Contemporary Readingsin Law and Social Justice
ISSN: 1948-9137, e-ISSN: 2162-2752
Vol 17 (01), 2025
pp. 1294 - 1304

Civil liability of the promoter in clinical studies

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ABSTRACT:

Clinical research is increasingly recognised as a regulated field that enables high-quality studies to be conducted while ensuring the safety and protection of participants' rights. The aim is to develop biological or medical knowledge, initiated by the promoter with the assistance of the research physician. The process involves preparing the study protocol, obtaining authorisation from the minister responsible for the pharmaceutical industry and adhering to legally specified conditions. Participants must also give their informed consent after being made aware of the associated benefits and risks. The promoter's civil liability arises as soon as harm occurs to an individual participating in the study.

Keywords: Clinical study, protocol, human subject, promoter, liability.

Received: 12/05/2025 **Accepted: 26/10/2025** **Published: 12/12/2025**

Introduction

Undoubtedly, advancements in medicine and pharmacy are the result of scientific research and continuous studies initially conducted[1] on animals and then on humans. These studies are fundamental to the progress of science, especially in the medical field.

Clinical studies are necessary to achieve physical and health well-being, and therefore must continue. However, individuals participating in clinical studies may face numerous risks while attempting to discover new treatment methods for combating diseases, especially challenging ones. The results of these studies may harm the individuals themselves. Consequently, modern health laws adopt the principle of rejecting risks to participants' health in the pursuit of new therapeutic and diagnostic methods. Clinical studies may be conducted on healthy volunteers as well as patients[2].

Clinical research is becoming an increasingly regulated field, enabling high-quality research while ensuring the safety and protection of participants' rights[3].

The issue addressed in this topic is: What is the legal basis for the promoter's liability in the event of a breach of their obligations or failure to observe legally stipulated guidelines when conducting a clinical study, depending on whether the study offers direct individual benefit?

To address this issue, I have divided the topic into three main sections. The first section addresses the concept of clinical studies and the conditions required for their conduct. The second section focuses on the

1- Priscilla Mortio, 'L'air'. The Different Regulatory Procedures to Be Followed in Health Research in Haute-Normandie: Development of a Computer-Aided Tool', Doctorate in Medicine, Mixed Faculty of Medicine and Pharmacy, Rouen, 2017, p. 21.
2- Salha Al-Amri. 'Medical Doctors' Civil Liability for Medical Experiments in Algerian Law', Judicial Jurisprudence Journal, No. 15, 2017, p. 220.
3- Frairrot Marjolaire. 'Regulatory Developments in Clinical Research', Doctorate in Pharmacy, Pharmacy Department, University of Rouen, 2019, p. 22.

obligations and restrictions placed on promoters in clinical studies. The third section explores the basis of promoters' liability for breaching their legally stipulated obligations.

Section One: The Concept of Clinical Studies and the Conditions Required to Conduct Them

Clinical studies have attracted legislative attention over time because they involve sensitive research on human subjects. These studies often involve new types of drugs and intensify research on specific age groups in response to public health concerns, particularly with regard to epidemics, communicable diseases, diagnosis and treatment, and the development of health practices. This is addressed by the legislator in Chapter Seven, titled 'Ethics and Medical Bioethics', specifically in Section Four: Provisions Related to Research in Biomedicine.

Therefore, it is necessary to define clinical studies (Subsection One), outline the role of the promoter (Subsection Two), and summarise the previously specified legal conditions (Subsection Three).

Subsection One: Definition of Clinical Studies

There is a distinction between the legislative definition of clinical studies (First) and the doctrinal definition (Second).

First: Legislative definition of clinical studies

The legislator defined clinical studies as biomedical research involving human subjects, with the aim of developing epidemiological, diagnostic, biological and therapeutic knowledge, particularly with a view to improving medical practices. Clinical studies may be purely observational, involving no intervention on human subjects, or interventional. The latter category includes therapeutic, diagnostic and preventive studies, as well as bioequivalence and bioavailability studies, along with epidemiological and pharmacological epidemiological studies[4].

The French legislator defines clinical studies in Article L. 1121-1 of the Public Health Code as follows: 'An organisation of research conducted on human subjects aimed at developing biological or medical knowledge, authorised according to the conditions specified in this book and referred to as "research involving human subjects".'

Three categories of research involving humans:

1. Interventional research: This involves interventions on individuals that are not justified by their usual healthcare.

2. Interventional research with minimal risks: This category includes research involving only minimal risks and constraints, as set out in a decree by the Minister for Health, following consultation with the Director General of the National Agency for the Safety of Medicines and Health Products.

3. Non-interventional research: This type of research does not involve any risk or limitations[5].

Second: doctrinal definition

Legal doctrine defines clinical studies as follows: 'A deviation from established medical and technical principles for the purpose of collecting scientific and technical data or acquiring new knowledge, aimed at advancing medical science and conducted by a research physician on a patient or healthy volunteer to test the effects of a specific drug.[6]'

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[4]- Article 377 of Law No. 18/11 dated 2 July 2018 concerning health, as amended and supplemented (Official Gazette No. 46).

[5]- The French legislator used the term 'clinical research' (recherche clinique) instead of 'clinical study' (étude clinique) in the amendment made by Order No. 2022/1086 on 29 July 2022 to the French Public Health Code, considering that 'research' encompasses a broader meaning than 'study'.

[6]- Rahma Mu'tab Sultan Al-Adwan. 'Criminal Protection of the Human Body from Pharmaceutical Experiments: A Comparative Study', Arab Journal for Scientific Publishing, No. 22, Al-Ahliyya Amman University, 2020, p. 241.

Subsection Two: Definition of the Promoter in Clinical Studies

The promoter may be a natural person with the necessary qualifications and scientific competencies, or a legal entity, such as a pharmaceutical company, aiming to find treatments for challenging medical conditions[7]. This activity is characterised by complexity and ambiguity, while respecting the scientific foundations and ethical principles established by law that govern medical practice during clinical studies[8].

The legislator defines the promoter in Article 384 of Law No. 18/11 concerning health: '... the promoter is a natural or legal person who initiates the clinical study, and may be a pharmaceutical laboratory, a service provider accredited by the ministry responsible for the pharmaceutical industry, a healthcare institution, a scientific association, a research organisation or a qualified healthcare practitioner.'

This definition is broader than that provided by the French legislator in Articles L1121-1 and L1121-2, which state that the promoter is a natural or legal person who is responsible for research involving human subjects, manages it, and ensures that funding is available.

The European Union defines the promoter in Regulation No. 536/2014, Article 2, Point 14, as follows: 'The person, company, institute or organisation responsible for initiating, managing, organising and funding clinical trials[9].'

Subsection Three: Required Conditions for Conducting Clinical Studies

A promoter may only initiate a clinical study involving human subjects if all the conditions specified in Article 380 of Law No. 18/11 concerning health are met. This ensures that the welfare of individuals participating in the study is prioritised above all else. These conditions are as follows:

1. Foundation on current research and knowledge: The study must be based on the latest advancements in clinical research, scientific knowledge and sufficient preclinical experience. It should rely on existing data and prior knowledge related to the study topic, including tests and predictions of potential risks[10]. The promoter must be well-versed in modern scientific principles, and the study must be evaluated by the Ministry of the Pharmaceutical Industry[11]. It must also be reviewed by the medical ethics committee for clinical studies, particularly with regard to the risk/benefit assessment, and by the National Ethics Committee in Health Sciences[12].

2. Favorable Benefit-Risk Ratio: The expected benefits must outweigh the proposed risks for each individual involved in the study. No study should be conducted if the benefits do not outweigh the expected risks for the participant. The principle of proportionality applies in all situations to protect those involved. This is particularly emphasised for minors, who can only participate in therapeutic studies if they will directly benefit, and for pregnant and breastfeeding women, who should generally not take part in clinical studies unless it can be assured that they will not be at significant risk to their health, and unless

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[7]- Imad Eddine Barakat, Hamadi Mohammed Reda. 'The new legal constraints on conducting medical experiments on the human body in light of the new Algerian health law no. 18/11', International Law and Development Journal, vol. 8, no. 2, 2020, pp. 95–119, p. 98.

[8]- Nasaf Souad. 'Guarantees for conducting medical and scientific experiments on humans according to Health Law No. 18-11', Research Journal in Contracts and Business Law, Vol. 6, No. 4, 2021, p. 29.

[9]- Article 2(14) of Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use and repealing Directive 2001/20/EC.

[10]- Ibtisam Si Ali. 'The Idea of Legal Balance between the Right to Conduct Medical Experiments on the Human Body and the Right to Compensation', Journal of Legal and Economic Research, Vol. 5, No. 2, 2022, p. 209.

[11]- The legislator subjected clinical studies to the opinion of the Medical Ethics Committee, as stated in Articles 382 and 383 of Law No. 18/11. However, to date, no regulatory text has been issued to clarify the committee's role, tasks, formation, organisation and operation.

[12]- Nadia Khadoudja Hammadi. 'Legal Protection of the Human Body in Biomedical Research and Its Applications in Algerian Law', Doctorate in Law, Faculty of Law, University Aboubekr Belkaid, Tlemcen, 2014, p. 205.

the research is essential for understanding pregnancy[13], childbirth or breastfeeding. The research physician must evaluate the anticipated risks against the expected benefits and avoid clinical studies that do not adhere to the principle of proportionality.

3. Conducted under qualified supervision: The study must be conducted under the management and control of a qualified research physician, who may be a general practitioner or a specialist appointed by the promoter. The promoter relies on the researcher's qualifications and competencies concerning participant safety and the proper conduct of the clinical research[14].

4. Suitable human, material and technical conditions: The study must take place in conditions that align with the requirements of clinical research, adhere to scientific rigour, and ensure the safety of participants.

5. Compliance with good practice guidelines: The clinical study must be conducted in accordance with the relevant good practice guidelines, ensuring the reliability of the information collected and compliance with the laws and regulations that protect the rights of individuals involved in clinical research. Accredited and authorised structures must be established for this purpose, according to the methods specified by the minister responsible for the pharmaceutical industry.

Section Two: Obligations Imposed on the Promoter in Clinical Studies

One of the promoter's and the research physician's most important obligations before beginning a clinical study is to obtain the consent of the individual participating in the study (Subsection One) and to prepare the study protocol (Subsection Two) in order to secure authorisation for the clinical study (Subsection Three).

Subsection One: Obtaining Consent from the Potential Participant

Informed consent from the participant is a fundamental requirement for any intervention that may affect their physical integrity, given the associated risks. This consent is necessary at every stage, after the participant has been informed of the risks and expected benefits of the study. However, it may be impossible for the promoter to obtain the patient's consent in exceptional urgent cases.

First: informed consent of the participant.

In the field of biomedical research, informed consent is an essential procedural guarantee and a means of protecting the participant[15]. It is enshrined in legislation and judicial interpretations[16]. Consent must be given in writing and signed by the participant in the clinical study. This consent must be given voluntarily, after the participant has been informed of the nature, scope, consequences and risks of the study. The individual must be competent and their consent must be explicit, involving a handwritten signature and a fingerprint to confirm their participation in the clinical research.

Second: Informing the Participant in Clinical Research

Both the promoter and the research physician are obligated to inform the participant about the nature of the study, its subject, and the objectives intended by conducting it, along with potential risks. This information allows the individual to make a well-informed decision about their participation. The information provided must be accurate and detailed, meaning consent cannot be granted under coercion[17].

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[13]- Nadia Khadoudja Hammadi, op. cit., p. 217.
[14]- Nadia Khadoudja Hammadi, op. cit., p. 216.
[15]- François Vialla. Major Decisions in Medical Law, Edition Alpha, L.G.D.J., 2010, p. 462, no. 702.
[16]- Nadia Khadoudja Hammadi, op. cit., p. 205.
[17]- Audrey Mellac. 'The Influence of Urgency on Obtaining Consent for Medical Acts under the Direction of the French Association of Health Law', Anne Laude, Dalloz Acts, AFDS, University of Paris, 2014, p. 93.

This consent requires the research physician to present adequate information beforehand, so that the participant fully understands the facts and implications of the study. Key elements of this information should include:

- The purpose of the research

- the methodology employed

- the expected duration of the study

- the potential benefits;

- Anticipated risks and limitations, including the possibility of stopping the research before completion.

In this context, the research physician should identify and detail any risks deemed minimal or exceptional. Furthermore, any restrictions associated with the study must be explained to the participant both verbally and in writing, in order to facilitate open dialogue with those involved in the research and their families.

It is also crucial for the research physician to inform participants of their right to decline or withdraw from the study at any time without facing legal repercussions, harm or loss of subsequent medical care. Participants should be given ample time to consider and decide on their participation[18].

The research physician should also propose possible medical alternatives, particularly in studies that do not offer direct individual benefits, and assess the impact of such trials on the community. Ultimately, both the promoter and the research physician must maintain a written medical file for each patient or participating individual[19].

In cases where obtaining informed consent is not feasible, such as when the participant is unable to provide consent, a legal representative may provide it instead. If the individual is unable to write, they may, in exceptional circumstances, give their personal consent in the presence of at least one witness.

In this context, a ruling was issued by the First Civil Chamber of the French[20] Court of Cassation concerning a patient suffering from glandular cancer who was subjected to a harmful clinical study. The objective of this study was to compare two types of adjuvant chemotherapy and to prove that the drug combination administered to this patient was likely to increase his chances of survival by 10%. After the tumor was removed and the clinical study protocol was applied, the patient experienced complications that necessitated his readmission to the hospital and several surgical interventions.

On 17 October 2008, the patient appealed against the decision of the Paris Court of Appeal, which had rejected all requests to hold the promoter (the Cancer Research Association at the Nancy Hospital, L'APREC) and the hospital's private insurance company liable[21].

The civil chamber held that, once the patient had been subjected to a harmful and foreseeable clinical study, it was necessary to establish whether they could expect any benefit from it. The Chamber affirmed that the promoter was liable because evidence demonstrated that L'APREC had not made any errors that caused the patient irreparable harm. However, the chamber was criticised for not verifying whether the patient could anticipate any benefits from the clinical study in which he had consented to participate.

Before conducting biomedical research on an individual, the research physician must provide clear and adequate information regarding the expected benefits and risks, including the possibility of stopping the research. The patient claimed to have experienced all the side effects mentioned in the information sheet provided to him, including rare occurrences such as persistent tearing and recurrent conjunctivitis, which

[18]- Nadia Khadoudja Hammadi, op. cit., p. 207.
[19]- Marie Maguin. 'Regulatory Launch of Clinical Trials Involving Human Medicinal Products in France and the UK: Towards a Unique European Procedure', Doctorate in Pharmacy, Faculty of Pharmacy, University of Lorraine, 2014, p. 20.
[20]- Court of Cassation, First Civil Chamber, 14 January 2010, No. 8-21683: Biomedical research – Liability – Sponsor – Duty to inform.
[21]- Association for Cancer Research.

rendered these injuries irreversible. This contradicted the written information document, which stated that the likelihood of these side effects was minimal or non-existent. The patient also argued that the information sheet listed so many side effects that it became incomprehensible.

The ruling indicated that L'aprec had fulfilled its duty to provide information prior to initiating the clinical study, but had not verified whether this information was clear and accessible to the average person. Consequently, the Court of Appeal overturned its decision with regard to the application of Article L1122-1 as formulated by the law of 20 December 1988.

Third: cases where obtaining consent from the participant is not possible.

In urgent situations, it may not be possible to obtain prior consent from the individual; however, the protocol must specify that consent from the person is not required. Instead, consent should be sought from family members or another trusted individual.

Article L1122-1-2 of the Public Health Code stipulates that consent from these individuals must be obtained after they have been informed upon their arrival, and that this consent must be given in writing. Furthermore, nothing prevents biomedical research from being conducted in the absence of family members or a trusted person, without their consent, as indicated by the aforementioned article.

A ruling from the Criminal Chamber of the French Court of Cassation addressed a study conducted on a patient with acute respiratory syndrome who was admitted to the emergency department. He was treated with a drug that was part of a clinical study focused on pneumonia without following the necessary procedures for clinical research. The research physician was faced with an urgent situation that did not allow him to obtain prior consent from the patient. Despite his severe weakness, the patient was conscious upon arrival at the hospital and refused to sign the consent form associated with the informational document regarding the comparative study of the two trial drugs, Du Zirecin versus Ceftriascone, for treating acute pneumonia infections[22].

The Criminal Chamber upheld the decision to convict the research physician of conducting the clinical study without the patient's consent. The patient was in a weakened state and thus unable to provide free, informed and explicit consent. The physician was sentenced to two months in prison, suspended. The court deemed that this research did not constitute absolutely necessary treatment, which can only be administered in emergency situations.

Biomedical research is not a therapeutic act in the strict sense; therefore, it cannot be performed on a patient who refuses to participate, even in urgent situations, unless it is essential for the person's survival. Furthermore, refusal cannot be considered rejection of a life-saving therapeutic intervention. Since biomedical research constitutes an intervention that goes beyond the ordinary medical care of the patient, the rules that protect individuals and their dignity in the context of medical research must not be disregarded due to urgency[23].

Subsection Two: Preparing the Protocol for Clinical Studies

The protocol is a reference document that accurately describes the research and specifies the conditions under which the study should be conducted and managed, in order to avoid ambiguity in interpretation or subsequent improvisation[24]. In other words, it outlines the study's objectives, design, methodology and organisation. The term 'protocol' also encompasses successive versions and amendments[25].

This essential document includes a detailed plan that provides clear answers to all questions posed by participants in the clinical research. It ensures the scientific quality of the trial. Initially, the promoter must detail the research project as thoroughly as possible, adhering to the requirements of good clinical

[22]- Crim, 24 February 2009, No. 08-84436, Bull Crim, February 2009, No. 45.
[23]- Andray Mellac, op. cit., p. 94.
[24]- Order No. 388, dated 31 July 2006, setting out the procedures for conducting a clinical trial.
[25]- Article 2(22) of Regulation (EU) No 536/2014 of the European Parliament.

practice[26]. According to Article 385 of Law No. 18/11, the promoter must prepare the clinical study, the research physician must sign it, and the physician must express their consent to the protocol and commit to complying with the study's conditions. The protocol must also include the individual's consent to participate in the study[27].

Subsection Three: The necessity of obtaining authorisation for research

The process of conducting clinical studies, whether therapeutic or non-therapeutic, requires authorisation from the minister responsible for the pharmaceutical industry. After the promoter submits a medical and technical file, along with a declaration regarding the implementation of the clinical study on human subjects, the minister must make a decision within three months regarding acceptance or rejection. The file includes the research protocol, and the minister has three months to decide whether to accept or reject it.

Amendments to the clinical study file are permitted after authorisation has been obtained; however, it must be determined whether the amendment is substantial. If the amendment is substantial, the promoter must notify the minister of this change and obtain new authorisation. Examples of substantial changes include altering the participants in the study, changing its subject or objective, extending its duration, changing its location, or increasing or decreasing the number of medical staff.

The purpose of obtaining authorisation for the study is to prevent any deviations from the content specified in the authorisation. It serves as a guarantee and security for the participants, ensuring their safety[28].

Subsection Four: Implementing Necessary Measures for the Safety of the Experimental Drug According to Quality Standards

The promoter's involvement does not end with the completion of the clinical study. They are responsible for continuously evaluating the safety of the experimental drug, as it may cause serious, undesirable or unexpected side effects or new safety issues during or after the study. They must promptly notify the minister in charge of the pharmaceutical industry, the relevant medical ethics committee and all concerned research physicians within seven days at most.

The promoter must implement written measures that meet the required quality standards for each stage of data collection. This ensures the protection of data, as well as the documentation of incidents and adverse effects. These measures must be validated, assessed, archived and reported accordingly[29].

Subsection Five: Prior supervision of the clinical study process

The clinical research project is subject to prior supervision by the relevant administrative authorities, specifically the Directorate of Production, Industrial Development, Export Promotion and Research. This directorate is primarily responsible for promoting biomedical research through clinical studies[30]. The directorate reviews applications to conduct clinical research, prepares the necessary authorisations and monitors their execution[31]. It does this after receiving the National Agency for Pharmaceutical Materials' opinion on the clinical study requests. According to the precautionary principle, it evaluates the potential

[26]- Marie Maguin, op. cit., p. 19.
[27]- The first paragraph of Article 387 of Law No. 18-11 on health, as amended and supplemented.
[28]- Imad Eddine Barakat and Hamadi Mohammed Reda, previous reference, p. 100.
[29]- The second paragraph of Article 395 of Law No. 18-11 concerning health, amended and supplemented.
[30]- Article 2 of Executive Decree No. 20-272, dated 29 September 2020, concerning the organisation of the Central Administration of the Ministry of the Pharmaceutical Industry (Official Gazette No. 58, dated 1 October 2020).
[31]- Article 9 of the resolution of 28 June 2022 setting out the internal organisation of the National Agency for Pharmaceutical Materials (Official Gazette No. 57 of 4 September 2022).

risks to patient health and takes the necessary and appropriate measures in cases of significant health risks[32].

If any risks are identified, the agency or minister responsible for the pharmaceutical industry can prohibit biomedical research at any time.

Section Three: Basis of Promoter Liability in Clinical Studies

Law No. 18/11, as amended, establishes a liability system for biomedical research involving human subjects, with the aim of advancing biological or medical knowledge. The law asserts that the interests of individuals participating in the study take precedence over the interests of science and society.

1. No-Fault Liability System: The law adopts a no-fault liability system, meaning that the promoter can be held liable without needing to prove fault or negligence on their part (Subsection 1).

2. Presumption of Fault: In contrast, the French legislator has implemented a presumption of fault on the part of the promoter in clinical research (Subsection Two). This means that the burden of proof may shift to the promoter, who must demonstrate that they acted responsibly and without fault.

3. Mandatory insurance coverage: Regardless of the liability system in place, the promoter must obtain insurance coverage to protect against their liability (see Subsection Three). This ensures that there is adequate financial backing to address any claims or damages resulting from the clinical study.

Subsection One: Promoter Liability Without Fault

Through Article 391 and subsequent provisions of Law No. 18-11, the legislator established a system of no-fault liability for the promoter. Under this system, the promoter is considered the initiator of the clinical study and is therefore responsible for any adverse outcomes, particularly in studies that do not offer direct individual benefits and must not endanger the health of participants. This represents a heightened level of responsibility for the promoter.

According to Article 393 of Law 18/11, the promoter is liable in all cases, even if no fault is proven. In other words, if a participant can prove that any harm they suffer, such as disability or death, is caused by their participation in the clinical study, they can claim compensation for the harm suffered.

The law imposes genuine obligations regarding safety and outcomes, meaning the promoter cannot evade responsibility by proving an external cause. Furthermore, the legislator distinguishes between clinical studies that result in no direct individual benefits and those that do. In the latter case, promoter liability only arises if the participant is proven to be at fault.

Furthermore, the promoter may provide compensation to individuals willing to participate in a study due to the difficulties they may face in a study that does not offer direct individual benefits. The law stipulates that participants in a clinical study should not receive any direct or indirect financial compensation, except reimbursement of expenses incurred. However, an exception permits financial compensation for participants if the study involves no direct individual benefits[33].

Subsection Two: Liability Based on Presumed Fault

Before the introduction of the European approach on 4 April 2001 in public health law, the promoter's responsibility depended on the type of research initiated. It depended on whether the research provided benefits to the individual participating in it. This criterion was adopted by the French legislator in the Law of 20 December 1980. However, the distinction between types of research was abandoned in the Law of 4

[32]- Mourad Medjnah. Procedural Regulation of Biomedical Research and the Proceduralisation of Bioethics Law, Thémis Editions, Faculty of Law, University of Montreal, 2005, p. 470.

[33]- Article 398 of Law No. 18-11, mentioned above.

March 2002 due to its ambiguity[34]. Protection for research participants was enhanced by requiring prior approval from the relevant authority after a mandatory positive opinion had been obtained from the committee for the protection of persons. This expanded the committee's mandate to include the scientific evaluation of projects. This enabled the committee to assess the risks faced by participants more effectively and strike a better balance between the expected benefits and risks to individuals or public health.

Thus, the liability systems for all damages resulting from clinical research were unified[35]. According to Article L1121-10 of the Public Health Code, the promoter is liable for damages incurred by participants and beneficiaries, unless they can prove that the damage is not attributable to their own or another participant's fault[36], or that of a third party (i.e. the participant), or that of the individual who initially consented to participate in the clinical study and then withdrew their consent.

The promoter's liability is based on presumed fault and functions as a simple presumption, meaning they can escape liability by demonstrating their own or the victim's absence of fault.

Subsection Three: Liability Insurance

Under Article 397 of Law No. 18/11, promoters of interventional clinical studies must obtain insurance that covers their civil and professional liability for their activities. In order to activate the compensation system, the promoter must have insurance in place beforehand. This insurance aims to cover all adverse outcomes, particularly in the context of surgical interventions. Participants in clinical studies, particularly those without direct individual benefits, are entitled to proportional compensation based on the severity of the harm caused.

Under French law, all damages resulting from clinical research are eligible for compensation, either from the promoter's insurance company if their liability is confirmed based on presumed fault, or from the National Office for Compensation of Victims of Medical Accidents through a national solidarity system. However, the promoter must provide evidence that the damage is not attributable to their own or any other intervening party's fault, such as the research physician's[37].

Conclusion:

Scientific research is essential for advancing human knowledge, eradicating epidemics and life-threatening diseases, and improving health practitioner standards and treatment methods, ultimately benefiting society and humanity as a whole. Consequently, the legislator has imposed a series of conditions and regulations on clinical research, designating the promoter as the sole initiator of studies involving human subjects. These activities are subject to prior oversight by the Minister for the Pharmaceutical Industry and other relevant bodies.

Results:

1. Clinical research is fundamentally based on human subjects.

2. The promoter is solely responsible for preparing the clinical study protocol.

3. Authorisation for the research must be obtained from the Ministry of the Pharmaceutical Industry.

4. Clinical studies must comply with the legally defined conditions.

5. The promoter must obtain explicit, informed and written consent from each participant in the clinical study.

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[34]- Djazia Gamouh. Medical Liability in Algerian Law: Internal Realities and Proposals for Updating in Light of French Medical Law', doctoral thesis, Aix-Marseille University, France, 2023, p. 243.
[35]- Anne Laude, Bertrand Mathieu and Didier Tabuteau. Health Law, 3rd edition, PUF, Thémis Law, 2007, p. 470.
[36]- Camille Kouchner. 'Liability in Human Research', Health Law, Gazette du Palais, 2009, pp. 33–34.
[37]- Anne Laude, Bertrand Mathieu and Didier Tabuteau, op. cit., p. 471.

6. The promoter must compensate participants or their beneficiaries in clinical studies without direct individual benefits as soon as harm occurs, regardless of whether the promoter was at fault.

Recommendations:

1. The distinction between clinical studies that provide direct individual benefits and those that do not should be eliminated, ensuring that promoter liability applies in both cases, either on a no-fault or presumed fault basis.

2. Situations preventing consent from being obtained from the participant or a trusted individual (such as a family member) should be clearly defined, enabling the research physician to administer the experimental drug under specific circumstances.

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