requested by the CE;

13.2.3 Format of the request, with clear reference to title, date and version protocol;

13.2.4 Documentation, (see below 13.3) study protocol, form information and informed consent, the investigator's brochure, the CV of the principal investigator, the certificate of assurance obtained

13.2.5 Language(s) in which the (essential) documents must be deposited;

13.2.6 Number of copies to deposit;

13.2.7 Application deadlines, depending on examination dates (15 days before the meeting).

13.2.8 Means by which receipt of requests will be acknowledged, including the communication of the incomplete nature of a request;

13.2.9 Time limit for notification of the decision after review (within 15 days);

13.2.10 Deadline to be respected in the event that the Works Council asks the applicant for information additions or changes to the documents;

13.2.11 Fee for reviewing an application, if any;

13.2.12 Standard Procedure for Requesting Protocol Amendments.

13.3 Documentation required

All the documentation required for a complete and thorough evaluation of the ethical aspects of the proposed research must be filed by the applicant.

This includes, but is not limited to, the following points:

13.3.1. Application form dated and signed by the principal investigator;

13.3.2 Proposed research protocol (clearly identified and dated), describing the objectives, data collection procedures, ethical considerations and details of the research process.

13.3.3 Attached documents for information not detailed in the protocol.

13.3.4. When the research involves an investigational product (such as a drug or medical device), an adequate summary of all safety data, pharmacological, pharmaceutical and toxicological available on the product evaluated, together with a summary of the clinical experience acquired to date with this product (e.g. recent investigator brochure, publications, summary of Product Features) ;

13.3.5. Curriculum vitae of the investigator(s) up to date, dated and signed (Appendix);

13.3.6. Means provided (including advertising by classified advertisements) for the recruitment of potential research participants, if not described in the protocol;

13.3.7. Description of the procedure followed to obtain the informed consent of the subjects according to the level of instruction, if not sufficiently described in the protocol

13.3.8. Information note (clearly identified and dated) and other forms of information intended for potential participants, in the language(s) understood by them and, if necessary, in other languages;

13.3.9 Informed consent form (clearly identified and dated) in the language(s) understood by the potential participants and, if necessary, in other languages ;

13.3.10 Statement regarding possible compensation for subjects who lend themselves to the research, for their participation (including reimbursement of costs and access to medical care), if not sufficiently described in the protocol

13.3.11 Description of arrangements made, if any, for compensation in respect of case of harm, if not sufficiently described in the protocol or in the insurance certificate

13.3.12 A copy of the “Policy insurance” taken out by the promoter, for the coverage participants' insurance (if in a language other than French, a French translation must also be provided);

13.3.13 Declaration of the investigator by which he undertakes to respect the principles ethics set out in appropriate guidelines, if not sufficiently described in the protocol;

13.3.14 Any significant previous decisions (e.g. favorable decision or unfavorable or request for modification of the protocol) taken by other CEs or regulatory authorities about the research in question (whether in the same research site or another) and indication of the change(s) made to the protocol in this regard. Reasons for previous decisions unfavorable must be provided.

13.3.15 Any other information (for example, the establishment of a committee of monitoring of tolerance data (CSDT) also called Data Safety and Monitoring Board (DSMB) or Independent Committee (IC), etc.

Guideline 14: Protocol Review

All properly filed applications must be reviewed within 15 days and according to an established standard evaluation procedure.

Guideline 15: Meeting Requirements

ECs must meet regularly, on dates scheduled and announced in advance
in a calendar which must be public. The requirements should include the points
following:

15.1. Meetings should be scheduled according to a pre-established schedule, which may be modified according to the workload;

15.2. EC members must be given sufficient time, defined before the meeting to review submitted documents;

15.3. Meetings must be recorded in minutes; there must be a procedure approval of minutes;

15.4. The applicant, the sponsor and/or the investigator may be asked to present their proposal or to develop certain specific points;

15.5. Independent consultants may be invited to the meeting or to deliver written comments, subject to applicable confidentiality agreements.

15.6. The ethics committee must transmit its opinions within 15 days following the meeting.

Guideline 16: Elements to consider in a research proposal

The main task of an EC is to review research proposals and
supporting documents, paying particular attention to the process of obtaining the
informed consent, documentation, and the appropriateness and feasibility of the
protocol. The EC should take into account previous scientific assessments and
ethics, if any, and the requirements of applicable laws and regulations.
The following points should be considered, as appropriate:

16.1. Scientific design and conduct of research

a) Adequacy of the research design in relation to its objectives at the research previously carried out in the same field, using the method statistics (including the calculation of the sample size) and the possibility of reach valid conclusions;

b) Justification of the foreseeable risks and disadvantages in relation to the benefits expected for research participants and affected communities;

c) Rationale for the use of control groups and the choice of the “control” group;

d) Criteria for early withdrawal of research participants;

e) Criteria for suspension or permanent termination of research;

f) Adequacy of the arrangements made for the monitoring and auditing of research, including creation of a tolerance data monitoring committee (CSDT or DSMB or CI independent committee);

g) Adequacy of the research site, including personnel, facilities, and available premises and sufficient procedures to guarantee the safety of patients;

h) Procedure by which research results will be reported and published.

i). Other specific elements of the subject of the research (impossible to make a complete list)

16.2. Recruitment of research participants

a) Characteristics of the population from which the research participants will be drawn (including including gender, age, education, culture, socio-economic status;

b) Means by which initial contact and inclusion will be conducted;

c) Means by which complete information will be transmitted to participants prospects or their representatives;

d) Criteria for inclusion of participants;

e) Criteria for exclusion of participants;

16.3. Care and protection of research participants

a) Relevance of the qualifications of the investigator(s) and experience of this one (these) for the proposed research;

b) Possible plans for withdrawing or suspending customary treatments for the purposes of research and justification of such action;

c) Medical care to be provided to research participants, during and if necessary after its completion for the pathology object of the study and for pathologies concomitant

d) Adequacy of medical monitoring and psychosocial support for participants in the research as part of the study;

e) Procedure for ensuring medical follow-up and non-discrimination of participants if they exit the study prematurely (for example, for tolerance problems or if they voluntarily withdraw during the research, etc.) ;

f) Practical arrangements, if any, for informing the usual doctor of the participant,

g) Description of any plans to keep the tested product available for participants, or becomes available to the community, after the end of the research ;

h) Allowances for participants (including free hospitalization costs and complementary medicines, reimbursement for travel expenses, food, services and/or gifts, e.g. mosquito nets);

16.4. Protecting the privacy of research participant data

a) Description of the persons who will have access to the personal data of the participants, including medical records and biological samples;

b) Measures taken to ensure the confidentiality and security of information personal information about the participants.

16.5. Informed consent process

(Non-exhaustive list, see details in the Declaration of Helsinki and in the GCPs)

has. Detailed description of the process for obtaining informed consent, including the identification of the persons responsible for obtaining this;

b. Relevance, completeness and clarity of the written and oral information that will be provided to research participants and, where applicable, their representative(s) legal (legal);

vs. Clear rationale for the intention to include subjects in the research that cannot be give their consent, and a detailed description of the arrangements made for obtain consent or permission to participate from such persons;

d. Assurance that research participants will receive information that is not would be known only during the course of the research and relating to their participation, including their rights, safety and well-being;

e. Arrangements made to receive and respond to inquiries and complaints from research participants or their representatives during the course of a research project.

f. Provisions if the patient is illiterate.

g. Provisions if the patient is a minor or under guardianship (child or adolescent)

h. Arrangements if the patient is unable to consent (coma, emergencies, psychosis)

16.6. Community considerations

has. Impact and relevance of the research on the local community and on the communities where the research participants come from;

b. Measures taken to consult the communities concerned during the preparation of the research project ;

vs. Influence of the community or family on the consent of individuals;

d. Proposal, if necessary, of consultation of the community during the course of the research ;

e. Potential contribution of research to improving capacities such as strengthening of local healthcare networks, research, the ability to respond to public health needs

f. Description of financial availability and accessibility, for communities concerned, to any effective experimental product, after the research;

g. Methods by which research results will be made available to research participants and affected communities.

Guideline 17: Expedited Review

The EC should establish procedures for expedited review of proposals for research. These procedures must specify the following points:

has. Nature of requests, amendments and other considerations acceptable to accelerated assessment;

b. Quorum requirements for expedited review;

vs. Status of decisions (e.g. whether or not subject to confirmation by the entire works council).

Guideline 18: Decision making in an ethics committee

When making decisions about submissions for ethical review of
biomedical research, an EC must take into account the following points:

has. Any member must exclude himself from a meeting whose purpose is decision-making
concerning a file for which there is a conflict of interest; this conflict must be
indicated to the president before the examination of the file and recorded in the minutes
Of the reunion ;

b. A decision can only be taken when sufficient time has elapsed (see the procedures
of the EC) has been granted for the examination and discussion of a file, this in
the absence of non-members (e.g. the investigator, sponsor representatives,
independent consultants) of the meeting, with the exception of EC staff;

vs. Decisions can only be taken at meetings where a quorum
is achieved (as stipulated in the EC's written operating procedures);

d. The documents required for a full review of the application must be
complete and the necessary items listed above (see 6.2) shall be
considered before making a decision;

e. Only members who participated in the examination of the file should participate in the
decision ;

f. There must be a previously defined method for arriving at a decision (e.g.
: by consensus, by vote) it is advisable to reach the decision by consensus,
if possible; when a consensus seems unlikely, it is advisable to proceed
to a vote;

g. In conditional decision cases, clear suggestions for review
will be made and the procedure for reconsidering the application will be specified;

h. Any unfavorable decision must be motivated by arguments clearly
statements.

Guideline 19: Communication of the decision

a) A decision must be communicated in writing to the applicant according to the procedures
of the EC, within the period established in these procedures. This period should not exceed
two weeks from the date of the meeting at which the decision

will have been taken. The decision must be notified in writing, and include in particular the following items:

b) Exact title of the research proposal under review;

c) Clear identification of the proposed research protocol or amendment, date and version number;

d) Names and specific identification numbers (version number/date) of documents reviewed, including the information note and informed consent the potential research participant;

e) Name and quality of the applicant;

f) Designation of the research site(s);

g) Place and date of the decision;

h) Designation of the EC making the decision;

i) Clear description of the decision taken;

j) Any recommendations given by the EC;

k) In the event of a conditional decision, description of the requirements set by the EC, with suggestions for review and procedures for reconsidering the application (letter of commitment from the applicant or resubmissions of the complete amended file);

In the event of a favorable decision, if necessary an annexed document can be attached with the following elements :

l) Statement of applicant's responsibilities, for example, confirmation of acceptance of the requirements imposed by the EC, submission of progress reports research and their periodicity, need to notify the Works Council in the event of amendment of the protocol (other than amendments relating only to the aspects administrative or logistical aspects of the research), need to notify the EC in the event of amendments relating to the conditions of recruitment, the information of potential participants or the informed consent form, need to report serious and unexpected adverse events related to the conduct of the research, need to report unforeseen circumstances, closure/suspension of research or significant decisions taken by other ECs, the information that the EC expects to receive in order to proceed with the current review, final summary or final report;

m) In the event of an unfavorable decision, the clearly stated reason(s) for the decision

n) List of EC members present during the deliberation with a certificate of attendance (signature)

o) Signature (dated) of the chairman of the EC (or other authorized person).

Guideline 20. Monitoring research progress

The EC must establish a procedure for monitoring the progress of all research having been the subject of a favorable decision, since the date the decision was made until the end of the search. The current means of communication between the EC and the applicant must be clearly specified in public EC procedures. The follow-up procedure must take into account the following elements:

1. The requirements relating to the quorum, the examination procedure and the communication for follow-up checks, which may vary from the initial decision requirements and procedures;
2. Follow-up monitoring intervals, which should be determined based on the nature of studies and events, although each protocol must be subject to a follow-up check at least once a year during the recruitment period;
3. The following examples or events require a follow-up check of a research: a. any amendment to the protocol that may affect the rights, safety and/or well-being of participants, or the conduct of research;

has. Serious or unexpected adverse events related to the conduct of research or the product tested; and the actions taken by the investigators, the sponsor and the regulatory bodies;

b. Any event or new information likely to modify the report benefit/risk of research;

4. A follow-up control decision must be communicated to the applicant. She must indicate any modification, suspension or termination of the EC's initial decision, or confirm that this decision remains valid;
5. In the event of suspension/premature termination of a search, the applicant must indicate to the Works Council the reasons for the suspension/termination; a summary of the results obtained so far there will then be communicated to the CE;

6. ECs must be notified by the applicant at the time of closing
a study;
7. ECs should receive a copy of the final abstract or final research report.

Guideline 21: Documentation and archiving

All EC documentation and correspondence must be dated and archived according to written procedures. It is necessary to draw up a document defining access to and consultation procedure for the various documents, files and archives (with names of authorized persons).
It is advisable to archive these documents for a minimum period of 5 years after the end of the search.
The documents to be filed and archived include:

1. Composition, written EC standard operating procedures and reports regular (annual);
2. Curriculum vitae of all EC members;
3. All CE income and expenditure, including allowances and reimbursements granted to the secretariat and to the members of the EC;
4. Procedures established by the EC, for the submission of a file;
5. Agenda of EC meetings;
6. Minutes of EC meetings;
7. Copy of all documents filed by an applicant;
8. Correspondence of EC members with claimants or parties concerned by the request, the decision and the follow-up;
9. Copy of the decision and any advice or complaint sent to an applicant;
10. All written documentation received during follow-up;
11. Notification of Normal Termination, Suspension or Early Termination of a research ;
12. Final summary or report of the research.

Guideline 22: Sanctions

An ethics committee is not generally empowered to impose sanctions on against researchers who violate ethical standards in the conduct of research involving human beings. He can, however:

- withdraw its ethical clearance from a research project if it deems it necessary.
- monitor the implementation of an approved protocol and its progress through reports received and if possible monitoring in the field.
- report to the administrative or state authorities any serious violation or repeated to ethical standards
- Ask the competent authorities to suspend the authorization to receive a funding for research, to perform experimental interventions, or license to practice medicine.
- Solicit scientific journals that have published the results of a study of retract any article that is later found to be based on falsified data or fabricated from scratch, or which is based on research contrary to ethics
- Inform the Department of Pharmacy, Medicines and Medicinal Plants

Guideline 23: Ethics review of research sponsored by an outside body

The external sponsoring organization and the individual investigators must as much as possible to submit the research protocol to an ethical and scientific evaluation in the country of the sponsoring organization, and the applicable ethical standards should not not be less stringent than those that would apply to research in the country of the organization in question. The health authorities of the host country as well as a committee local or national ethics committee must ensure that the proposed research corresponds to the health needs and priorities of the country in which the research is carried out and complies current ethical standards. The same procedures apply to any research, regardless of whether the promoter and/or the donor are national or foreigners.

3. Guidance for informed consent (including community consent) (24 to 32)

Guideline 24: Individual informed consent

For all biomedical research involving human beings, the investigator must obtain the free and informed consent of the prospective subject or, if the latter is not in able to give it, the authorization of a representative duly mandated for this purpose in accordance with applicable law. The waiver of informed consent must be considered unusual and exceptional and must, in any case, be approved by an ethics committee.

Informed consent is the decision to participate in research made by a capable individual who has received the necessary information, who has understood it well and who, after having considered it, arrived at a decision without having been under pressure, direct influence or indirect or undue incitement, or intimidation.

Informed consent is based on the principle that capable individuals have the right to freely choose whether or not to participate in research. informed consent protects individual freedom of choice and respects individual autonomy. Some individuals have a limited capacity to give informed consent. It is vulnerable populations. Research on these populations must be justified in details (see above);In particular, they may be young children, adults with serious mental or behavioral disorders, people with a decreased level of consciousness and, as well as vulnerable people for socio-economic reasons. Directly obtaining the consent of these persons vulnerable may sometimes be impossible and every effort should be made to obtain the consent of the legal guardian of these patients.

Obtaining informed consent is a process that begins when a contact initial is established with a prospective subject and which continues throughout the study. In informing the prospective subjects by repetition and explanation, responding to their questions when they are asked and making sure everyone understands each procedure, the investigators, or the qualified person delegated by the investigators, seek informed consent from subjects and, in doing so, demonstrate respect for

their dignity and autonomy. Each individual should be given sufficient time to reach a decision, including consulting with family members or other people. Informed consent procedures must be given enough time and resources.

Informing each subject should not be done by simple ritual recitation of the content of a written document. On the contrary, the investigator must convey the information, orally and in writing, in a language that corresponds to the level of understanding of the person concerned. The investigator should bear in mind that the ability of the prospective subject to understanding the information required to express informed consent depends on the maturity, ability to understand, level of education and system of beliefs of the person concerned. It also depends on the ability and willingness of the investigator to communicate with patience and sensitivity.

The investigator must then ensure that the prospective subject has understood information. The investigator should give everyone the opportunity to ask questions and he must answer them honestly, promptly and completely. In some cases, the investigator may administer an oral or written test or proceed in any other way to determine whether the information has been understood.

Consent can be expressed in various ways. The subject can show his consent implied by voluntary acts, expressing consent orally or sign a consent form. As a general rule, the subject must sign a consent form or, if incapacitated, the legal or other guardian duly authorized representative must do so in his place (if the patient is illiterate, the consent will be signed by an independent witness etc.). The ethics committee can authorize, in ***extraordinary cases,*** the dispensation of a consent form signed, for example when the existence of a signed consent form would pose an undue threat to the privacy of the subject. In in any case, it is advisable to give the subjects information sheets to keep; such sheets can be similar in all respects to consent forms but the subjects will not be required to sign them. The drafting must be approved by the ethics committee. Where consent has been obtained orally,

investigators are required to provide documentation or proof of consent.

When material changes occur in the terms or procedures of a study, or periodically for long-term studies, the investigator must again seek the informed consent of the subjects. By example, new pieces of information may have come to light, from the study or other sources (other studies, pharmacovigilance, etc.), about the risks or benefits of products under investigation or about products intended to replace them. This information should be promptly communicated to the subjects if they modify the risk incurred. On the contrary, the results of the trial will be disclosed at the end after analysis of the data.

In some cultures, the investigator cannot access a community to conduct research or contact potential subjects there to obtain the individual consent only after having obtained the authorization of a person in charge of the community, council of elders or other designated authority. Those customs must be respected. Under no circumstances, however, the authorization of a responsible for a community or any other authority cannot replace the individual informed consent. In some populations, the use of various local languages can make it difficult to communicate information to potential subjects and prevent the investigator from verifying that this information has been understood. In all cultures there are many who are unfamiliar with the scientific concepts such as those of placebo or randomization or which do not not easily understand. Sponsors and investigators should make available development of culturally appropriate methods for conveying information necessary and meet the required standard of obtaining informed consent. In In addition, they must describe and justify in the research protocol the procedure they intend to use to communicate the information to the subjects.

Consent forms for the research protocol should include a separate section for clinical trial subjects invited to give their consent to the use of biological samples for research purposes. A

separate consent may be desirable in some cases (for example, if the investigators seek permission to conduct basic research that do not constitute a necessary part of the clinical trial, ancillary study or complementary) but not in other cases (for example, the clinical trial requires the use of biological samples from subjects). If biological samples are kept after the end of the research, their use will only be possible within the framework of a study not initially planned only if the subject has given his consent to it. He it may be necessary to trace the subjects to have them sign a consent specific to this new study.

Patients, by signing the informed consent, have the right to know that their file or their samples may be used for research purposes. The refusal of patients to participate or their reluctance do not constitute difficulties sufficient practice to warrant waiving the informed consent requirement. The archives and biological samples of individuals who expressly refused these uses in the past can only be used in the event of health emergencies public with CE approval

Sometimes investigators want to use the records or samples biological material that another investigator has used or collected in another institution in the same or another country. This raises the question of whether such records or samples contain personal identifiers, or may be attached to these identifiers, and by whom (see also Guideline 18: *Preserve confidentiality).* If informed consent or authorization was required for permit the initial collection or use of such records or samples biologicals for research purposes, secondary uses are generally limited by the terms set out in the original consent. Also it is necessary that the original consent process includes, to the extent possible, a plan for future use for research purposes of records or samples. Thereby, in the original process of seeking informed consent, a member of the research team should interview the prospective subjects and, when appropriate, ask them for their agreement on the following points:

(i) Whether there will or may be secondary use and, if so, whether this
secondary use will be limited as to the type of study that can be performed on
such materials;
ii) The conditions under which the investigators will be required to contact the subjects
to obtain additional authorization for secondary use;
iii) The arrangements made by the investigators, if necessary, to destroy the
records or samples or erase personal identifiers therefrom;
iv) The rights of subjects to request the destruction or anonymization of samples
biological or files or certain elements of the files that they can
consider to be particularly sensitive such as photographs or
video or audio recordings.

Guideline 25: Essential information for obtaining informed consent from prospective subjects

Before seeking a person's consent to participate in research,
the investigator must, using a language or any other form of communication
intelligible, tell him the following:

- That she is invited to participate in the research as a subject, the reasons for
  which it meets the required conditions and that participation is voluntary;
- That she is free to refuse to participate and may at any time terminate her
  participation without being penalized or losing any advantage
  to which she would normally have been entitled;
- What is the object of the research and what are the procedures to be employed by
  investigator and subject, and how research differs from medical care
  usual;
- For controlled trials, what are the research methods
  (randomization, double-blind, for example) and that the subject will only be informed of the
  assigned treatment only when the study has been completed and the procedure
  double blind will have ended;
- The expected duration of participation (including the number and duration of visits to the
  research center and the resulting total duration) and the possibility of a stop
  anticipation of the trial or of the subject's participation in this trial;

- If money or other types of material gratification will be given in consideration for the subject's participation and, if so, their nature and amount;
- That, after the completion of the study, the subjects will be informed of the conclusions of research in general terms and that they will be individually informed of any conclusions relating to their personal state of health;
- That the subjects will be able to access, on request, the data concerning them even if these data have no immediate clinical utility 9) All risks, any foreseeable pain or discomfort or inconvenience to the subject (or other persons) arising from participation in research, including the risks for the health or well-being of the subject's spouse or partner;
- If applicable, the direct benefits that subjects can expect from their participating in research;
- The expected benefits of the research to the community or society, or the contributions of this research to scientific knowledge;
- If, when and how any products or interventions whose research has demonstrated to be safe and effective will most likely be released disposal of the subjects after the latter have ceased to participate in the research.
- Any currently available alternative intervention or treatment;
- The measures that will be taken to ensure respect for the privacy of subjects and the confidentiality of records where subjects are identified;
- Limits, legal or otherwise, on the ability of investigators to preserve the confidentiality, and the potential consequences of breaches of confidentiality;
- Applicable rules regarding the use of test results genetics and family genetic information, and the precautions taken to prevent disclosure of a subject's genetic test results to family relatives or third parties (insurance companies or employers, for example) without the consent of the subject;
- The sponsors of the research, the institution to which the investigators belong and the nature and sources of research funding;

- The possible uses, direct or secondary, of the subject's medical file and of their biological samples taken as part of clinical care.
- If it is anticipated that biological samples collected in research will be destroyed when the search is complete, and if not, a description details of how they will be preserved (where, how, for how long time, and how it will be disposed of) and anticipated future uses, and whether the subjects have the right to decide on these future uses, to refuse the preservation, and to require the destruction of the material in question
- Whether commercial products can be derived from biological samples, and whether the participant will receive pecuniary or other advantages as a result of the development no such products;
- If the investigator's sole function is to be an investigator or if he is both subject's investigator and attending physician;
- The extent of the investigator's liability in terms of benefits to be dispensed to the participant;
- That treatment will be provided free of charge for certain specified types of research-related bodily injury or for complications related to the research, the nature and duration of this treatment, the name of the organization or the individual who will provide the treatment, and if there are any uncertainties about the financing of said treatment;
- How and by what organization the subject or the family, or the persons at the charge of the subject, will be compensated for any disability or death resulting from such bodily injury (or, where applicable, that nothing is provided for this);
- If, in the country where the prospective subject is invited to participate in the research, the right to compensation is guaranteed by law, and in any case what measures are taken In this study
- That an ethics committee has approved or authorized the research protocol (Name and date).

This list is not exhaustive and it is recommended to follow the latest edition of Helsinki and the GCPs of WHO and ICH

Guideline 26: Obtaining informed consent: Obligations of sponsors and investigators

Sponsors and investigators have a duty:

- To refrain from unwarranted deception, attempt to exert undue influence (direct or indirect) or intimidation;
- To seek consent only after ensuring that the prospective subject has fully understood the ins and outs of participation and that it was allowed to think about it;
- As a general rule, to obtain from each prospective subject a declaration signed document attesting to informed consent – investigators must obtain the approval of the ethics committee in the event of an exception
- To re-obtain informed consent from each subject in the event of material change in research terms or procedures, or if any new pieces of information appear which are likely to have an impact on the will of the subjects to continue to participate;
- To request renewal of consent at predetermined intervals informed of each subject in long-term studies even if there is no modification of the research design or objectives.

Guideline 27: Consent of minor children and adolescents

Obtaining the consent of minor children who participate in research poses a double ethical problem: the ability to obtain meaningful consent and the abuse of consent by a person responsible for the child. Here comes the use of assent, a concept that designates the fact that a child agrees to participate in a research when it is legally, psychologically and culturally impossible to give consent

The consent of the child to participate in the research should be obtained when he/she has reached a suitable age and that the complexity of the research project envisaged on allow. But since the epithet "suitable" renders such an effort imprecise, this line guideline recommends that children be included in the decision to participate in research, according to their capacity for physical, psychological and social development.

Since the more a search is complex and amenable to consequences, the more the child must understand and have subtle reasoning to give assent enlightened, this capacity of the child is established globally at the minimum age of 13 years but the research team will have to consider other aspects to raise this age but never go below.

In principle, a minor does not give consent. Their parent or guardian does in its place. But as soon as he has reached the minimum age of 13, he too must give his consent. From that moment, the sole acceptance of the parents, even by a free and informed consent, is no longer sufficient to enroll a child in a study, not more than just the consent of the child. It is therefore necessary the agreement of the parent first and then of the child.

In the same order of reasoning, the refusal of one of the parties of this binomial constitutes dissent (an expression of a desire not to participate in research) and blocks the child's participation in research.

Guideline 28: Collective consent

A researcher who proposes research relating to traditional knowledge or sacred rights of an indigenous community, or with its members as persons indigenous peoples, should consult with community leaders and obtain their consent before approaching individual members. After getting the consent of the community, the researcher must still ensure that he has the prior free and informed consent of each participant. The consent collective differs from and is additional to individual consent.

The word "free" means without coercion, intimidation or manipulation. Word “prior” means that consent has been requested long enough before any authorization or start of activities and that he respects the deadlines inherent in Indigenous consultation/consensus processes.

The word "informed" means that information is provided on the aspects following:

- full disclosure of the risks and benefits of participating in the research, to individuals and to the community;
- the nature, scale, pace, reversibility and scope of any project and/or activity propose;

- the reason(s) or purpose of the project and/or activity;
- the duration of the project and/or activity;
- the places or territory that will be affected;
- a preliminary assessment of the economic, social, cultural and
  likely environmental factors, including potential risks and fair and equitable sharing of benefits
  in a context that respects the precautionary principle5 ; –
- the terms governing the collection, use, retention and disclosure of
  personal information.
- personnel expected to be involved in the execution of the project (including Aboriginal people,
  private sector personnel, personnel of research institutions,
  government employees, etc.);
- the procedures that the project may entail; and
- the sources of financing and support for the project, as well as the obligations towards
  ces sources.

It is advisable to establish early enough before the start or authorization of the research

a mechanism for the free, prior and informed consent of communities and
individual participants, which should take into account the decision-making processes
legitimate interests of the communities with respect to all stages of planning,
implementation, monitoring, evaluation and closure of the research project. We
now recognizes that consent is an ongoing process and must be
reaffirmed periodically, according to the needs of the research project.

Guideline 29.: Confidentiality and protection of privacy

The researcher, individual participants and the community should, prior to the start
of the research, clearly agree on their expectations regarding the anonymity of the
community and participants and the confidentiality of the data and results of the
research.

In other words, as early as possible in the process, the researcher should discuss with
the community and the proposed participants of the measures that will be taken to
protect the anonymity of subjects and the confidentiality of their medical records, as well as
only to ensure compliance with applicable laws. Although research should be
approved by the community, the personal information of the participants does not
will not be publicly accessible, only anonymously.

Guideline 30: Inclusion and protection of cultural knowledge in research

In the context of research ethics, local communities and other traditional knowledge holders have the right to decide what constitutes their knowledge and culture, their own innovations and practices, as well as the ways to define them. Values such as respect, wisdom, love, honesty, humility, confidence and bravery are common among local communities, but they do not have the same meaning or the same relevance in all communities, or even within one of them.

Any research relating to local communities presupposes the exchange of certain cultural knowledge, practices and/or traditions, even if these are not the objects of study, as they provide the necessary context. However, when knowledge is transmitted outside of its original context, there is a risk of misunderstanding and misuse.

Protection of local cultural knowledge means its transmission in a way respectful of the sanctity of certain knowledge - that is, of their link with the recognized spiritual entity, the Earth and the Ancestors. The interpretation of knowledge should be adapted to the particularities of the context and the community. It is therefore recommended that researchers ensure that the information culture considered confidential by the community is obtained from a person recognized in the community as the repository of knowledge and empowered to share it. Given the importance of traditional and sacred knowledge in cultures indigenous peoples, it is advisable to note in a research agreement the details relating to access to this knowledge and its protection.

Guideline 31: Benefit sharing

The research should benefit both the community and the researcher. The sharing of benefits must offset the investment in research. The benefits can take various forms, depending on the type of research. They can be immediate or longer term, tangible or intangible, financial or non-financial (such as general right of access of the community to the final results of the study).

Thus, a study on diabetes could provide scientific circles with a deeper understanding of the causes and effects of disease, but in benefit-sharing perspective, it could also help the local community to know the foods or eating habits that contribute to an incidence high diabetes in her home. Even if there are no direct economic advantages here, the community derives significant social and health benefits.

Guideline 32: Language and communication

The researcher should provide a simplified and layman's summary of the results of the research in the language of the community.
Translation and cultural mediation may require the help of a specialist in language within the community.
The researcher should make sure to communicate in a continuous, accessible and understandable with the community.

The researcher should communicate in a way that is clearly understood by the community and expand opportunities for knowledge transfer from the project. Technical language should be kept to a minimum and be defined or explained to need.

4. Processing of biological samples

Guideline 33: Ownership, storage and transfer of data and biological samples

If one of the original parties to a research agreement wishes to transfer data and biological samples to a third party, it must obtain the consent of the other original party or parties.

Any secondary use of data or biological samples requires the specific consent of the individual or, if appropriate, of the community that is the source. However, if the research data source or biological samples from the source is undeterminable, the Consent for the secondary use is not required on his part but a CE approval

Similarly, if it is not possible to identify the community from which the data originated research or biological samples, consent for their use secondary is not required, but CE approval is required.

When he knows that data or biological samples come from subjects indigenous peoples, the researcher should consult the indigenous organizations concerned before proceeding with secondary (retrospective) use. The secondary use must be submitted for review by the REB.

The transfer of data or biological samples to a third party requires the consent of the researcher, the participant concerned and the community (If at abroad, it is often necessary to give the authorities the “Materials Transfer Agreement”. Yes the third party intends to make a secondary use of the data or samples biologics, she must obtain additional consent for this purpose. This consent should determine how privacy and protection of life privacy will be protected. If it is not provided for in the research agreement, secondary use of data or biological samples requires a new consent.

Guideline 34: Biological samples on loan

Biological samples should be considered as a "loan" made to the researcher, unless otherwise provided in the research agreement. This article is inspired by Bantu philosophies of "bodily wholeness", according to which any product and part of the human body is an essential and sacred constituent of nobody. Thus, the researcher should see himself as the custodian of the samples, rather than the owner.

5. Investigators and Sponsors

Guideline 35: The Principal Investigator

The principal investigator (PI) is a scientist, based in the Democratic Republic of Congo, which is solely or jointly responsible for designing, conducting, delegate responsibilities for research activities, particularly clinical ones, their analysis and reporting. The principal investigator reports to the Sponsor and to the regulatory authorities and ECs, as recommended by the guidelines. The IP should be

a person qualified and experienced in the field of research and having a understanding of research concepts and activities, the drug, its toxicity and its safety. In the case of a multicenter trial, there will be a "coordinating investigator", who coordinates the principal investigators attached to each site. It is unacceptable to have an absentee IP who is based elsewhere.

The well-being and integrity of the participants are the responsibility of the investigator major. He must scrupulously follow the guidelines set out in the Declaration of Helsinki, WHO and ICH guidelines for good clinical practice and guidelines guidelines for biomedical research involving human subjects (CIOMS 1993).

In most cases, clinical trials are conducted by a principal investigator (usually, but not always, a doctor with appropriate qualifications to conduct a study) who has made commitments with a sponsor to conduct a clinical study or trial.

The BPCs also provide for the possibility of Investigator-Sponsor, where the investigator is also promoter of research.

If the sponsor and principal investigator are different, they should work closely collaboration whether in the design, conduct and writing of the report.

In the case of non-commercial research, the promoter and the donor are often two different entities (see BPC).

In the context of the Democratic Republic of Congo, if the promoter comes from externally, he will work closely with the local principal investigator(s) (to), from the partner institution(s) with which the promoter external signs a memorandum of understanding. Each local principal investigator will work on his turn in collaboration with one or more local investigators at the level of his site.

35.1 Profile and qualifications

The investigator should be a qualified person with experience in the specific area of study. A recent Curriculum Vitae (CV) must be submitted to this end. He must also demonstrate his knowledge of the regulatory requirements and Good Research Practices, in particular Good Clinical Practices

(PCBs). As for young researchers, proof of support from one or several experienced researchers is required.

34.2 Availability

Before the start of the trial or study in general, the principal investigator must:

- Be based in the Democratic Republic of Congo, with some exceptions;
- Ensure that the approval of a recognized ethics committee and that of the ministry are obtained. Have read and accepted the information package developed by the sponsor, with respect to clinical trials.
- Have a good knowledge of the protocol, the related documents and the regulatory requirements of the regulatory authority or other body regulatory;
- Have read, understood and agreed to work in accordance with the protocol, the Declaration of Helsinki, WHO and ICH guidelines on good clinical practices or other applicable legal and regulatory documents;
- Use the product under study or comparison only for the purpose of the study as as described in the protocol;
- Take responsibility for the products under study to report to whom by right;
- Document the sequence of events to be followed in conducting the trial clinic, including timeline, roles and responsibilities;
- Ensure the availability of all the necessary infrastructure, of all equipment and all finances for the conduct of the trial or study;
- Develop any appropriate mechanism to ethically obtain from the participant informed consent;
- Accept the involvement of the monitors to review and verify the procedures of quality control and verification of driving data;
- Accept the possibility of an audit and/or inspection by an auditor independent contractor engaged by the sponsor, regulator or ethics committee;
- Obtain the right to publish; it is unethical for the sponsor to reserve the right to publish research data;

- Ensure adequate security reporting procedures, etc. (see ICH and WHO GCP).

Guideline 36: Publication of results

- Information collected during the study should be shared with the Aboriginal community, in the research community Researchers must consider community feedback and allow voices dissidents to speak in public if the differences of opinion have not been resolved before.
- • For reasons of availability to the wider scientific public, any study that has gone through this evaluation process must be registered in one of the public databases when published in compliance with DoH 2008.
- Community leaders should receive an appropriate report specifically for their understanding, with relevant information. The results should be shared with participants via any means appropriate depending on the context and budgetary constraints (e.g. meetings, newsletters, mailings, public forums, etc.)

Guideline 37: Intellectual property and commercialization

- The sponsor and the researchers should clearly disclose the possible commercial applications of the results of their research and their intention to market them, including any “access” program project to facilitate the availability to local and poor populations.
- The sponsor and researchers should work with their institution and the Indigenous community to fully understand and communicate the commercial potential of their research results (if any) and agree on the intellectual property rights, the limits to the exploitation marketing, distribution of marketing profits and any reasonably foreseeable negative consequence.

Glossary

Regulatory authority

It is any body of power in a country, which has the proven official competence to register, control and grant rights to manage, implement, test and use medicines or other devices in the context of research or biomedical interventions.

Charity

By ***beneficence,*** we mean the ethical obligation to bring the greatest possible good and to reduce as much as possible all that can cause harm.
From this principle are derived standards requiring that the risks inherent in research be reasonable in relation to the expected benefits, that the design of the research be judicious and that the investigators be qualified and competent both to carry out the research work and to preserve the subject well-being. The principle of beneficence also prohibits deliberately inflicting harm on others; this last aspect of the principle of beneficence is sometimes expressed as a separate principle, called ***non-maleficence.***

The principle of beneficence is based on recommendations of the type: do good to your patient, to your research participant; one should do everything to prevent harm or pain, do everything to remove the evil, promote good and all that is good to the patient or to the research participant, considering that the good must outweigh the evil in all circumstances. The counterpart of the principle of beneficence is that of non-maleficence, which is based on recommendations of the type: do no harm, do no pain, avoid inflicting what causes harm to the patient or research participant.

Research Ethics Committee

Independent organization (institutional, regional, national, foreign (from the country of origin of the sponsor or supranational), approved by a competent authority, composed of professionals from the medical circles and members of other circles, whose responsibility consists in ensuring the protection the rights, harmlessness and well-being of human subjects participating in a study and to publicly guarantee this protection, on the one hand, by examining the protocol of the study, the competence of the investigators, the installations as well as the methods and documents to be used to obtain the informed consent of the subjects after having informed them adequately and, on the other hand, by formulating an approval/favorable opinion in this regard.

The legal status, composition, operation, activities and regulatory requirements related to independent ethics committees may differ from one country to another, but they must allow these committees to carry out their activities in accordance with Good Practices Clinics described in international guides and this document. It is a group of people who do the ethical review of research protocols involving human subjects by applying ethical principles

recognised.

Sponsor/ promoter (sponsor)	Person, company, institute or organization responsible for initiating, managing and/or financing a clinical trial, and who has legal responsibility for it. In non-commercial research, it often happens that the sponsor and the funding body are different entities: in this case, the legal responsibility lies with the sponsor. Natural or legal person who takes the initiative for biomedical research on human beings, who manages it and who checks that its funding is provided. GCPs allow that the sponsor and the investigator can be the same person (“sponsor-investigator”).
Community	In the general sense, a community designates a social group made up of people sharing the same characteristics, the same way of life, the same culture, the same language, the same interests. They interact with each other and also have a common feeling of belonging to this group. In the context of these guidelines, we understand by community a social group of people within which research will be carried out and whose members lend themselves to this research.
Informed consent	Process by which a subject voluntarily confirms their willingness to participate in a study involving the human subject, after being informed of all aspects of the study that may influence their decision. Informed consent is recorded on a written, signed and dated form.
Clinical test	Any investigation carried out on human subjects with a view to discovering or verifying the clinical and pharmacological effects of an investigational product or other pharmacodynamic effects related to this product, to identify any adverse reaction to an investigational product, to study how a research product is absorbed, distributed, metabolized and excreted in order to assess its safety or efficacy. The terms “clinical trial” and “clinical study” are synonymous.
Trial multicentric	Clinical trial carried out according to a single protocol and identical methods, carried out in different sites (in the same country or in several countries) and therefore by more than one principal investigator.
Adverse event	Any adverse event experienced by a person during a clinical trial, whether or not considered related to the study drug(s).
Serious adverse event	A serious adverse event is an adverse event whose outcome may be fatal, or which poses a risk to the life of the person, which is likely to cause permanent disability or which results in the hospitalization of the patient or the prolongation of his hospitalization. . In addition, any birth defect or malignancy is considered a serious adverse event.
Unexpected adverse event	An unexpected adverse event is an event whose type, severity or incidence is not mentioned in the investigator's brochure, in the general file of the trial or elsewhere.

Investigator The person who methodically and systematically studies different hypotheses to help generate new knowledge.

Principal/ local investigator He is a person with adequate experience, and who, working in collaboration with the sponsor or the coordinating investigator who appointed him, is, within the framework of biomedical research on human beings, based on the site where the research takes place and is in charge of its daily implementation. It is also any principal investigator of a given site within the framework of a multicenter study.

Justice Justice ***means*** the ethical obligation to treat everyone according to what is morally fair and appropriate, to give everyone their due. In the ethics of research involving human subjects, this principle refers essentially to the notion of ***distributive justice,*** which presupposes the equitable distribution of both the constraints and the benefits of participation in research. Disparities in the distribution of burdens and benefits are only justifiable if they are based on distinctions between morally relevant persons. One such disparity is vulnerability.

Opinion leaders and human subjects Opinion leaders are women and men who have some influence in decision-making within a population. They can be politico-administrative authorities, health authorities, education authorities, religious authorities, youth representatives, village or group chiefs, etc.

The populations in which research involving human subjects is carried out must have a real chance of benefiting from the results obtained.

Subjects suitable for medical research must be volunteers informed of the terms of their participation in the research project.

The subject's right to the protection of his integrity must always be respected. All precautions must be taken to respect the privacy of the subject, the confidentiality of the data concerning him and to limit the repercussions of the study on his physical and psychological balance.

The person agreeing to the research must be informed in an appropriate manner of the objectives, methods, financing, possible conflicts of interest, membership of the investigator in one or more institutions, expected benefits as well as the potential risks of the study and the constraints that could result for it.

The subject must be informed of the right he has not to participate in the study and that he is free to revoke his consent at any time without fear of prejudice.

Particular attention will be paid to subjects belonging to categories of vulnerable people, including children and adolescents, women and pregnant women, prisoners, the socio-economically disadvantaged, etc.

Funding organization	It is any entity, in particular pharmaceutical laboratories, industries, cooperation organisations, non-profit entities, scientific societies or others, which makes financial means available for biomedical research on human beings with a view to its launch, management and/or financing. In any case, the legal responsibility for the research rests with the promoter.
local partner	It is any person or institution (including national or provincial disease control programs, research institutions, scientific or university departments, faculties or institutions) that collaborates with one or more foreign institutions in the realization of a biomedical research on human beings.
Memorandum of Understanding	Written document, dated and signed between two or more parties establishing all the provisions concerning the delegation and distribution of tasks and obligations and, if applicable, the financial arrangements. The study protocol can serve as the basis for this agreement.
Research protocol and documents annexes	Document drawn up by the researcher(s) which should contain a summary of the project, general information, a brief justification of the project, bibliographical references and a documentary review. It should also describe the aims and objectives of the study, its design and the methodology employed; and address safety or tolerability considerations, monitoring, data management and statistical analysis, quality assurance, expected results and dissemination, and publication policy; indications should also be given on the duration of the project and the problems anticipated, on the management of the project and the ethical considerations, on the documents used to obtain the informed consent of the subjects, on the budget and the funding bodies and on the collaborators . Finally, the protocol should append the curriculum vitae of each researcher and list all the projects in which he is currently involved and the percentage of time he will devote to the project; any financing or insurance arrangements should also be specified in the documents presented to the Works Council in the appendix.
Adverse drug reaction	When, following the evaluation, a probable relationship between taking the drug and the adverse event is established, this adverse event is considered an adverse reaction.
Research involving human subjects	Any biomedical, behavioral, epidemiological or social science study involving the systematic collection or analysis of data to generalize the results
Vulnerability	"Vulnerability" means the marked inability to protect one's own interests due to obstacles such as the inability to give informed consent, the lack of other means of obtaining expensive medical care or other necessary services, or subordination or submission within a hierarchical structure.

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