

# Ethics charter for research *in developing countries*

WRITTEN 2002, REVISED 2008 AND 2017

“While the primary purpose of medical research is to generate new knowledge, this goal can never take precedence over the rights and interests of individual research subjects”

(DECLARATION OF HELSINKI, 2013)

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## PREAMBLE

World health is a collective responsibility and its improvement strongly relies on research. The ANRS<sup>1</sup> (France REcherche Nord & sud Sida-hiv Hépatites), the French agency for research on AIDS and viral hepatitis, has thus set research with developing countries as one of its key priorities.

Respect for ethics is a prerequisite for the conduct of research. Since the 2000s, and in collaboration with its partners in the South, the ANRS has worked on setting out the principles and commitments that must prevail in any research on human subjects that is supported by the agency, and to specify the conditions under which the agency finances and coordinates this research.

A first version of this Charter was published in 2002 in a context of strong mobilization for HIV/AIDS research in the South. It was revised in 2008 in order to include research on viral hepatitis as part of the new missions of the ANRS .

### **PARTNER COUNTRIES**

*countries located in the South and with which the ANRS develops research programmes*

The current version of the Charter takes into account the evolutions in the research landscape on HIV and viral hepatitis, as well as the amendments to major international documents and changes in the legislative contexts in France and in **PARTNER COUNTRIES**<sup>2</sup>. The Charter applies to clinical research, as well as to public health and human and social sciences research.

The Charter formulates universal principles, but also takes into consideration the specificities of the settings where the research is conducted, in terms of cultural and political contexts, resource limitations and heterogeneity in patient care and management conditions. When health care services are not optimal, the boundary between care and research can be particularly tenuous and fluctuating for people.

The ANRS, as a research organization, cannot substitute for health systems. However, the agency works in close partnership with the national authorities of the countries in which the research is carried out, in particular as regards access to treatment, skills transfer and staff training. Collaboration with the civil society and **ORGANISATIONS REPRESENTING AFFECTED OR INFECTED PEOPLE** is pivotal in the research process.

### **ORGANISATIONS REPRESENTING AFFECTED OR INFECTED PEOPLE**

*Associations representing people living with and/or affected by HIV and/or viral hepatitis.*

<sup>1</sup> Website: <http://www.anrs.fr/>

<sup>2</sup> The terms in bold are explained in the text (within boxes) and/or defined in the glossary (Appendix 3)

The ANRS thus has the dual goal of supporting development and of contributing to universal knowledge through the projects it supports. ANRS policy is thus to preferentially, although not exclusively, conduct research in a limited number of so-called “ANRS sites”<sup>3</sup>.

After multiple exchanges with researchers, organisations representing affected or infected people, members of Ethics Committees and institutional partners, from the North and the South, the Charter was designed from the outset as a didactic document, contributing to building partnerships with the South, especially within ANRS sites. The Charter should invite to constant questioning. It should remain open, flexible, and basis for discussion, susceptible to change, as evidenced by this second revision.

The ANRS therefore expects all actors of the research projects supported by the agency to engage in dialogue by promoting the principles of this Charter.

## I. GENERAL PRINCIPLES

### 1.1. Consistency with existing texts

Any research supported by the ANRS falls within the framework of the ethical principles already issued by the international community. It also complies with existing national legislation.

Moreover, the ANRS takes into account a number of specific texts when they are deemed relevant, such as those issued by UNAIDS<sup>4</sup>, the WHO or the French National AIDS and Viral Hepatitis Council (CNS).

#### \* International texts<sup>5</sup>

The key reference texts are the Helsinki Declaration, the Council for International Organizations of Medical Sciences (CIOMS) Guidelines, the UNESCO Universal Declaration on Bioethics and Human Rights, the Oviedo Convention and its Additional Protocol, Good Clinical Practices ICH<sup>6</sup>, and the Convention on Biodiversity and its Nagoya protocol<sup>7</sup>.

<sup>3</sup> Cf. Appendix 2. The ANRS sites are located in Senegal, Burkina Faso, Côte d'Ivoire, Cameroon, Cambodia and Vietnam, Egypt, Brazil.

<sup>4</sup> Ex: WHO, UNAIDS, 2012. Ethical considerations in biomedical HIV prevention trials - Additional guidance

<sup>5</sup> These documents are available at [www.anrs.fr](http://www.anrs.fr).

<sup>6</sup> International Conference of Harmonization.

<sup>7</sup> The Convention on Biological Diversity, the Nagoya protocol on access to genetic resources (or Traditional Knowledge) and the fair and equitable sharing of benefits arising from their use under the Convention on Biological Diversity, 2010

### \* National texts

In addition to the legislation of the partner countries where it exists, the ANRS refers to French law: Law No. 2012-300 of 05 March 2012 (Loi Jardé) amended by Ordinance n°2016-800 of 16 June 2016 relative to human subjects research, the law on importing and exporting organs (article R1235-8) and tissues, cells and products (Article R1245-20 of the Public Health Code), as well as the data protection law of January 6, 1978 modified by the January 22, 2017 law.

## 1.2. A priority: improving the health of populations

- \* Research supported by the ANRS aims at fighting disease and promoting population **HEALTH** as defined by WHO. The ANRS supports for this purpose research projects in all disciplines, from basic research, clinical and therapeutic research, prevention research, social sciences research to public health research.
- \* This research takes into account the public health objectives and research priorities of the countries. But the ANRS is also proactive, especially when it comes to innovative or fundamental research.
- \* By all means at its disposal, the ANRS encourages its institutional and professional partners to promote access to the treatments or interventions that are being investigated. In particular, the agency is committed to promote the dissemination of research results at national and international level.
- \* The ANRS relies on the community and organisations representing affected or infected people, and consults them every step of the way.

**“HEALTH IS A STATE OF COMPLETE PHYSICAL, MENTAL AND SOCIAL WELL-BEING AND NOT MERELY THE ABSENCE OF DISEASE OR INFIRMITY”<sup>8</sup>.**

## 1.3. Partnership and consultation

- \* Research in partnership is a continuous process. ANRS support for research in developing countries therefore extends beyond project financing. It aims to enhance capacity and to ensure maximum impact of research on society.
- \* To achieve this goal, the ANRS is committed to long-term partnerships and guarantees the sustainability of its scientific, political, financial and logistical support. The agency promotes the creation of North-South and South-South exchange networks and integrates training within the overall research process in order to improve the knowledge and expertise of all actors.

<sup>8</sup> Preamble to the World Health Organisation constitution, as, adopted by the International Health Conference held in New York from 19 June to 22 July 1946.

- \* ANRS sites form the most effective setting for implementing these principles. The ANRS contributes to the development of research infrastructure, the strengthening of scientific evaluation and ethical skills, and the writing of joint publications based on shared data.
- \* Responsibility sharing and consultation contributes to strengthening the competence and level of information among partners, thereby encouraging respect for and promotion of ethical principles. This is why research supported by the ANRS implies the involvement of all actors in the research process, from its conception to its dissemination – researchers from the North and South, partner institutions, **COMMUNITY**, non-governmental organizations. Support for research is thereby defined in terms of shared objectives and commitments.

## II. ETHICAL CONSIDERATIONS PRIOR TO RESEARCH INITIATION AND DEVELOPMENT

- \* Before initiating an ANRS research project, all actors must be aware of the ethical considerations developed in the present Charter and these must be explained in the protocol (cf. Appendix 1).
- \* The principles of **AUTONOMY** of the person, **BENEFICENCE** and non-maleficence as well as **JUSTICE** guide all actors of an ANRS research project, at all stages, regardless of the discipline concerned.

### **AUTONOMY**

*autonomy refers to the ability to think, decide and act freely and on one's own initiative. It implies having received clear information that is understood.*

### **BENEFICENCE**

*beneficence refers to the promotion of what is "most beneficial" to the person. It is based on finding the best compromise between the researcher's judgment and what the person desires.*

### **JUSTICE**

*stipulates that all people in similar situations receive equal care.*

## 2.1. Prior enrolling a subject in a research project

- \* Clear scientific and ethical rules, previously known to all, must be applied during the enrolment process.
- \* Fairness, scientific rigor, transparency and no conflict of interest are required in the application of the eligibility, inclusion and non-inclusion criteria within the research project.
- \* Respect for human dignity, rights and security requires taking into account the impact research may have on people's lives within the community. Vigilance must be exercised regarding potential adverse effects of the research and this can justify specific support measures such as the involvement of a resource person or another mechanism chosen in consultation with the subject and/or the local associations representing the people living with and/or affected by HIV and/or viral hepatitis.
- \* Within interventional research:
  - All care options are discussed with the person prior to enrolment in the project, to ensure that her/his decision is as informed as possible to allow the exercise of autonomy;
  - For people enrolled in the research project, the care and management procedures throughout the research period and beyond are always specified in the protocol and the information sheet;
  - For people who ultimately are not enrolled in the research project, every effort is made to direct them towards the best local medical and psychosocial support system;
  - If necessary, the family members and guardian of the research participant are also guided and supported, while preserving confidentiality.
- \* The ANRS is committed to ensuring that at the end of the research project, the treatments and interventions that have proved effective are made available to those who were involved in the research; this means, among others, obtaining written commitment from the local health authorities before the start of the research.

### Vulnerable people

- \* Any person willing to participate in a research project will be assessed, prior to enrolment, for their potential vulnerability, so as to evaluate his/her level of autonomy.
- \* In fact, many situations related to the societal or legislative environment or to the health status of people make them temporarily or permanently vulnerable, which limits their ability to make choices and thus exercise their autonomy.

### KEY POPULATIONS

*WHO defines "key populations" as population groups with higher HIV prevalence rates than those of the general population. These include, for example, but not exclusively, men who have sex with men, transgender people, injecting drug users, sex workers and their clients.*

This is particularly the case for certain population groups, called "**KEY POPULATIONS**" because of their high level of exposure to HIV and/or viral hepatitis; they are however the most likely to benefit from research.

- \* Strengthened protection in terms of confidentiality and support during the research will be implemented if necessary.
- \* Vulnerable people should only be approached for research if it cannot be conducted among other people.

## 2.2. During the research project

- \* Within interventional research, the ANRS supports the care of participants throughout the research period, according to the best local standards, and whether or not people remain in the project. This support is focused on HIV and/or viral hepatitis-related care (according to the research protocol); treatments must be prescribed or validated by the study physician.
- \* When people infected with HIV and/or viral hepatitis are invited to participate in non-interventional research projects, they should be informed of the medical care options available locally.
- \* In the case of research conducted among people who are not infected with HIV and/or with one of the hepatitis viruses, the ANRS is committed to ensuring that locally-available counselling services and prevention tools are proposed to all participants, and that they are informed about all the protection means approved by their country and by WHO. The ANRS undertakes not to carry out any preventive research without first guaranteeing that access to care for people who, despite the above measures, contract HIV and/or a hepatitis virus during the research project, is secured.
- \* Any new information deemed important for the conduct of the research is transmitted to the participants, whether directly or indirectly related to them.

## 2.3. At the end of the research project

- \* The ANRS is committed to ensuring that each of the research studies it supports reaches its completion, by providing the human and material resources necessary for its conduct and accompanying researchers throughout the research process.
- \* If the treatments or interventions that have demonstrated their effectiveness through research are not available at the end of the project, or if their availability is delayed, treatments or interventions of equivalent efficacy must be provided. This

warrants a prior discussion between the investigators and the **SPONSOR**, with the health authorities and patient associations.

\* Participants shall be informed, as much as possible prior publication, and in any case without undue delay, of the positive or negative results of the research, individually or collectively, as defined in consultation with the local organisations representing affected or infected people.

### III. COMMITMENTS TO RESEARCH PARTICIPANTS

\* Diagnosis and care must subject to the rules of medical deontology. This means preliminary information, individual consent seeking and adequate support before any investigation is conducted and/or any result is provided to the research participant.

\* The organisations representing affected or infected people are key partners throughout the research consent process. They are invited to act as **MEDIATORS** or recourse for people. **COMMUNITY ADVISORY BOARDS** may be established.

#### 3.1. Information

\* Information sharing aims for transparency and to facilitate understanding. It is a continuous process up until the results of the research are communicated. Adequate space should be made available to allow unrestricted dialogue between the researcher and the potential participant.

\* Free and informed consent results from information that is adapted, clear, accessible and understood. This requires, in addition to written information, oral communication, allowing sufficient time to discuss with the person and taking into account her/his culture to make sure that the information is properly understood. In some cases, translation into local languages, the use of educational tools, the involvement of a third party or collective information sessions are necessary.

\* The implications of participating in the research project, both the benefits and risks, must be considered and discussed with the subject.

### 3.2. Informed consent

- \* No derogation from informed consent is allowed. Obtaining a person's consent is a necessary condition of her/his participation in research. Consent can only be obtained after sufficient time was given for reflection.
- \* Obtaining consent is evidence that the researcher and sponsor have sought and obtained a person's agreement to participate in a research project. It is the result of negotiation; it is not a contract but a reciprocal commitment between the researcher, the sponsor and the participant, in which everyone recognizes his or her role, rights, duties and responsibilities.
- \* Only the researcher and the sponsor share obligations, but by agreeing to participate in a research project, the person agrees to the terms and conditions of this research. The reciprocity of commitments allows participant's autonomy.
- \* A person should always be made aware of the fact that she/he is free not to participate in the research project.
- \* The project investigator should regularly make sure that the person enrolled is willing to remain in the research project and understands its ins and outs. A participant may withdraw from the research project at any time, and must be made aware of the fact that project withdrawal does not affect the care provided, unless wished otherwise by the participant.
- \* If the terms and conditions of the research project change, consent must be renewed.
- \* Written proof of consent is common practice. However, consent can be sought otherwise, using another method as defined and validated by the research partners and the ethics committee(s), using in particular new information technologies (audio, video or telephone recording, for example).
- \* In the case of people who are unconscious, incapacitated or unable to give their consent, the person entitled to authorize their participation in the research project is identified following national legal rules, in addition to the main international principles.

#### Child and adolescent research

- \* In research involving children and adolescents<sup>9</sup>, who are not empowered to give consent, the legally authorized representative (as per national rules) needs to give permission for research participation. Every effort should be made to obtain the consent of the two parents or guardians, following the regulations of the country where the research is being carried out.

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<sup>9</sup> Minors, according to the law of each country

- \* Researchers must also ensure that a child and/or an adolescent able to understand the implications of her/his participation in the project, give his assent, to the extent of her/his capacities, as per conditions described above (§3.2, 7<sup>th</sup> paragraph). Not all children and adolescents have the same maturity, thus a case-by-case process is recommended.
- \* The child or adolescent must be informed of a diagnosis in the presence of, or through, the parents or legal representatives, to whom the information was communicated in a clear and accessible manner. Parents or legal representatives may, themselves, be supported, in particular by mediators, during the process of receiving and understanding the consequences of the diagnosis.

## IV. PERSONAL DATA AND BIOLOGICAL MATERIAL

- \* Personal data and biological material are valuable resources for research. They are also considered as heritage and part of the public good, essential to future research, and this implies ensuring their storage, protection and management in a sustainable way.
- \* Respect for communities implies identifying and taking into account not only the biological aspects of the collection of material, but also the sociological and cultural context (representations, symbols, perceptions of the body, etc.).

### 4.1. Collection and storage

- \* The quality criteria defined in the international Good Clinical Practice (GCP) and Good Laboratory Practice (GLP) documents are applied.
- \* The collection and storage of personal data and biological material must be carried out in consultation with the health authorities of the partner countries.
- \* Data or material transfer agreements (MTA) must be negotiated and signed in order to define the conditions of ownership, retention, use and commercialization, as per the applicable laws of the countries where the research is carried out.
- \* Researchers and the sponsor share personal information and biological material to the maximum extent possible, in order to enhance research. In order to facilitate this sharing, data should be stored within repositories (Open Data) rather than destroyed after the end of the project. This data will only be accessed with the express consent of the participants.

\* The collection and storage of personal data and biological material may involve different models of consent that take into account local characteristics and the willingness of participants, as well as the constraints of research<sup>10</sup>. Use of genetic resources is always subject to specific consent.

## 4.2. Confidentiality

- \* All research actors are required to comply with the rules of confidentiality regarding all paper documents, computerized records and biological material.
- \* When the people conducting the research are not subject to a confidentiality obligation or professional secrecy, they sign a commitment of confidentiality.
- \* Researchers ensure that the personal data and biological material collected are anonymised, coded and stored using all appropriate measures necessary to protect the confidentiality of sensitive information. They must ensure that the publications resulting from these data do not contain any name or other information, which involves a risk of direct or indirect identification.
- \* The participant must be informed of the limits of confidentiality (unblinding for certain research needs, data piracy...).
- \* The participant must be informed of the purpose of the **DATABASE** or **BIOBANK**, its **RIGHTS OF ACCESS AND WITHDRAWAL**, the conditions and duration of storage, use and re-use of the data or material concerned.

## V. SPONSOR RESPONSIBILITIES

- \* The ANRS assumes the role and responsibility of a **SPONSOR** in the research it supports, as per the definition in French law, *Loi Jardé* (see Appendix 3). In particular, the ANRS:
  - validates the protocols and any substantial amendments before they are submitted to ethical committees.
  - takes out an insurance to cover the possible harm suffered by the people participating in an interventional research during the duration of the intervention. The harm caused by the experimentation can de facto justify a right to compensation and, in some cases, medical follow-up beyond the end of the trial.
  - within therapeutic research, ensures the availability of the experimental drugs throughout the duration of the research.

### SPONSOR

*Natural person or legal entity, which takes on the responsibility for the research, and specifically for arranging the management and financing for the research.*

<sup>10</sup> Refer to articles 11 and 12 of the 2016 CIOMS revised version, International Ethical Guidelines for Health-related Research Involving Humans.

- records serious adverse events and ensures that appropriate procedures, including those defined by national legislation, are implemented.
- \* The ANRS liaises with the project investigators and the coordinators of the ANRS sites to ensure that the medical and paramedical staff involved in the research are informed of the precautions required in case of accidental exposure to viral risk and that they benefit from prophylactic treatment if necessary.
- \* The ANRS provides all research actors (researchers, NGO representatives, etc.) with the means to train in Ethics and Good Practices. It ensures that this training has been effectively carried out.

## APPENDIX 1 – Measures taken to ensure respect for ethical rules

### Preparation and submission of projects to the ANRS

Any research project shall be jointly designed by research teams from the partner country(ies) in the South and one or more teams in France (and other countries in the North according to the research). Thus, all studies are submitted to the ANRS Call for Projects jointly by a North Scientific investigator and a South Scientific investigator.

Projects are submitted for advisory opinion to associations representing the people living with and/or affected by HIV and/or viral hepatitis, as much as possible prior submission to the ANRS Call for Proposals and in any case before the start of the research. They review and discuss in particular the information tools. They ensure that the principles of this Charter are respected.

### Research protocol and ethical reflection

Any research protocol submitted to the expertise of the ANRS needs to present and argue, if necessary within a specific chapter, the ethical reflection that accompanied the development of the project, and so by integrating the principles outlined in this Charter. The key components to include in the protocol are:

#### Protection of the person

- Evaluation of the benefit/risk ratio of project participation for the subject.
- Description of the means used to ensure confidentiality (regarding serological status, personal data, etc.) and to prevent the possible discriminatory consequences of the research.
- Identification of a referring Doctor or medical centre if needed.

#### Management and care

- Within interventional research, description of the alternatives to research participation,
- Description of the screening and pre/post-test counselling modalities.
- Description of the medical care modalities during the research period (by the project, by the health system, etc.).
- Definition of post-research support conditions.
- Modalities for communicating the research results and access to the research benefits for the participant.

### Expected Outcomes

- Description of the potential public health impact of the research for the community.

### Good practices

- Description of the following:
  - establishment of a scientific committee for interventional research and an independent committee for therapeutic trials,
  - consultation with qualified representatives of the community or with the organisations representing affected or infected people during the preparation, set-up and implementation of the research project,
  - submission to national ethics committees and health authorities in agreement with the national regulations of the countries where the research is carried out.
- Declaration of potential conflicts of interest.

### Documentation

- The information sheet and the consent form, if required for the research, are provided at the same time as the application is submitted to the Call for Projects.
- The researchers must commit in writing to respect the Ethical Charter.

### Evaluation of projects by an ANRS Independent Scientific Committee

Each research protocol is reviewed at the ANRS by an independent Scientific Committee, which includes experts from different disciplines and representatives of the organisations representing affected or infected people from countries of the North and the South.

The independent Scientific Committee reviews the project, the information sheet and the consent form if they exist, and provides a considered opinion. It reviews the scientific quality of the project, its relevance to international research, its relevance in the context of the country or countries where it is to be implemented, the methodological tools used, the feasibility, the benefit/risk ratio, and the individual and collective impacts of the research. It also reviews compliance with good practice and the ethical principles as set out in this Charter.

The decision to fund a research project is taken by the Director of the ANRS, on the basis of the propositions made by the independent Scientific Committee.

### Evaluation of projects by the ethical committees and regulatory procedures

After final approval by the ANRS, the projects are submitted to the National Ethics Committee of the country or countries where the research is carried out.

For interventional research or when required by the Ethics Committee of the country or countries concerned, the protocol can also be submitted for an advisory opinion to a French ethics committee.

Projects are submitted to the competent health authority of the country or countries concerned as required by national regulations.

The research is implemented only after approval from these bodies and completion of the required French regulatory procedures (insurance, declaration to the French Commission Nationale Informatique et Libertés – CNIL, authorizations to import samples, data, etc ...).

A progress report, presenting in particular the safety data for clinical trials, is provided to the Ethics Committee and the competent health authority of the country or countries concerned, as per their request.

Any substantial amendment to the protocol during the implementation of the research is submitted to the same bodies under the same conditions and is implemented only with the agreement of ANRS.

### Scientific Committee and Independent Monitoring Committee<sup>11</sup>

A Scientific Committee is set up for any interventional research and on a case-by-case basis for other research according to the rules defined by the ANRS in its procedures.

Within therapeutic trials, an Independent Committee is established. It ensures compliance with good practices and ethical rules, analyses any effects detrimental to the interests of the persons concerned, evaluates intermediate data, and recommends whether or not to pursue the research. The mission of this advisory body is to alert the Scientific Committee and the sponsor of any change in the benefit/risk ratio of the research project.

### Financing method

Grants are paid directly to the relevant research organizations in the North and the South.

An "emergency relief fund" may be established within the project. Its set up should be discussed with the ANRS prior the start of the research and its conditions of use be defined. It can help to address particular distress situations before continuing with the person's follow-up in the research.

<sup>11</sup> <http://www.anrs.fr>

## APPENDIX 2 – ANRS sites

An ANRS site is established on the basis of a prior collaboration between research teams from the North and the South and is not created de novo.

The official creation of an ANRS site formalizes this collaboration within a broader institutional and political partnership. An agreement signed by the ANRS and the Ministry(ies) (Health, Research and Finance as appropriate) of the partner country defines the research field, the framework and the functioning rules of the site.

Sites are managed by 2 coordinators appointed by each partner after mutual agreement (a North coordinator and a South coordinator).

They are the cornerstone of the site, have a privileged relationship with the ANRS and are in charge of:

- the scientific orientations of the site, through the joint construction of the research agenda;

- the coordination between projects, in particular between the different disciplines;
- the development strategy of the site in terms of training, logistical support, development of south/south, north/south partnerships etc...;
- the interactions with the National Authorities

The coordinators of all sites meet periodically, within the Coordinated Action (CA) n°12 of the ANRS, whose role is to facilitate research in the South and develop strategic reflection fed back to the Director of ANRS.

The ANRS sites are the product of operational partnerships between research organisations in different disciplines, clinical centres (hospitals, health facilities at various levels...), laboratories, project management and data management services etc...

In addition to financing research projects, the ANRS provides sites with financial support for

equipment, construction of buildings and assistance to teams (missions, meetings, training courses, staff, etc.)

Inter-sites operational and scientific partnerships are developed, in particular for the design of multi-site research projects.

## APPENDIX 3 – Glossary

**BIOBANK:** biobanks are structures that ensure, at a minimum, the collection and storage of biological samples with associated data. By extension, they can also make their resources available to the scientific community. Biobanks can manage samples of human, animal or plant origin, each of which has specificities, for example regarding the management of participant consent or the application of the Nagoya protocol.

**BIOLOGICAL MATERIAL OR BIOLOGICAL SAMPLES:** material from the human body can be obtained from people for the purposes of a research project. It may come from patients who have undergone diagnostic or therapeutic interventions, from autopsies, organ or tissue donations from living or dead persons, from excreta (including urine, sweat and saliva) or from abandoned tissues. Once the biological samples have been collected, they can be stored in biobanks and used as research resources for many years.

**COMMUNITY:** refers to a group of people sharing a common identity, history, language, culture, and socio-economic status.

**COMMUNITY ADVISORY BOARD (CAB):** the CAB is an institutional means of ensuring that the design and implementation of the research project respect the social values of the research. The CAB negotiates the research conditions, such as access of local communities to research drugs, to ensure benefit sharing and local capacity building. The CAB may be composed of representatives of associations of people living with HIV/AIDS, family members, village members, doctors, anthropologists, etc.

**DATABASE:** A database is a tool used for storing and retrieving all raw (unprocessed) data or information related to a theme or activity.

**KEY POPULATIONS:** WHO defines “key populations” as population groups with higher HIV prevalence rates than those of the general population. Members of key populations include men who have sex with men, transgender people, injecting drug users, sex workers, and their sexual partners. Other groups may qualify as key populations, depending on the context, such as people in closed settings (such as prisons or detention centres), people with

disabilities, HIV-negative partners within serodiscordant couples, migrant and mobile workers. “Key populations” also refers to the fact that their mobilization and involvement in building risk reduction programs is pivotal to the success of the response to the epidemic.

**MEDIATOR:** the mediator supports the participant throughout the research process, from enrolment to the feedback of the research results. The mediator can be a medical staff, a member of an association, or a community member, such as a peer-caregiver. The mediator functions as an appeal body for the person enrolled in the research.

**ORGANISATIONS REPRESENTING AFFECTED OR INFECTED PEOPLE:** numerous associations of people living with and/or affected by HIV and/or viral hepatitis have been established in the North and in the South. They are distinct from the community (cf. definition).

**PARTNER COUNTRIES:** refers to countries in the South where ANRS research is carried out, in particular the countries where ANRS sites are located.

**PERSONAL DATA:** European Directive 95/46/CE on the protection of individuals with regard to the processing of personal data and to the free movement of such data defines personal data as any information relating to a natural person, who is or can be identified, directly or indirectly, by reference to an identification number or to one or more factors specific to them. Personal health data are generally considered sensitive data requiring specific protection.

**PRINCIPLE OF BENEFICENCE:** beneficence refers to the promotion of what is most beneficial to the person. The definition of what is “most beneficial” is based both on the researcher’s judgment and on what the person wants, by finding the best compromise between the two opinions. Beneficence means taking into account the patient’s suffering, quality of life, and overall risks beyond those specific to the research project.

**PRINCIPLE OF JUSTICE:** justice stipulates that all people in similar situations receive equal care. This involves assessing the impact that resources allocated to a certain group of people

may have on other people, including the family circle (who may have the same needs): what burden for them?

**RESPECT FOR AUTONOMY:** autonomy refers to the ability to think, decide and act freely and on one's own initiative. It implies having received clear information that is understood. Respect for autonomy consists in supporting a decision made by a person, even if it does not look good from a medical point of view for example.

**RIGHT OF ACCESS AND WITHDRAWAL OF PERSONAL DATA:** as defined in the french data protection

law, the right of access to personal data is the possibility for a person to contact the person in charge of a data file, enquire whether it contains information concerning her or him and request that it be entirely communicated to her or him. Exercising the right of access to data enables to check the accuracy of the data and, if necessary, to have it rectified or deleted.

**SPONSOR:** natural person or legal entity, which takes on the responsibility for the research, and specifically for arranging the management and financing for the research.

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