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People's Democratic Republic of Algeria

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Ministry of Higher Education and Scientific Research

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Directorate General for Scientific Research and Development Technological

الوكالة الموضوعاتية للبحث في علوم الصحة
Agence Thématique de Recherche en Sciences de la Santé

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Thematic Agency for Research in Health Sciences

CODE OF ETHICS

RESEARCH IN HEALTH SCIENCES

Edited by:
The Thematic Agency for Research in Health Sciences

- 2018 -

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SUMMARY

I. FOREWORD ON THE DESIGN OF THE CHARTER OF ETHICS OF THE THEMATIC AGENCY FOR RESEARCH IN HEALTH SCIENCES

-ATRSS-

The idea is certainly not new, but its maturation required time and reflection. Attempts have been made before, but they have failed as a result. events that have occurred or postures displayed from the start of its preparation. The opportunity has never been so perfect as at the end of 2017 when the General Management of the Thematic Agency for Research in Health Sciences (ATRSS) has decided to force the hand of fate and finally create its own **Charter Ethics;** she had just achieved the feat to which a good number of personalities national scientists have tried before, but without noticeable results, **it is that of its design.** The pugnacity of the ATRSS leaders as well as that of a limited number of scientists and researchers eventually overcame the difficulties to finally bring together a **caucus** whose task is to draft a Charter of Ethics for this learned institution.

The Workshop which was organized by the ATRSS on December 17 and 18, 2017 and generously hosted by the University and the National Center for Research in Islamic Sciences and Civilization of Laghouat gave the signal to a work of effective and consensual research. It was the culmination of a desire affirmed by the leaders of the ATRSS to mobilize and finally make the dream come true. The rest was a work of methodology, pedagogy and research.

In the circumstances, three workshops were set up, chaired by eminent Professors and including researchers with proven multi-disciplinarity:

I er Workshop: Ethics Charter of the Thematic Research Agency in Health Sciences.

th 2 Workshop: Informed consent.

3th Workshop: Institutionalization of Ethics.

A large number of Professors who are part of the Agency's Scientific Committee Theme of Research in Health Sciences, to which researchers have joined volunteers mastering the Human and Legal Sciences, set to work at the headquarters of the institution: the mission was carried out with method, discipline and rigor to take advantage of the results resulting from the relevant reflections of the members of the three workshops.

The head office was then the witness of a very high number of working sessions, meetings and get-togethers to draw up the long-awaited document.

Concepts and phrases have been dissected, their implications have been singularly analyzed, their compliance with the rules, canons and standards international standards were respected to refine a document with value and strength morals.

The countless hours of work and reflection and the necessary and unavoidable questions have finally paved the way for the design **of an Algerian product** designed and thought by Algerian Scientists.

The Thematic Agency for Research in Health Sciences had just reached one of the major objectives of its load plan by designing this important document strategy, the **Charter.**

The void - represented by the lack of benchmarks for **Moral Values -** which has long raged in this institution was finally filled, by the contribution of a scientific work put now within the reach of research establishments and scientific institutions related to life sciences.

The Thematic Agency for Research in Health Sciences, represented by its Director General, Professor AOUFFEN Nabil as well as by its President of the Scientific Council, Professor BACHIR BOUIADJRA Noureddine, would like express its gratitude to the researchers who have contributed with ardor and competence in the design of the Ethics Charter.

These Professors are named:

L. MOKHTARI. - Chairman of the Scientific Committee -

A. ABOUBEKER.

F. BENRAHAL.

Y.BERRABAH.

S. BOUMESLOUT.

Y. FEHIM.

K. LAYADI.

A. OSSOUKINE.

JM YOUSFI

Joined by the collaborators of this institution:

B. KHERCHOUCHE. - Secretary General of the ATRSS -

A. BENABBAD.

FL BOUSSAFI MIRALI.

HK DRAOU BOUDJELTIA.

K. LAMRI TAYEB.

F. MESSAOUD CHALALI.

Thanks are due to them for having thus contributed to making available to the Scientific Community a strategic document and instrument in scientific and biomedical research.

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II. ETHICAL CHARTER OF THE THEMATIC AGENCY OF HEALTH SCIENCES RESEARCH - ATRSS –

- GENERAL PRINCIPLES -

Of the Inviolability of the Human Being

All research targeting specific objectives **and ideally humans,** must obey the rules of ethics, morality and law derived from mores and behavioral habits in modern States. They must be because of the sacred and inviolable character of **the Human Being,** of his sociability and his universality.

Health taken in its broadest sense must respond appropriately to an institutional framework and regulations that must govern the relationship between the researcher, the doctor and his patient: this is what creates the intimacy and the meeting of the medical sciences with the human sciences, that is to say **Health** with **Sociology.** Above all, it is the nature and quality of the exercise of medical practice by health professionals that generates highly appreciable and scientifically viable behavior. We then say that the practice of Health is underlying a legal process in its daily acts, in other words that it is institutionalized by a law, a code of conduct called **Ethics.** It is then that the spirit of research and the act of caring are moralized. Their relationships, during trials and experiments, between scientists, researchers, practitioners and their subjects or patients are regulated and apply postures and behaviors of sociability determined and codified by rules of law drawing their substance from positive law, natural laws and philosophical and religious precepts.

Morality and probity must guide the steps of the scientist in each act of daily life and especially in the exercise of his eminently human functions to put his knowledge and knowledge at the service of society: this is what is universally recognized as **Ethics.** First philosophers, then theologians, sociologists and jurists have made it their main subject of research and have appropriated it to place it at the center of human morality.

Of Morality and Science: what Morality is it?

The one that decrees that everyone must be given the same chances in the face of illness and pain, not to contravene the rules of ethics and sincerity and that of considering the human being as an inviolable entity, and respecting his integrity. physical and mental; to do this, the States have determined legal instruments, a powerful legal barrier to protect the patient but also to support the doctor and the researcher in their quest for **“human well-being”.** Since the depths of the ages, philosophers have striven to "universalize" the sacred character of man and his body and have set out the principles that should govern their understanding.

Emmanuel KANT, German thinker who died on February 12, 1804, analyzes in his triptych of " **criticisms"** the fundamental principles of universalist philosophy and states **"always act in such a way that you treat humanity in your person and in that of others, always at the same time as an end, never only as a means".** These fundamentals of philosophy are shared by Morality, Religion and Law.

As an extension, modern times have been nourished by a legal arsenal coming upstream and downstream from the medical act which is nourished by the rules of law of the States but also and above all by morality and philosophy: Algeria n is no exception to this and must also focus its scientific research on the principles enacted by ethics: attempts to formulate ethical rules have been attempted by officials in **the former ANDRS,** but for various reasons, they have not not been led
eventually.

The adage states that "necessity makes law", therefore:

Today and more than ever, research in Health Sciences being placed at the heart of the concerns of the Public Authorities, and especially targeting Scientific Research, Algeria must reposition itself as quickly as possible with regard to this generous and noble problem, one that places Man at the center of the concerns of researchers, practitioners and professions that orbit around this formidable and formidable adventure.

But such an ambition can only be achieved when all the scientific, psychological, sociological, material, religious and certainly many other ingredients are brought together so that the **Politician** finally decides to harmonize, regulate and institutionalize a **Code . of Ethics and Deontology capable** of supervising and humanizing Research in Health Sciences and its counterpart, the practice of medicine.

The urgency is all the more marked as at the beginning of the 21st century, the intrusion of technology into medicine is becoming urgent and the resulting instrumentation, invasive.

Biomedicine has acquired its letters of nobility and must respond to new regulatory instruments with the appearance of **Bioethics :** Biomedicine and bioethics are intimately concerned by new invasive techniques which explore down to genomes and which can manipulate cells at the most depth of the human body; Medical engineering has burst into classical medicine and we are already talking about medical equipment, imaging, nuclear medicine as if the hospital or the clinic were transformed into a factory, but into a factory producing the **"human thing** ". The scientific, social, commercial and economic motivations will objectify as a common denominator the cure and the well-being of the patient, from an instrumentation of a technical "armament" which evolves according to the discoveries of new processes and new techniques.

Ramparts against drifts

This is where the need to mark out, frame and institutionalize the relationships between scientists, practitioners, researchers, doctors, biologists, physicists and the patient appears; the human being being global and indivisible is likely to be the subject of multidisciplinary explorations, that is to say that the disease of a single organ can concern several specialists, but also that the disease affecting an organ can lead to the harm of another organ.

The surgeon's intervention must lead to the preservation of the uniqueness of the human body, to take care not to distort the integrity and functioning of this perfect whole.

This construction is not a machine: you cannot change a defective part for another: you must preserve the diseased organ and treat it: the surgical act or experimentation must only take place within the framework **of informed consent.** of the patient or under certain equally well-defined and hierarchical emergency conditions: minor children, prisoners, patients in a state of distress, people with mental disorders, in other words, those who do not have their free will!

Free and informed consent must benefit the patient: before giving their consent to care, they must benefit from honest, clear information adapted to their level of understanding from the medical teams. He must not be under the influence of any pressure or constraint: he is entitled to know the treatments and all the possible therapeutic alternatives, including their advantages and especially their disadvantages. The patient's wishes take precedence over all other considerations. The principles of **freedom** and **truth** must be placed at the top of the pyramid of **morality.**

The research themes initiated and financed by **the ATRSS** must respond to these main principles. As a funder, it will systematically prohibit any attempt to resort to plagiarism, falsification and the fabrication of results, in other words the recovery of the thought, intellectual, scientific, technological work of others and to appropriate paternity for avowed or unavowed purposes. Whatever the reasons, the process is detestable!

The preservation of knowledge and knowledge with dignity is the ultimate goal of the ATRSS mission!

While it is true that most schools of thought have adopted this methodology, it is equally true that scientific research is growing exponentially, that ultra-specialization is becoming more and more advanced, and that In this respect the applications may be somewhat different from one institution to another.

These are sufficient reasons to legislate validly and place all actions in the field of medical science within a legal framework which, while encouraging

research, clinical trials, expertise and acts, must situate the responsibility of the practitioner and his duties towards the man, the patient.

With irrefutable legal value and opposing third parties, regulations backed by a legal framework in the form of a decree with its implementing texts must be made available to research centers, laboratories, hospitals, clinics, etc. .. with the aim of being inspired by the moral values which must prevail when it comes to the care of a healthy or sick being in a medical environment. Clinical trials and laboratory experiments are primarily concerned by the intrusion of legislation in circles whose objective is health research and taking man as a “guinea pig”.

Containing, directing, supervising, controlling after the fact, shrouding these works in secrecy to safeguard the identity and the private life of the donor or of the "subject" having undergone the experimentation, are the major assets for the practice of an irreproachable Ethics and which fits into the major themes of sociability and spiritual and moral values.

The essential place of the ATRSS

A guide, **the guide** on **Ethics** is required more than ever in an Algeria open to international influences and undergoing the scholarly or perverse effects of Western research turned towards profit and the interests of the richest.

The commodification of human organs removed in Africa and Asia, benefits such wealthy Westerners, without scientific or even material compensation.

"The market for children" whose promoters without faith or law find their happiness in the ghettos, still provokes endless discussions in the bodies responsible for Child Protection at the global and regional level without found a real solution. Is there a sincere desire to eradicate this dirty work which consists, for a fee, in “commodifying” the children of poor countries and selling them in rich countries? The denial of the rights of these children continues to delight wealthy couples who want “at all costs” to have a child because Mother Nature has not allowed them to have children.

“The Stock Exchange ” of human organs taken from fragile people in Africa and Asia is a veritable financial windfall which every day “enriches” the Frankensteins of the human body and “impoverishes” the organism of the unfortunate donor.

To the semantics of the 20th century which used the concepts of “man-prosthesis, baby-test tube, predictive medicine, human genome, came to be superimposed a more generic and more factual “code”:

A language, a glossary of modern times, soon to become universal at the start of the The 21st century was born to describe "these manipulations, these applications" that researchers frequently use in their language, such as the child-medicine, the

bio-market, the bio-bank, in short and in a way a human fair and by extension **“the Human Market”.**

The ban has burst into the realm of human morality: it is violence, a violation of human values.

But then what to do so that Algeria does not undergo the perverse and immoral breath of this vast machination and this research without conscience? What place will it take in universality and morality?

An appropriate legal arsenal that responds in quality to the research themes in the territory must be developed and benefit Algerian researchers.

In addition, this arsenal must arouse, unleash and release the initiatives of Algerian scholars and researchers and offer them an environment conducive to health research.

The delay taken in the institutionalization in **Algeria** of an **ethical** reflection is unforgivable for a country which has an appreciable number of high-level practitioners, who only ask to be part of a dynamic research of high university density and to great scientific value.

The urgency to be part of the immediate present, that is to say to **act** on a set of rules, becomes obvious and commands all the actors summoned by this center of interest to do “ **Ijtihad” work.**

The purpose of this work being the moralization of the scientific sphere.

The ATRSS lays today with force and conviction the bases leading to a consensus between research and morality, between scientific applications and the institutionalization of acts converging towards **Health.**

The pugnacity with which all wills will take charge of this learned problem will ultimately be expressed through the drafting and execution of **the Ethics Charter.**

Finally, and notwithstanding all the obstacles that could arise during this noble and generous mission, isn't it time for Algerian thinkers and researchers to offer decision-**makers** a guide to moralizing the scientific act and medical?

Thus **the ATRSS** will have contributed to designing one of the fundamentals of Morality in Algeria.

III. CHARTER OF RESEARCH ETHICS IN HEALTH SCIENCES

The main missions of the ATRSS are the promotion and financing of health research, its monitoring and evaluation as well as the exploitation of its results.
It is a service to the scientific community and to society to which are attached moral requirements that confer a particular responsibility on it. This responsibility applies to all members of the scientific community in the context of their relationships and activities.

The purpose of this Health Sciences Research Ethics Charter is to recall the major principles to which the institution and its members have a duty to adhere in order to ensure legitimacy and consideration for all the achievements and Agency actions.

principle of truth

The quest for knowledge, an essential axis of research, is inseparable from the demand for truth. This is why the Agency must give priority to the critical examination of the knowledge that it generates and transmits. This requires the critical observation of facts, the confrontation of points of view based on competence, mastery of knowledge and intellectual rigor.

Compliance with this principle presupposes adherence to the principles of freedom and integrity of research.

The research must, and during all the stages of its accomplishment, respond to a rigorous, explicit and clearly stated methodology, ensure respect for the rights, security and protection of the people who lend themselves to the research.

Principle of freedom

The Agency respects academic freedom in the choice of research topics within the limits set by national choices. This principle, one of the foundations of scientific activity, is essential for the development and sharing of knowledge as well as for its transmission.

The Agency guarantees compliance. Researchers must be able to present a critical opinion without being censored or repressed, while respecting the rights of others. Freedom must be exercised in compliance with the laws, the obligations of scientists and the principles of this charter.

Principle of integrity and fairness

Integrity, probity and honesty are fundamental in scientific activity. Anyone engaged in research must apply the principle of integrity in their scientific work. In particular, it must recognize the contributions of any other person to the realization of the research project.

Integrity implies objectivity, impartiality and independence. The latter must not be compromised by the acquisition of advantages in any form whatsoever.

The free sharing of results is the surest guarantee of the accuracy and objectivity of scientific results.

Any conflict of interest, of a pecuniary or moral nature, must be declared. The same applies to all sources of financing linked to activities carried out under the auspices of the Agency. Under no circumstances will the influence conferred by the function be used for personal purposes or in favor of relatives.

The Agency ensures compliance with the principle of fairness. Objectivity and impartiality are essential requirements when hiring, appointing or evaluating.

Any evaluation must be carried out in full transparency, in accordance with appropriate procedures.

Principle of respect for the person

The person in all research is an end and a means. For this reason, she needs a certain degree of protection which will be determined according to the risk she incurs and the probability that she obtains an advantage. The welfare of the people who take part in investigations and trials is a cardinal principle. In this sense, they must be approached with beneficence and not maleficence.

The Agency is committed, like each of its members, to fostering a work environment in which people are treated with respect and fairness, regardless of their hierarchical level.

People occupying an academic or administrative position must set an example and foster a stimulating work atmosphere and a climate of trust.

They must clearly communicate their expectations of their employees and do everything possible to avoid conflicts or resolve them quickly.

They respect their colleagues, the assistants, in a spirit of cooperation, while arousing healthy emulation.

They support them in their professional development and monitor their moral behavior.

A well-understood collegiality allows for diversity of opinion and criticism with mutual respect and recognition of the right of others to express their opinion.

The principle of respect for the individual also means that employees are entitled to fair compensation for their services, to personalized specifications, to periodic assessment and information interviews, as well as to the confidentiality of personal data.

Any form of discrimination is to be prohibited, whether of a social, religious, ethnic, gender or other nature.

Research must be carried out in strict compliance with the laws and rules of ethics that govern the use of living beings. It must use it with moderation and balance.

The researcher must benefit from moral support, material assistance and the necessary equipment to enable him to carry out his research activity successfully.

Accountability principle

The Agency is a stakeholder in the Company. It is responsible for working to promote its scientific and cultural influence. This duty is part of the search for quality and the promotion of excellence, in the recognition of the complementarity of disciplines.

The researchers who are members of the Agency and its partners are responsible for their actions vis-à-vis the scientific community. They need to be aware of and account for their impact. As such, they must avoid performing acts likely to taint their research by committing the following errors in particular:

- Falsify or invent data totally or partially;
- Plagiarize what has been published by other authors in whole or in part;
- Include as authors those who have not contributed substantially to the design of the work and repeatedly publish the same conclusions.

The principle of responsibility recognizes scientific research's right to innovation, but asks it to consider the precautionary principle, to question its own purpose and the potential consequences of its results on society and the environment.

The researcher must mention the Agency in his work carried out within the framework of its activities (given that it is the funder).

The Agency reserves the right to reject any work contrary to its stated principles.

The Agency must carry out a constant evaluation of the research activity.

By virtue of the principle of responsibility, the Agency must make every effort to achieve its main objectives, as defined by its mission. It also undertakes to respect the standards and procedures governing its operation. Members of the scientific community must be available to the institution. They must also make wise use of the resources made available to them.

disposal, whether public or not, and to be able to account for their rational and transparent use.

In its contractual relations with third parties, the Agency must be able to demonstrate its respect for ethical principles, in particular those of fairness and integrity.

Philosophical principle

The principles set out in this charter commit each member of the scientific community. They can be supplemented by specific directives and be the subject of teaching. By adhering to this charter, each member of the research teams affiliated with the Agency is required to respect the guiding principles set out above.

These principles are demanding, but they must also allow everyone to guide themselves in problematic situations by offering them a basis for reflection in the choice of their attitude. Neither static nor intangible, they form a basis for discussion where other moral values also have their place, such as tolerance, dignity, solidarity and generosity.

IV. FREE AND INFORMED CONSENT

The primacy of the person and his autonomy (freedom, power to decide), physical and mental integrity are certainly philosophical notions but they establish the legal and ethical legitimacy of the act of scientific research on the human person.

Before starting a clinical trial or research requiring the participation of people, they must be properly informed, i.e. put in a position to understand the nature of the information transmitted, the purpose of the processing of data. The same is true for the recipients of this data.

These people have a right of access directly or through a doctor designated for this purpose, a right of rectification and a right of opposition.

They need to know the risks and benefits so they can consciously decide whether or not to participate.

Any adult can designate a person of trust who can be a parent, a close friend or the attending physician and who would be consulted in the event that they themselves are unable to express their wishes and receive the information necessary for this. end, then she will give an account of the will of the person, her testimony will prevail over any other testimony. This formality is made in writing and co-signed by the designated person. It is reviewable and revocable at any time.

This principle is now contained in a multitude of international declarations since Nuremberg, via the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Applications of Biology and medicine: Convention on Human Rights and biomedicine (Oviedo Convention/Council of Europe: April 4, 1997) to the present day.

“An intervention in the field of health cannot be performed only after the data subject has given free and informed consent.

This person receives prior adequate information as to the purpose and nature of the intervention as well as its consequences and risks.

The data subject may, at any time, freely withdraw his consent. »

The person, patient or healthy volunteer, who voluntarily submits to trials and research must be understood as a valid interlocutor, a subject capable of understanding, interacting and consciously choosing the processes of biomedical research.

Minors may only be asked to take part in research if research of comparable effectiveness cannot be carried out on adults and under the following conditions: Importance of the expected benefit for these people such as to justify the foreseeable risk incurred and the significance in terms of the expected benefit to other minors.

Appropriate consent for minors: authorization from a single parent if the risk is minimal, if another holder is absent, if there is not a healthy volunteer and if he becomes of age before the end of the research, then confirmation of consent must be collected. In the event of a serious risk of invasion of privacy or the integrity of the human body, authorization is required from the family council (if one is constituted) or from the guardianship judge.

For adults under guardianship (alteration of their bodily or mental faculties), need to be represented in a continuous way in the acts of their civil life, their personal adhesion is necessary with a legal representative in the event of minor risks with negligible constraints. If the risk is serious, authorization is obtained by the family council or by the guardianship judge.

For adults under curatorship (impairment of their bodily or mental faculties), without needing to be represented on a continuous basis, need to be assisted, advised or controlled in the acts of their civil life, personal consent with assistance from the curator (minor risk), authorization by the guardianship judge who, in the event of incapacity to consent, can decide whether or not to authorize the research (serious risk).

The researcher proposing a clinical study must therefore not only protect the health of the person involved, but also guarantee their integrity and dignity by informing them. Involving them in the decision-making process. Information of the subject is mandatory.

For a researcher, the presentation of a research project to a person is a particularly delicate moment: it is a question of putting the potential participant in the best intellectual conditions, allowing him to make a free and conscious choice, despite the vulnerability, to which he exposes his pathological condition, and his legitimate expectations of care and health.

The information is always given by the investigator or the doctor representing him, carried out using a document distinct from the consent, written in Arabic, French and Tamazigh languages (understandable for the participant) dated and recorded.

The essential information that must be delivered by the investigator to the patient are: the objectives of the research project, the methodology, the duration, the expected benefits, the foreseeable risks, the constraints, the conditions for stopping the research

before its term, the right to refuse to participate, to withdraw consent without incurring any prejudice.

The quality of the relationship established at this preliminary stage will play a decisive role during the clinical trial. Informed consent is, in fact, a continuous information process that takes place throughout the clinical study, including during the subsequent period. It is not an act determined in time.

The information that will be delivered during or at the end of the trial is: the evolution of the protocol, the new orientations, the new risks identified, the overall results of the research and the impossibility of being informed about the individual results.

Consequently, it is necessary to recognize in the person concerned from the first meeting, a partner in the study and an active subject.

Understanding and the possibility of exchanging information generates fruitful participation and contributes to the quality of research. Thus, informed consent is above all a process of co-production of knowledge between the researcher and the participant.

For these reasons, free and informed consent must be provided by a written document signed by the two actors involved (model attached). It is by no means an annoying bureaucratic procedure, but a solemn moment that will seal two wills working for the common good, that of science.

The moment of signing must be a culmination that crowns a path of personalized information during which the person involved, through the explanations provided to him, has the possibility of receiving and discussing relevant and appropriate information in about :

- The reason and purpose of the study;
- The answer to the participant's doubts; •
  The reasons for its involvement;
- The design of the study, the phases that characterize it and the procedures that will be implemented;
- The description of the therapy used (risks and benefits, efficacy, effects side effects, dosage, etc.);
- The number of participants and the duration of the treatment and the study;
- Control and follow-up visits;
- The freedom not to participate and to receive (in the case of a patient), in any case the best care available, and to discontinue participation provided that this decision does not harm the state of health of the patient. the person participating in the trial;
- Respect for the requirement of confidentiality, and the assurance to this person that his personal, sensitive and possibly genetic data will be treated in the most total secrecy;

- The possibility of informing the person, sufficiently in time, that his consent is revocable at any time.

During the first presentation of the study, the dialogue could be supported by any type of documents and / or tools that can provide better information and facilitate the participant's understanding (possibly these would be drawings, images , films, especially with children, rather than an esoteric schematization of the study with scientific documents that are incomprehensible to the participant).

The informed consent form must include two parts:

1. a section on protocol information and personal rights;
2. a section for the expression of consent.

In the absence of a law on the protection of automated personal data, it is useless to seek authorization to process personal and sensitive data, and genetic data, when this is envisaged.

(See standard documents, “A” and “B” in the appendix).

V. APPENDIX “A”

INFORMATION NOTE

INTENDED FOR PATIENTS OR HEALTHY PERSONS FOR

PARTICIPATION IN HEALTH SCIENCES RESEARCH

Mrs Miss Mr,

Your doctor has suggested that you take part in the biomedical research protocol

(Protocol No. UF XXXX__) entitled "……;" coordinated by Dr./Pr. ……..... in the building ……..

We suggest that you read this information note carefully, the purpose of which is to answer any questions you may have before making your decision to participate.

After reading the information note, you have a period of time (X days) of reflection to submit this signed document.

At any time during the trial, you can contact your investigating doctor to ask any additional questions.

The objective of the research

Example :

This Research is part of a Public Health context where a large segment of the population is affected by the pathology / better prevention would allow a reduction in the number of cases / the implementation of an innovative treatment would allow better care pathology...

The objectives of this research are:….

We undertake this research with the aim of obtaining better care / a reduction in adverse effects / an improvement in the quality of life of patients / better compliance with treatment...

Methodology

Example :

This is a “double-blind” trial, meaning that neither you nor your doctor will know whether you are taking xxx or the placebo. The treatment you take (xxx or the placebo) will be determined by a computer drawing lots (this is called randomisation).

This trial will be conducted in xxx healthcare facilities.

- Inclusion period: XX months
- Duration of follow-up: XX months
- Planned number of inclusions: XX patients
- Single-center / multi-center study.

Information on treatment schedule and medical follow-up

Describe precisely the management of the subject participating in the research.

If you agree to enter the study and if you meet all the conditions required to participate, you will be followed in the establishment. ___.

At any time your doctor will be available to answer your questions about the study.

You can find in the table below the schedule of your visits, the type of examinations that will be carried out as well as the tests and assessments planned.

The inclusion assessment corresponds to a medical examination prior to research:

Visit	**Inclusion report**	**Visit 1**	**Visit 2**	**Visit 3**
Dated		Day 1	Month 1	Month 6
Information				
Consent				
		Randomization		
Clinical examination X			X	X
Blood test	X*			
Urinary collection X				
Survey Quality of life	X*		X*	X*
Processing		X*	X*	

* specific to the project (if Biomedical Research)

If the project includes one or more biological samples: The biological elements collected during the study will be destroyed/retained for later use.

The duration of participation

If you agree to participate in this study, your participation will be for a period of XXX.

Example :

You will receive treatment XXX during this study.

The expected benefits

There will be no direct benefit / there will be direct benefits (quote them) for you in the immediate future. In the longer term, the expected benefits are: ……..

Example:

If you are in the group receiving the drug at the end of the draw, the benefit you can expect by participating in this study is …….

However, if you are in the group that will receive the placebo / reference treatment, this study will allow you to benefit from monitoring.

Foreseeable risks

Example :

Possible side effects are: ……..

These side effects described in detail are not systematic and are most often well tolerated.

You are advised to inform your doctor if any of these effects occur or any other intercurrent problem so that appropriate care can take place.

Rare cases have been reported: ……

If you were to develop these symptoms, measures are planned to manage them as effectively as possible and in such a way that you have the least possible impact: …… .

We keep the possibility of stopping your participation in the study prematurely and you we will keep you informed of the reasons why the investigator wishes to withdraw you.

The terms and justification for direct debits

As part of this study, we wish to carry out an evaluation of: ……

Also, if you agree to have blood samples taken from you (blood samples) and these will be of ……, frozen at -80°C/-20°C and kept until the end of the study at …… ……. (specify the site), and analyzed in the following laboratories: ……

The tubes and samples will be anonymous by a code number. Thus, only persons authorized for the study and subject to professional secrecy will be able to make the link between this number and your identity.

No other analysis can be performed on these samples, which will be destroyed once the study is completed. At any time, until the analyzes are carried out, you can withdraw your consent and the samples will then be destroyed without any analysis having been carried out. If we wish to carry out additional analyses, nothing can be done until you have been informed and have given your consent again.

The results of the analysis of all the samples may be published. In none case, you cannot be identified as a participant in this study.

It is possible that not all of the samples will be used in this study.

In this case, after a period of reflection, you can choose that:

- The rest of the samples are kept at - 80°C in the ……. laboratory for a period of ……. year(s) under the responsibility of Pr. /Dr. ……. used in other research protocols collaborating institutions or sold to be ……

- The rest of the samples are destroyed at the end of the research. The tubes and samples will be anonymous by a code number. Thus, only persons authorized for the study and subject to professional secrecy will be able to make the link between this number and your identity.

Depending on your decision, you will be asked to sign the corresponding consent.

Possible medical alternatives

Example:

There are medical alternatives to this research that you can benefit from for your support if you do not wish to participate in this research: …….

Rights as a participant in this research

You can withdraw from the trial at any time without justification, without consequences for the continuation of your treatment or the quality of the care that will be provided to you and without consequences for the relationship with your doctor; you can be followed by the same medical team.

Your participation in this research will not generate any additional costs compared to those you would have in the usual follow-up of this disease. If you agree to participate in this project, all costs related to the study will be borne by the promoter.

The protection you benefit from within the framework of this research (Research and/or Health Establishment).

The sponsor of this trial, which manages it and is responsible for this research, is the Research Center, eg: University Hospital of …….. located at ……...

The Research Center of ……. has taken all the measures provided for by the regulations in force relating to the protection of persons taking part in biomedical research, in particular Order 387 of July 31, 2006 relating to clinical trials and Order 388 setting the procedures for clinical trials "Text attached as an appendix".

The Thematic Agency for Research in Health Sciences (ATRSS) has authorized this trial under the the ____ number ____. The Agency's Ethics Committee issued a favorable deliberative opinion the ____.

Confidentiality of data

Your medical file will remain confidential and may only be consulted under the responsibility of the doctor in charge of your treatment as well as by the health authorities and by persons duly authorized by the sponsor of the trial and subject to professional secrecy.

As part of the biomedical research in which you are offered to participate, a

automated and anonymized processing of your personal data will be implemented to allow the analysis of the results of the research with regard to the objective of the latter which has been presented to you. To this end, the medical data concerning you and the related data (to be specified) will be transmitted to the Sponsor of the research or to the persons or companies acting on its behalf, in Algeria.

Information concerning your identity will be kept confidential by your investigating doctor.

If you wish, you will be informed, at your request, of the overall results of the trial by the investigating doctor.

Who should you contact in case of questions or problems?

In case of problems, adverse events during the trial or questions, you you can contact the following people:

Your contacts in the study (title, surname, first name, address and telephone):

……

……

Contact details of the patient's referring doctor:

……

When you have read this information note and obtained the answers to the questions you are asking yourself by questioning the doctor, you will be offered, if you agree, to give your written consent by signing the consent form prepared for this purpose. .
Signing the form will attest to your final agreement to participate in the research. You will be able to benefit from additional information on research at any time.

You will only enter this study after signing the consent form.

VI. APPENDIX “B”

INFORMED CONSENT FORM

FOR PARTICIPATION IN A RESEARCH IN

HEALTH SCIENCES

I, the undersigned)

Last name and first names : ……………………………………………..

Age: ………………………..…… Gender: ………………..…….

Address : ……………………………………………………………………………………

Hereby agrees to participate in the research entitled: “ ………………………. »
(same title as on the protocol and the insurance) whose promoter is the …………….. (The name of the establishment or organization) and coordinated by the Doctor/Professor ……………… . and conducted by Doctor ……………………………within your establishment.

This form has been established in accordance with the regulations on research in Health Sciences.

I have read today the information note reserved for the patient, and I am fully aware of the objective of the study, the expected benefits, the constraints and the foreseeable risks.

Moreover, the conditions of its realization were clearly indicated to me by the research investigator / researcher.

I have noted that this consent does not release the sponsor and the investigator from their responsibilities and I retain all my rights guaranteed by law.

My participation is voluntary. I am aware of the possibility reserved for me at any time to interrupt my participation without giving the reason and without this harming me or affecting the care that will continue to be provided to me.

I received the results of the preliminary medical examination which were communicated to me through the intermediary of the doctor of my choice, **(Medical clinical trial), Article 16 of Order 387 of July 31, 2006.**

I have been informed that the samples will be kept in the laboratory of ………… for …….. year (s) at the end of the research and I accept that they will be used for other purposes of research within the framework of subsequent studies relating to ……. other subjects of research or consent within that of the rights holders and in accordance with the regulatory provisions.

I have noted that I can request the destruction of the samples at any time during the research.

The following paragraph is to be kept only if the collection is destroyed at the end of the research.

I record that the samples will be destroyed at the end of the research.

I undertake not to participate in any protocol for the duration of the study, nor for …… days following the end of the present study, in order to avoid any overlap in the reliability of the results.

I have noted that I have the right to be informed of the overall results of this research according to the methods that have been specified in the information note.

The data from this study will be kept strictly confidential. I don't allow them consultation only by the persons collaborating in the research, designated by the investigator.

I agree that the data recorded during this study, including so-called sensitive data (ethnic origin, religion, political affiliation, etc.), may be processed by the sponsor or on its behalf. I have noted that a right of opposition, the rights of access and rectification, which the texts open to me, may be exercised at any time with Dr. …….. and that the data concerning me may be communicated to me directly or through a doctor of my choice.

I have had sufficient reflection time between this information and the present consent.

I have read and received a copy of this form and I agree to participate in this protocol.

Surname and first name of the patient:

The : ……..

Read and approved
Signature of the patient or his legal representative:

Part to be completed by the patient

I orally explained to the patient in appropriate and understandable terms. I believe I fully informed the patient about the nature of this study, its potential benefits and risks.

The ……..

Surname and first name of the investigating doctor: ……..……
Signature of the investigator:

Part to be completed by the investigating physician

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ÿ *Order No. 387 of July 31, 2006 relating to clinical trials:*

- *Chapter 1: Object – definitions (06 articles)*
- *Chapter 2: General provisions (24 articles)*
- *Chapter 3: Consent of the person (03 articles)*
- *Chapter 4: Protection of persons taking part in clinical trials (06 items)*
- *Chapter 5: Special provisions for clinical trials without direct individual benefit (07 articles)*
- *Chapter 6: Miscellaneous and final provisions (03 articles)*

ÿ *Order No. 388 of July 31, 2006 setting the procedures for carrying out a test clinical.*

LEGAL TEXTS

People's Democratic Republic of Algeria

Ministry of Population Health and Hospital Reform

Order No. 387 of July 31, 2006 relating to clinical trials

The Minister of Health, Population and Hospital Reform;

- Having regard to law n° 85-05 of February 16, 1985, amended and supplemented, relating to the protection and promotion of health, in particular its articles 178, 168/2, 168/3 and 168/4;

- Given Ordinance No. 95-07 of 23 Châabane 1415 corresponding to 25 January 1995 relating to insurance;

- Having regard to Executive Decree No. 93-53 of June 28, 1993 creating the official bulletin of the Ministry of Health and Population;

- Having regard to Executive Decree No. 96-66 of 7 Ramadhan 1416 corresponding to 27 January 1996, establishing the powers of the Minister of Health and Population;

- Having regard to Executive Decree No. 05-428 of 5 Choual 1426 corresponding to 7 November 2005 on the organization of the administration of the Ministry of Health, Population and Hospital Reform;

- Having regard to presidential decree n°06-176 of 27 Rabie Ethani 1427 corresponding to 25 May 2006 appointing the members of the Government ;

- Having regard to Order No. 112/MSP/MIN of October 22, 1995 establishing good clinical practices;

- Having regard to Order No. 44 of September 21, 1998 on the declaration of intent form for testing a drug or similar product.

- Having regard to Order No. 48 of October 7, 1998 relating to the declaration form for a serious effect likely to be due to biomedical research on a medicine or a pharmaceutical product;

- Having regard to Order No. 67 of December 6, 1998 establishing the clinical trials unit.

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Chapter 1: Object - definitions

Article 1 : The purpose of this decree is to define the conditions under which clinical trials on human beings are carried out.

Article 2: Clinical trial means any investigation carried out on human subjects with a view to discovering or verifying the clinical and pharmacological effects of a pharmaceutical product, to identify any adverse reactions in order to assess its efficacy and safety. .

The clinical trial focuses on:

- therapeutic, diagnostic and preventive trials; - observational studies; - bioequivalence studies.

Article 3: A clinical trial is said:

- with direct individual benefit (BID) when the patients included in the trial benefit directly from a possible therapeutic benefit for the management of their pathology.

- Without direct individual benefit (SBID) when the healthy subjects included in the trial derive no direct therapeutic benefit.

Article 4: Clinical trials require promoters, and/or research organizations called contract research organization (CRO) and investigators.

Article 5: Sponsor means any natural or legal person who takes the initiative of a clinical trial.

“Contract research organization” (CRO) means any company providing services in the field of clinical trials. This company is assimilated to a promoter.

Investigator means any general practitioner or specialist who directs and supervises the performance of the clinical trial.

Article 6: The terms and concepts commonly used in the field of clinical trials are defined in the glossary attached in Appendix A of this Order

Chapter 2: general provisions

Article 7: Companies providing services in the field of clinical trials are approved by the Minister of Health, Population and Hospital Reform.

Article 8: Any promoter of a clinical trial on human beings must declare their intention to carry out this trial to the Minister of Health, Population and Hospital Reform, who issues an authorization to this effect.

The declaration of intent is formulated in accordance with the form attached in appendix B to this order.

The Minister of Health, Population and Hospital Reform may, at any time, ask the sponsor for additional information on the clinical trial. It may also, at any time, suspend or prohibit a clinical trial.

Article 9: No clinical trial may be carried out on humans:

- if it is not based on the latest state of clinical research, scientific knowledge and sufficient pre-clinical experimentation;

- if the foreseeable benefit/risk ratio is not in favor of the subject included in the research.

Article 10: Clinical trials can only be carried out:

- under the direction and under the supervision of a doctor justifying appropriate experience;

- in material and technical conditions suitable for the clinical trial and compatible with the imperatives of scientific rigor and the safety of the people taking part in this trial;

Article 11: Any serious effect likely to be due to research on a pharmaceutical product must be declared by the promoter to the Minister of Health, Population and Hospital Reform, in accordance with the form attached in Annex D of this Order. .

Article 12: Minors and persons admitted to a health or social establishment may only be requested for a clinical trial if a direct benefit to their health can be expected.

Pregnant women and nursing mothers may exceptionally be admitted to clinical trials if they do not incur any foreseeable serious risk to their health or that of their child and if this research is useful for understanding the phenomena of pregnancy, childbirth or breastfeeding and if it cannot be done otherwise.

Article 13: Persons who cannot take part in clinical trials are:

- persons deprived of liberty by a judicial or administrative decision;

- patients in emergency situations and people hospitalized without consent.

Article 14: For clinical trials without direct individual benefit, the sponsor assumes, even without fault, the compensation for the harmful consequences of the trial for the person who takes part in it and that of his beneficiaries, without being able to oppose the fact of a third party or the voluntary withdrawal of the person who had initially consented to take this test.

For clinical trials with direct individual benefit, the sponsor assumes compensation for the harmful consequences of the trial for the person who takes part in it and that of his heirs, unless he proves that the damage is not attributable. to his fault or that of any intervening party without being able to oppose the fact of a third party or the voluntary withdrawal of the person who had initially consented to take part in the clinical trial.

Article 15: The promoter is required to take out insurance guaranteeing his civil liability for the activity he undertakes.

Article 16: The clinical trial does not give rise to any direct or indirect financial compensation for the persons who take part in it, except for the reimbursement of the costs incurred by the person taking part in the clinical trial.

Article 17: The performance of any clinical trial is subject to a financial agreement between the sponsor and the investigator.

The sponsor enters into a financial agreement with the establishment in the event that the clinical trial generates additional costs.

Article 18: The financial means made available to the investigator must be invested, among other things, for the acquisition of materials and equipment for the department where the clinical trial is taking place.

Article 19: The procedures determining the standards and methods applicable to the experimentation of pharmaceutical products are fixed by order of the Minister of Health, Population and Hospital Reform.

Article 20: Clinical trials must be carried out in accordance with the rules of good laboratory practice and the rules of good clinical practice.

Chapter 3: Consent of the person

Article 21: Prior to the performance of a clinical trial on a person, the free, informed and express consent of the latter must be obtained after the investigator has informed him of:

- the objective of the trial, its methodology and its duration;

- the expected benefits, the constraints and the foreseeable risks including in the event of termination of the trial before its end.

Article 22: The investigator must inform the person whose consent is sought of his right to refuse to participate in research or to withdraw his consent at any time without incurring any liability.

Article 23: Consent is given in writing or, if this is impossible, it is certified by a third party. The latter must be completely independent of the investigator and the sponsor.

Chapter 4: Protection of persons taking part in clinical trials

Article 24: Any clinical trial project must be submitted by the promoter to the prior opinion of the ethics committee for clinical trials created in article 25 below.

The ethics committee for clinical trials has a period of one month from the date of receipt of the project to give its opinion.

Article 25: The Minister responsible for health creates, in each health region, one or more ethics committee(s) for clinical trials.

Ethics committees for clinical trials have their headquarters within public health establishments.

The methods of organization and operation of ethics committees for clinical trials are set by instruction.

Article 26: The ethics committee for clinical trials is an independent body, it is composed of nine (09) people:

- five (05) doctors including a general practitioner; - a pharmacist ; - a senior health technician; - a lawyer ; - a representative of patient associations.

The ethics committee for clinical trials may call on any person likely to help it in its work.

Article 27: The committee gives its opinion on the conditions of validity of the research with regard to the protection of persons, in particular their information before and during the duration of the research and on the procedures for obtaining their consent, any compensation due, the general relevance of the project and the adequacy between the objectives pursued and the means implemented as well as the qualification of the investigator(s).

Article 28: The Minister of Health, Population and Hospital Reform may dissolve an ethics committee for clinical trials if the conditions of independence, composition or functioning necessary to ensure its mission are no longer met.

Article 29: The activities of ethics committees for clinical trials are supervised by the clinical trials control unit attached to the pharmacy department of the Ministry of Health, Population and Hospital Reform.

Chapter 5: Special provisions for clinical trials without direct individual benefit (SBID)

Article 30: Clinical trials without direct individual benefit must not involve any serious foreseeable risk for the health of the people who take part in them. They must be preceded by a medical examination of the persons concerned. The results of this examination are communicated to them prior to the expression of their consent.

Article 31: In the case of a clinical trial with no direct individual benefit for the people who take part, the sponsor may pay these people an indemnity in compensation for the constraints suffered.

Article 32: The number of clinical trials without direct individual benefit in which a volunteer can participate cannot exceed three (03) per year.

Article 33: No one can lend themselves simultaneously to several biomedical researches.

Article 34: Clinical trials carried out on minors cannot under any circumstances give rise to the payment of the indemnity provided for in article 31 above.

Article 35: Clinical trials without direct individual benefit can only be carried out in structures approved by the Minister of Health, Population and Hospital Reform.

Article 36: Trials without a therapeutic purpose are subject to the prior opinion of the National Council for the Ethics of Health Sciences.

Chapter 6: Miscellaneous and final provisions

Article 37: The Ministry of Health, Population and Hospital Reform shall keep a national register of declaration of clinical trials in accordance with the model attached in Annex C of this Order.

Article 38: The provisions of decrees n°44 of September 21, 1998 and n°48 of October 7, 1998 referred to above, are repealed.

Article 39: This decree will be published in the official bulletin of the Ministry of Population Health and Hospital Reform.

People's Democratic Republic of Algeria

Ministry of Population Health and Hospital Reform

Order No. 388 of July 31, 2006 laying down the procedures for carrying out a clinical trial

- Having regard to Executive Decree No. 93-53 of June 28, 1993 creating the official bulletin of the Ministry of Health and Population;

- Having regard to Executive Decree No. 96-66 of 7 Ramadhan 1416 corresponding to 27 January 1996, establishing the powers of the Minister of Health and Population;

- Having regard to Executive Decree No. 05-428 of 5 Choual 1426 corresponding to 7 November 2005 on the organization of the administration of the Ministry of Health, Population and Hospital Reform;

- Having regard to presidential decree n°06-176 of 27 Rabie Ethani 1427 corresponding to 25 May 2006 appointing the members of the Government ;

- Having regard to decree no. 387 of July 31, 2006 relating to clinical trials.

Stopped

Article 1 : The purpose of this order is to set the procedures for carrying out a clinical trial.

Article 2: The request to carry out a clinical trial may come from:

- pharmaceutical laboratories; - medical practitioners in the context of research; - administrative authorities in the context of registration of a pharmaceutical product ;
- research institutions within the framework of research projects; - service companies in the field of testing clinics.

Article 3: The applicant for a clinical trial submits a file to the department in charge of pharmacy of the Ministry of Health, Population and Hospital Reform, comprising the following documents:

- the declaration of intent to carry out a clinical trial in accordance with the form drawn up for this purpose; - the clinical trial protocol as provided for in article 7 below; - the observation book; - the investigator's brochure; - a copy of the civil liability insurance contract taken out by the promoter;
- a copy of the financial agreement entered into between the sponsor and the investigator.

The above documents must be filed in duplicate.

The file must be submitted at least two months before the planned start date of the trial.

Article 4: The directorate in charge of pharmacy of the Ministry of Health, Population and Hospital Reform has a maximum period of three months, from the filing of the file mentioned in article 3 above, to issue the authorization to carry out the clinical trial, to the applicant.

Article 5: The request to carry out a clinical trial may be rejected in the following cases:

- when the file is incomplete; - when the ethics committee for clinical trials has issued an opinion unfavorable;
- when the clinical trial protocol does not comply with the methodological principles described in good clinical practice; - when the place of performance of the clinical trial does not meet the appropriate conditions for the clinical trial as defined by instruction of the Minister of Health, Population and Hospital Reform.

Article 6: The sponsor appoints an investigator to direct and monitor the performance of the clinical trial.

In the case of a multicenter clinical trial, the sponsor entrusts the realization of the trial to several investigators, he appoints among them a principal investigator called the coordinating investigator.

Article 7: The clinical trial is the subject of a protocol which is signed by the investigator after he has expressed his agreement.

Article 8: The investigator must inform the sponsor of any critical event occurring during the clinical trial.

In the event that this event leads to a significant modification of the clinical trial protocol, this must be notified to the ethics committee for clinical trials.

Article 9: The investigator and his team must remain available throughout the duration of the clinical trial.

The investigator must inform the director of the hospital establishment where the clinical trial is taking place, before the start of the trial.

Article 10: When the products subject of the clinical trial do not have a marketing authorization in Algeria, an authorization for their customs clearance is issued by the direction in charge of pharmacy of the Ministry of Health, Population and hospital reform.

Article 11: When products remain at the end of the clinical trial, the pharmacy management issues an authorization for their destruction.

Article 12: At the end of the clinical trial, the sponsor must submit to the department in charge of pharmacy of the Ministry of Health, Population and Hospital Reform a report on the progress of the trial and the results obtained. .

Article 13: The performance of a bioequivalence or bioavailability study is subject to the same procedure as the clinical trial.

Article 14: For the realization of an observational study, the sponsor must only deposit at the level of the direction in charge of the pharmacy of the Ministry of health, the population and the hospital reform, the protocol of clinical trial and the form declaration of intent to carry out a clinical trial drawn up for this purpose.

Article 15: This decree is published in the official bulletin of the Ministry of Health, Population and Hospital Reform.

ANNEX A
Glossary

Amendment

Text modifying a provision of a clinical research protocol already approved by an ethics committee. The principal investigator of the trial sends the amendment to the ethics committee.

Two possibilities:
- the amendment does not significantly modify the protocol. In this case, the ethics committee is informed but does not give an opinion; - the amendment profoundly modifies the protocol and the possible risks for patients. In this case, the ethics committee deliberates and must give an opinion (favorable or not) on the amendment.

MA (Marketing Authorization)

Administrative authorization issued by the Director of Pharmacy and Equipment to the pharmaceutical establishment wishing to place a drug on the Algerian market. The Director of Pharmacy and Equipment makes his decision following the advice of the committee of clinical experts.

Archiving

All documents of a clinical trial must be kept for 15 years after the end of the trial, both by the investigators and by the sponsor.

Quality assurance

System implemented to ensure the quality of a clinical trial, the reliability of its results and compliance with ethics and the law during the trial. It includes: - the quality controls carried out by the clinical research assistant - the audit - the inspection carried out by the competent administrative authorities

Audit

Procedure for analyzing a clinical trial, carried out by an independent auditor of the trial and mandated by the sponsor in order to ensure the quality of the trial, the reliability of its results and compliance during the test of ethics, law and regulations in force. The audit report is the property of the promoter who assumed the financial burden of the audit.

Direct Individual Benefit (IDB)

It is said that clinical research is of direct individual benefit when the patients included in the trial will directly benefit from a possible therapeutic benefit for the management of their pathology.
Conversely, any other clinical research is said to be of no direct individual benefit when the healthy subjects or patients included in the trial do not derive

no direct therapeutic benefit from the research in which they agreed to participate.

Good Clinical Practice (GCP)

Set of provisions that guarantee in clinical research the quality and authenticity of the information collected and compliance with the law and regulations guaranteeing the rights of individuals in clinical research.

Bioavailability Study

of the speed and rate of release of the active principle of a pharmaceutical preparation, determined by its concentration curve in the general circulation as a function of time or by its excretion in the urine.

Bioequivalence

Two medicinal products are bioequivalent if they are equivalent from the pharmaceutical point of view and if their bioavailability (rate and rate of release), after administration of the same molar dose, is sufficiently similar for us to be able to expect effects essentially identical.

Investigator's Brochure:

Said of the exhaustive set of information collected at a given time on a drug, at the stage of development where it is before the MA.
The investigator's brochure must be given before the start of a clinical trial to any investigator taking part in this trial.
The trial sponsor is responsible for writing and regularly updating the brochure (dated, signed).

Observation notebook:

Document intended to collect as the trial progresses, for each subject, the information defined by the protocol. The information may be collected by any means guaranteeing editing and conservation, and allowing quality control.

Confidentiality:

The rule of medical professional secrecy applies to anyone who participates directly (investigating doctor) or indirectly (CRA, monitors, quality controllers) in clinical research.

Informed consent:

Free and formally expressed acceptance of a person to participate in clinical research. Consent is said to be “informed” when the person has received from the investigating doctor (or a doctor who replaces him) all the information concerning: the objectives of the trial, the benefits, the risks and the constraints.

The consent of the person can be withdrawn at any time without prejudice to himself.

Consent is evidenced by the person signing a “consent form” signifying that they have received all the information they wanted regarding the clinical trial.

Financial agreement

Contract governing the financial rights and responsibilities of persons involved in clinical research.

Test protocol

Text bringing together all the descriptive elements of clinical research and which specifies the conditions under which this research must be carried out and managed.

Additional cost of research

This term defines the cost of research which, in a patient included in a clinical trial, cannot be charged to the hospital budget but which must be borne either by the trial sponsor or by a third party who funds research. This cost of the research will be very clearly differentiated from the cost of the treatment the patient would have received anyway if he had not been included in this research.

Standard operating procedures A standard

operating procedure (SOP) presents in writing the details of the actions to be carried out during a measurement to be carried out or a decision to be made in a research protocol.

The advantage of a standard operating procedure is that it encourages all the investigators to work in the same way and that it avoids unfortunate oversights. All kinds of SOPs can be written in clinical research concerning the responsibilities of the sponsor, CRAs, investigators, auditors and inspectors. SOPs must be regularly updated, dated and signed by the person responsible for drafting them.

APPENDIX B
DECLARATION OF INTENT TO CONDUCT A TEST
OF A PHARMACEUTICAL PRODUCT

Declaration date ___/___/____/

1. Promoter (name or denomination and address)	Registration by the administration Number: Date: ___/___/_____/ Stamp

2. Essay Title:

3. Objective:

4. Research with direct individual benefit: Yes no

5. Clinical experimentation phase (I, IIa, IIb, III, IV):

6. Test:

controlled:	multicenter:	international:
randomized:	single-blind:	double blind:
crossover:	parallel groups:	open:
other, to be specified:		

7. Observational study: /___/
Pharmacovigilance /___/ Prevalence /___/
Pharmacoepidemiology /___/ Cohort / Pharmacoeconomics /___/
___/ other, to be specified: Case-controls /___/

8. Bioequivalence study: /___/

9. Expected start date of research: ___/___/_____/

10. Expected duration:

DRUG OR PRODUCT STUDIED

(If the trial involves multiple drugs or products,
use a page for each of them)

11. Special name:

12. Codename:

13. Scientific name and INN of the active ingredient(s):

14. Pharmaceutical form (pharmacopoeia):

15. Qualitative and quantitative composition (using common names international):

16. New active ingredient: yes no

17. Dosage:

18. Manufacturer(s) [name(s) or denomination(s) and place(s) of manufacture]:

19. D. E or MA: -

Algeria: yes refusal - Abroad (list the main countries): no suspension withdrawal

REFERENCE MEDICINE OR PRODUCT

20. Special name:

21. Scientific name and INN of the active ingredient(s):

22. Pharmaceutical form (pharmacopoeia):

23. Qualitative and quantitative composition of active principles (using the names international municipalities):

24. Dosage:

25. Manufacturer(s) [name(s) or denomination(s) and place(s) of manufacture]:

PLACEBO

26. Pharmaceutical form (pharmacopoeia):

27. Manufacturer(s) [name(s) or denomination(s) and place(s) of manufacture]:

INVESTIGATOR(S)

28. Surname(s) and First name(s)	31. Quality	32. Place of fulfillment

RESEARCH PEOPLE

29. Expected number of people:

30. Therapeutic indication:

31. Main inclusion criteria:

32. Duration of treatment or participation per person:

ETHICS COMMITTEE

33. Committee (name and address:

34. Favorable opinion
Unfavorable opinion

35. Date of notice:

ASSURANCE

36. Insurance company (name or denomination):

37. Contract number taken out:

Send 3 copies of this declaration to the DPHM

APPENDIX D
EVENT COLLECTION SHEET
SERIOUS UNWANTED

STUDY :

PROTOCOL:

1. PATIENT INFORMATION:

Last name : First name :

Patient number

Gender: F M

Date of Birth :

Weight : Cut :

2. DECLARER

Promoter:

Last name : Function :

Phone : Fax:

Investigator:
Test center:

Last name : Function :

Phone : Fax:

3 MEDICATIONS ADMINISTERED

Medications) of the study	Route Dose		Dated		Reason for prescription
			Start Stop		

Medications) associates	Channel Dose		Dated		Reason for limitation
			Start Stop		

4. DESCRIPTION OF THE EVENT

(clinical and paraclinical signs)

Date of occurrence *(day, month, year):* /__/__/ /__/__/ /__/__/

Delay after last intake (day, hour, minute) : /__/__/ /__/__/ /__/__/

Evolution : - Spontaneous regression Yes No

- Regression under treatment yes no

Corrector: - Persistence: yes no - Aggravation: yes no

Imputability: - Excluded: yes no - Possible: yes no

- Likely: yes no - Very likely: yes no

Taken measures :

Any

Corrective treatment

Discontinuation of suspected drug

Re-administration of suspected product: YES NO

Recurrence of the event: YES NO

5. COMMENTS

Dated **Stamp** **Signature of declarant:**

APPENDIX C

NATIONAL CLINICAL TRIALS REGISTER

No.	Date of filing	Promoter / Test monitor	Principal Investigator	Trial Product	Title of trial	Date of authorization	Type of trial (phase)	Report of results	Observation

COUNCIL OF EUROPE
CONSEIL DE L'EUROPE

European Treaties Series - No. 164

Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine *

Oviedo, 4.IV.1997

Preamble

The member States of the Council of Europe, the other States and the European Community which are signatories to this Convention,

Considering the Universal Declaration of Human Rights, proclaimed by the General Assembly of the United Nations on December 10, 1948;

Considering the Convention for the Protection of Human Rights and Fundamental Freedoms of November 4, 1950;

Considering the European Social Charter of 18 October 1961;

Considering the International Covenant on Civil and Political Rights and the International Covenant on Economic, Social and Cultural Rights of December 16, 1966;

Considering the Convention for the protection of individuals with regard to the automatic processing of personal data of January 28, 1981;

Also considering the Convention on the Rights of the Child of November 20, 1989;

Considering that the aim of the Council of Europe is to achieve greater unity between its members, and that one of the means of achieving this aim is the safeguarding and development of human rights and fundamental freedoms;

Conscious of the rapid developments in biology and medicine;

Convinced of the need to respect human beings both as individuals and in their belonging to the human species and recognizing the importance of ensuring their dignity;

Aware of acts that could endanger human dignity through improper use of biology and medicine;

(*) The Treaty of Lisbon amending the Treaty on European Union and the Treaty establishing the European Community entered into force on 1 December 2009. Therefore, from that date, any mention of the European Economic Community must be read like the European Union.

Affirming that advances in biology and medicine should be used for the benefit of present and future generations;

Emphasizing the need for international cooperation so that all of humanity benefits from the contribution of biology and medicine;

Recognizing the importance of promoting public debate on the questions posed by the application of biology and medicine, and on the answers to be given to them;

Wishing to remind each member of society of their rights and responsibilities;

Taking into account the work of the Parliamentary Assembly in this field, including Recommendation 1160 (1991) on the elaboration of a bioethics convention;

Resolved to take, in the field of the applications of biology and medicine, appropriate measures to guarantee the dignity of the human being and the fundamental rights and freedoms of the person,

Have agreed as follows:

Chapter I – General provisions

Article 1 – Object and purpose

The Parties to this Convention shall protect human beings in their dignity and identity and guarantee to everyone, without discrimination, respect for their integrity and for their other rights and fundamental freedoms with regard to the applications of biology and the medicine.

Each Party shall take the necessary measures in its domestic law to give effect to the provisions of this Convention.

Article 2 – Primacy of the human being

The interest and good of human beings must prevail over the sole interest of society or science.

Article 3 – Equitable access to health care

The Parties shall take, taking into account health needs and available resources, the appropriate measures to ensure, within their sphere of jurisdiction, equitable access to health care of appropriate quality.

Article 4 – Professional obligations and rules of conduct

Any intervention in the field of health, including research, must be carried out in compliance with professional standards and obligations, as well as the rules of conduct applicable in the case.

Chapter II – Consent

Article 5 – General rule

An intervention in the field of health may only be carried out after the person concerned has given his free and informed consent to it.

This person receives prior adequate information as to the purpose and nature of the intervention as well as its consequences and risks.

The person concerned may, at any time, freely withdraw their consent.

Article 6 – Protection of persons not able to consent

1 Subject to Articles 17 and 20, an intervention may not be carried out on a person not having the capacity to consent, only for his direct benefit.

2 When, according to the law, a minor does not have the capacity to consent to an intervention, this cannot be carried out without the authorization of his representative, of an authority or of a person or body designated by the law.

The opinion of the minor is taken into consideration as an increasingly decisive factor, depending on his age and degree of maturity.

3 When, according to the law, an adult does not have, due to a mental handicap, an illness or for a similar reason, the capacity to consent to an intervention, this cannot be carried out without the authorization of his representative, an authority or a person or body designated by law.

The person concerned must, as far as possible, be involved in the authorization procedure.

4 The representative, authority, person or body mentioned in paragraphs 2 and 3 receive, under the same conditions, the information referred to in Article 5.

5 The authorization referred to in paragraphs 2 and 3 may be withdrawn at any time in the interest of the data subject.

Article 7 – Protection of persons suffering from a mental disorder

A person suffering from a serious mental disorder may be subjected, without his consent, to an intervention intended to treat that disorder only when the absence of such treatment risks being seriously prejudicial to his health and under subject to the conditions of protection provided for by law, including monitoring and control procedures as well as remedies.

Article 8 – Emergency situations

When due to an emergency situation the appropriate consent cannot be obtained, any medically necessary intervention may be carried out immediately for the benefit of the health of the person concerned.

Article 9 – Previously expressed wishes

Previously expressed wishes regarding medical intervention by a patient who, at the time of the intervention, is not in a condition to express his or her wishes will be taken into account.

Chapter III – Privacy and right to information

Article 10 – Privacy and right to information

1 Everyone has the right to respect for his private life with regard to information relating to his health.

2 Everyone has the right to know any information collected about their health. However, the
a person's wish not to be informed must be respected.

3 Exceptionally, the law may provide, in the patient's interest, for restrictions on the exercise of the rights mentioned in paragraph 2.

Chapter IV – Human Genome

Article 11 – Non-discrimination

Any form of discrimination against a person because of their genetic heritage is prohibited.

Article 12 – Predictive genetic tests

Predictive tests for genetic diseases or allowing either the identification of the subject as a carrier of a gene responsible for a disease or the detection of a genetic predisposition or susceptibility to a disease may only be carried out for medical or medical research, and subject to appropriate genetic counselling.

Article 13 – Interventions on the human genome

An intervention aimed at modifying the human genome can only be undertaken for preventive, diagnostic or therapeutic reasons and only if its aim is not to introduce a modification in the genome of the offspring.

Article 14 – Non-selection of sex

The use of techniques of medically assisted procreation is not allowed to choose the sex of the unborn child, except with a view to avoiding a serious hereditary disease linked to the sex.

Chapter V – Scientific research

Article 15 – General rule

Scientific research in the field of biology and medicine is exercised freely subject to the provisions of this Convention and other legal provisions which ensure the protection of human beings.

Article 16 – Protection of persons undergoing research

No research may be undertaken on a person unless the following conditions are met:

i there is no alternative method to research on human beings of comparable effectiveness;

ii the risks that may be incurred by the person are not disproportionate to the potential benefits of the research;

iii the research project has been approved by the competent authority, after having undergone an independent examination in terms of its scientific relevance, including an assessment of the importance of the research objective, as well as a multidisciplinary review of its ethical acceptability;

iv the person undergoing research is informed of his rights and of the guarantees provided by law for his protection;

v the consent referred to in Article 5 has been given expressly, specifically and is recorded in writing. This consent can be freely withdrawn at any time.

Article 17 – Protection of persons who do not have the capacity to consent to research

1 A search may only be undertaken on a person who does not have, in accordance with Article 5, the capacity to consent thereto if the following conditions are met:

i the conditions set out in Article 16, sub-paragraphs i to iv, are met;

ii the expected results of the research include a real and direct benefit for his health;

iii research cannot be carried out with comparable efficiency on subjects capable of consenting to it;

iv the authorization provided for in Article 6 has been given specifically and in writing; and

v the person does not refuse it.

2 Exceptionally and under the conditions of protection provided for by law, research whose expected results do not entail any direct benefit to the health of the person may be authorized if the conditions set out in paragraphs i, iii, iv and v of the paragraph 1 above and the following additional conditions are met:

i the purpose of research is to contribute, through a significant improvement in the scientific knowledge of the person's condition, disease or disorder, to the eventual achievement of results allowing a benefit for the person concerned or for other persons in the same age category or suffering from the same disease or disorder or having the same characteristics;

ii the research presents only minimal risk and minimal burden to the person.

Article 18 – Research on embryos *in vitro*

1 Where research on *in vitro* embryos is permitted by law, the latter shall ensure adequate protection of the embryo.

2 The creation of human embryos for research purposes is prohibited.

Chapter VI – Removal of organs and tissues from living donors for the purpose of transplantation

Article 19 – General rule

1 The removal of organs or tissues for the purpose of transplantation may only be carried out on a living donor in the therapeutic interest of the recipient and when no suitable organ or tissue is available from a deceased person or alternative therapeutic method of comparable efficacy.

2 The consent referred to in Article 5 must have been given expressly and specifically, either in writing or before an official body.

Article 20 – Protection of persons who do not have the capacity to consent to organ harvesting

1 No organ or tissue removal may be performed on a person who has not the capacity to consent in accordance with Article 5.

2 Exceptionally and under the conditions of protection provided for by law, the removal of regenerative tissue from a person who does not have the capacity to consent may be authorized if the following conditions are met:

i there is no compatible donor with capacity to consent;

ii the recipient is a sibling of the donor;

iii the donation must be of a nature to preserve the life of the recipient;

iv the authorization provided for in paragraphs 2 and 3 of article 6 has been given specifically and in writing, in accordance with the law and in agreement with the competent body,

v the potential donor does not refuse it.

Chapter VII – Prohibition of profit and use of a part of the human body

Article 21 – Prohibition of profit

The human body and its parts should not be, as such, a source of profit.

Article 22 – Use of a removed part of the human body

When a part of the human body has been removed during an intervention, it may only be stored and used for a purpose other than that for which it was removed in accordance with the appropriate information and consent procedures.

Chapter VIII – Violation of the provisions of the Convention

Article 23 – Infringement of rights or principles

The Parties shall ensure appropriate judicial protection in order to prevent or put an end to any unlawful interference with the rights and principles recognized in this Convention without delay.

Article 24 – Compensation for unjustified damage

A person who has suffered unjustified damage resulting from an intervention is entitled to fair compensation under the conditions and in the manner provided by law.

Article 25 – Penalties

The Parties shall provide for appropriate sanctions in the event of failure to comply with the provisions of this Convention.

Chapter IX – Relationship of this Convention to other provisions

Article 26 – Restrictions on the exercise of rights

1 The exercise of the rights and the provisions of protection contained in this Convention may not be subject to restrictions other than those which, provided for by law, constitute measures necessary, in a democratic society, for public safety, the prevention of criminal offences, the protection of public health or the protection of the rights and freedoms of others.

2 The restrictions referred to in the preceding paragraph cannot be applied to Articles 11, 13, 14, 16, 17, 19, 20 and 21.

Article 27 – Extended protection

None of the provisions of this Convention shall be interpreted as limiting or impairing the option for each Party to grant more extensive protection with regard to the applications of biology and medicine than that provided for in this Convention.

Chapter X – Public debate

Article 28 – Public debate

The Parties to this Convention shall ensure that the fundamental questions raised by developments in biology and medicine are the subject of appropriate public debate in the light, in particular, of the medical, social, economic, ethical implications relevant legal and legal instruments, and that their possible applications are the subject of appropriate consultations.

Chapter XI – Interpretation and monitoring of the Convention

Article 29 – Interpretation of the Agreement

The European Court of Human Rights may, apart from any specific litigation taking place before a court, give advisory opinions on legal questions concerning the interpretation of this Convention at the request of:

– the Government of a Party, after informing the other Parties;

– the Committee set up by Article 32, in its composition restricted to the Representatives of the Parties to this Convention, by decision taken by a two-thirds majority of the votes cast.

Article 30 – Reports on the application of the Convention

Each Party shall provide, at the request of the Secretary General of the Council of Europe, the required explanations on the manner in which its internal law ensures the effective application of all the provisions of this Convention.

Chapter XII – Protocols

Article 31 – Protocols

Protocols may be drawn up in accordance with the provisions of Article 32, with a view to developing, in specific fields, the principles contained in this Convention.

The protocols are open for signature by the signatories of the Convention. They will be subject to ratification, acceptance or approval. A signatory cannot ratify, accept or approve the protocols without having previously or simultaneously ratified, accepted or approved the Convention.

Chapter XIII – Amendments to the Convention

Article 32 – Amendments to the Convention

1 The tasks assigned to the “Committee” in this Article and in Article 29 are carried out by the Steering Committee on Bioethics (CDBI), or by any other committee designated for this purpose by the Committee of Ministers.

2 Without prejudice to the specific provisions of Article 29, any member State of the Council of Europe and any Party to this Convention which is not a member of the Council of Europe may be represented on the committee, when the latter carries out the tasks entrusted by this Convention, and has one vote therein.

3 Any State referred to in Article 33 or invited to accede to the Convention in accordance with the provisions of Article 34, which is not a Party to this Convention, may appoint an observer to the committee. If the European Community is not a Party, it may appoint an observer to the committee.

4 In order to take account of scientific developments, this Convention shall be the subject of a review within the committee within a maximum period of five years after its entry into force, and thereafter at intervals which the committee may determine.

5 Any proposed amendment to this Convention and any proposed protocol or amendment to a protocol, submitted by a Party, by the committee or the Committee of Ministers, shall be communicated to the Secretary General of the Council of Europe and transmitted by it to the member States of the Council of Europe, to the European Community, to any signatory, to any Party, to any State invited to sign this Convention in accordance with the provisions of Article 33, and to any State invited to accede to it in accordance with the provisions of Article 34.

6 The committee examines the proposal at the earliest two months after it has been sent by the Secretary General in accordance with paragraph 5. The Committee submits the text adopted by a two-thirds majority of the votes cast for approval by the Committee of Ministers. After its approval, this text is communicated to the Parties with a view to its ratification, acceptance or approval.

7 Any amendment shall enter into force for those Parties which have accepted it on the first day of the month following the expiration of a period of one month after the date on which five Parties, including at least four member States of the Council of Europe, will have informed the Secretary General that they have accepted it.

For any Party which subsequently accepts it, the amendment shall enter into force on the first day of the month following the expiration of a period of one month after the date on which the said Party informed the Secretary General of its acceptance.

Chapter XIV – Final clauses

Article 33 – Signature, ratification and entry into force

1 This Convention is open for signature by member States of the Council of Europe, non-member States which have participated in its elaboration and the European Community.

2 This Convention shall be subject to ratification, acceptance or approval. Instruments of ratification, acceptance or approval shall be deposited with the Secretary General of the Council of Europe.

3 This Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date on which five States, including at least four member States of the Council of Europe, have expressed their consent to be bound by the Agreement, in accordance with the provisions of the preceding paragraph.

4 For any Signatory who subsequently expresses its consent to be bound by the Convention, it shall enter into force on the first day of the month following the expiration of a period of three months after the date of deposit of its instrument of ratification, acceptance or approval.

Article 34 – Non-member States

1 After the entry into force of this Convention, the Committee of Ministers of the Council of Europe may, after consulting the Parties, invite any State which is not a member of the Council of Europe to accede to this Convention by a decision taken by the majority provided for in Article 20, paragraph d, of the Statute of the Council of Europe and by the unanimous vote of the representatives of the Contracting States entitled to sit on the Committee of Ministers.

2 For any acceding State, the Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date of deposit of the instrument of accession with the Secretary General of the Council of Europe .

Article 35 – Territorial application

1 Any Signatory may, at the time of signature or when depositing its instrument of ratification, acceptance or approval, specify the territory or territories to which this Agreement will apply. Any other State may make the same declaration when depositing its instrument of accession.

2 Any Party may, at any time thereafter, by a declaration addressed to the Secretary General of the Council of Europe, extend the application of this Convention to any other territory specified in the declaration and for whose international relations it is responsible or for which it is empowered to stipulate. The Convention shall enter into force with respect to that territory on the first day of the month following the expiration of a period of three months after the date of receipt of the declaration by the Secretary General.

3 Any declaration made under the two preceding paragraphs may be withdrawn, in respect of any territory specified in such declaration, by notification addressed to the Secretary General. The withdrawal will take effect on the first day of the month following the expiration of a period of three months after the date of receipt of the notification by the Secretary General.

Article 36 – Reservations

1 Any State and the European Community may, at the time of signature of this Convention or of deposit of the instrument of ratification, acceptance, approval or accession, make a reservation in respect of any particular provision of the Convention to the extent that any law then in force in its territory is not in conformity with this provision. Reservations of a general nature are not permitted under this article.

2 Any reservation made in accordance with this article shall include a brief statement of the law relevant.

3 Any Party which extends the application of this Convention to a territory designated by a declaration provided for in application of paragraph 2 of Article 35 may, for the territory concerned, make a reservation, in accordance with the provisions of the preceding paragraphs.

4 Any Party which has made the reservation referred to in this article may withdraw it by means of a declaration addressed to the Secretary General of the Council of Europe. The withdrawal will take effect on the first day of the month following the expiration of a period of one month after the date of receipt by the Secretary General.

Article 37 – Denunciation

1 Any Party may, at any time, denounce this Convention by sending a notification to the Secretary General of the Council of Europe.

2 The denunciation shall take effect on the first day of the month following the expiration of a period of three months after the date of receipt of the notification by the Secretary General.

Article 38 – Notices

The Secretary General of the Council of Europe will notify the member states of the Council, at the European Community, to any Signatory, to any Party and to any other State which has been invited to accede to this Convention:

has any signature;

b the deposit of any instrument of ratification, acceptance, approval or accession;

c any date of entry into force of this Convention, in accordance with its sections 33 or 34;

d any amendment or protocol adopted in accordance with Article 32, and the date on which such amendment or protocol enters into force;

e any declaration made under the provisions of Article 35;

f any reservation and any withdrawal of reservation made in accordance with the provisions of Article 36;

g any other act, notification or communication relating to this Agreement.

In witness whereof, the undersigned, being duly authorized thereto, have signed this Agreement.

Done at Oviedo (Asturias), this 4th day of April 1997, in English and French, both texts being equally authentic, in a single copy which shall be deposited in the archives of the Council of Europe. The Secretary General of the Council of Europe shall communicate a certified copy thereof to each of the member States of the Council of Europe, to the European Community, to the non-member States which have participated in the elaboration of this Convention, and to any State invited to accede to this Convention.