Zanteris

ETHICS AND PATIENT RIGHTS IN CLINICAL TRIALS

A PRACTICAL HANDBOOK

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INTRODUCTION

The "Ethics and Patient Rights in Clinical Trials : A Practical Handbook" is a comprehensive guide. The aim of this handbook is to promote the ethical conduct of clinical trials and ensure that patients' rights and welfare are protected. The book emphasizes the importance of ethical principles and patient rights in clinical trials.

Clinical trials are at the forefront of medical research and involve human subjects. Ethics and patient rights are important in clinical trials to ensure that research is conducted in a respectful, fair, and transparent manner. This practical handbook serves as a valuable resource for researchers, healthcare professionals, ethics committees, and stakeholders involved in clinical trials.

It offers clear and concise guidance on navigating ethical problems and promoting patient rights during the research process. By adhering to the principles outlined in this handbook, readers can confidently design and conduct clinical trials that prioritize patients' rights and ethical standards.

CHAPTER 1

UNDERSTANDING ETHICS AND PATIENT RIGHTS
IN CLINICAL TRIALS

Ethics in clinical trials refers to the moral principles and values that guide the conduct of research involving human subjects. When people participate in research, it's important to protect their rights, safety, and well-being. Ethics provide the guidelines to make sure every clinical trial is done in a fair and responsible way.

Participants in a clinical trial have certain entitlements that are called patient rights. These rights make sure individuals are treated fairly and respectfully during their participation in the trial. Patients' rights include the right to make their own decisions about whether or not to participate in the trial. They also have the right to know what the trial involves and to have all the information they need. The history of ethics and patient rights in clinical trials dates back to the mid-20th century. Several unethical experiments, such as the Tuskegee. syphilis study and the Nazi experiments, were conducted during this time. These incidents led to the establishment of the Nuremberg Code and the Declaration of Helsinki. The Nuremberg Code was established in 1947 and outlines ten principles that have become the foundation of modern research ethics [1].

In 1964, the World Medical Association (WMA) developed the Declaration of Helsinki [1]. The Declaration has undergone several revisions and served as the foundation of the ethical principles that underlie the current ICH-GCP guidelines[1]. The Declaration of Helsinki highlights the significance of key ethical principles. These principles include informed consent, risk-benefit evaluation, and more. It cannot be emphasized enough how important ethics and patient rights are in the coordination of clinical trials.

ETHICS AND PATIENT RIGHTS ENSURE THE :

VALIDITY OF STUDY RESULTS

When researchers follow ethical practices, it helps make sure that the results of their studies are accurate and trustworthy. This is because data collected in an ethical way is less likely to be influenced by personal opinions or beliefs.

PROTECTION OF HUMAN SUBJECTS

Ethics is a set of principles that helps ensure that study participants are treated fairly and protected from harm. This means that researchers must ensure that participants are not exposed to unnecessary risks throughout the study.

TRUST IN MEDICAL RESEARCH

When clinical trials follow ethical standards, it helps build trust with both the people who volunteer to participate and the general public. This trust makes it more likely that people will want to participate in the trials, which is important for advancing medical knowledge.

REGULATORY FRAMEWORK FOR ETHICS AND PATIENT
RIGHTS IN CLINICAL TRIALS

The regulatory framework for ethics and patient rights in clinical trials is a set of rules and guidelines. This framework ensures that research studies involving people are done in a fair and safe way. By following the regulatory framework's ethical principles and guidelines, researchers can ensure their studies are ethical and safe. The four fundamental principles of ethics in clinical trials are [2]:

- **AUTONOMY**

  Autonomy is the ethical obligation that ensures researchers respect participants' right to make their own choices. The principle of autonomy requires that researchers obtain informed consent from participants before they can take part in a study. This means that researchers must provide participants with all the information they need to make an informed decision about whether or not to participate.

- **JUSTICE**

  The principle of justice ensures that research studies are fair to every participant. Researchers are to choose participants in a way that is not biased or unfair. This could mean using a random selection process or other methods to make sure that the group of people in the study represents the larger population. Researchers must also ensure that the benefits and risks of the study are shared fairly among all the participants.

- **BENEFICENCE**

  Beneficence is the ethical responsibility researchers have to promote participants' well-being and best interests in research studies. The principle of beneficence requires researchers to take steps in ensuring the benefits of a study outweigh its potential risks. For example, researchers may only use placebos in a study if they are confident that the placebo will not cause harm to participants.

- **NON-MALEFICENCE**

  The non-maleficence principle requires researchers to ensure that their studies do not cause unnecessary harm to their participants. This includes using the most up-to-date scientific knowledge and technology and designing the study in a way that minimizes the potential for harm. In light of the non-maleficence principle, researchers must also be prepared to stop a study if it becomes clear that it is causing harm to participants.

CHAPTER 2

ETHICAL CONSIDERATIONS

IN CLINICAL TRIALS

This chapter covers several critical ethical considerations that must be taken into account when designing and conducting clinical trials. Clinical trials are studies that test the safety and effectiveness of medical treatments, and they involve individuals who volunteer to participate. These individuals may be dealing with illness and may be in a vulnerable state. That's why it's crucial to protect their rights and well-being and carefully consider the trial's potential risks and benefits. Major Ethical considerations in clinical trials are [3]

INFORMED CONSENT PROCESS

Informed consent is a process in which people who want to participate in the study are given information about what it involves [4]. This information includes why the study is being done, what the risks and benefits are, and other vital information participants need to know [4].

This gives participants a chance to ask questions and make a decision about whether or not they want to be part of the trial. It's really important that the information is given in a way that each individual can understand and that respects their rights.

Informed consent isn't just a one-time thing; it's an ongoing process. Throughout the trial, participants should be kept up to date on any changes that might affect their decision to keep participating. They should also be reminded that they can stop being part of the trial at any time without any negative consequences.

CONFIDENTIALITY AND PRIVACY OF PARTICIPANTS

Maintaining the privacy and confidentiality of participants is a critical ethical consideration in clinical trials. Participants might share sensitive information, like their medical history during a trial. It's important to ensure this information is kept confidential and private.

To do this, the researchers and stakeholders must take steps to ensure that personal information is kept safe and secure. This might mean using encryption and access controls to make sure that only the people who need to see the information can access it. They should also have policies in place to deal with any situations where confidentiality might be breached.

MINIMIZATION OF RISK AND MAXIMIZATION OF BENEFITS

Clinical trials should be done in a way that keeps the people who participate safe and makes sure that the research has the potential to help people. This means that the research needs to be designed carefully and that the risks to participants are worth the potential benefits.

To make sure that risks are minimized, researchers need to plan the study carefully. They need to identify potential risks and do everything possible to minimize them. This includes choosing participants who are a good fit for the study and using small amounts of drugs or treatments.

If something does go wrong during the trial, the research team needs to be ready to respond quickly and take appropriate action. The research team should also work with an Ethics Committee (EC) or an Institutional Review Board (IRB). These groups can review the study design and ensure that it's being done in a safe and fair way for everyone involved.

MONITORING AND REPORTING ADVERSE EVENTS

During a clinical trial, the team should keep a close eye on what's happening and report any unexpected or unwanted medical events that occur. These are called adverse events, and they could be related to the treatment being studied or not related at all.

If an adverse event happens, the research team needs to take action to make sure that the person gets the right medical care. This might mean changing the treatment being studied, providing extra medical care, and up to stopping the trial if serious.

The research team must report any adverse events to the right people, like regulatory authorities and ethics committees as per their local regulations. This helps make sure that the trial is being done in a responsible and ethical way and that everyone involved is kept safe.

CHAPTER 3

PROTECTING PATIENTS' RIGHTS

IN CLINICAL TRIALS

Clinical trials are essential for developing new medical treatments and making sure they're safe and effective for patients. Ensuring the people who participate in these trials are treated fairly is also as important as the reason for conducting clinical trials. In this chapter, we'll address the rights of people participating in clinical trials and how researchers can protect these rights.

RIGHT TO PRIVACY AND CONFIDENTIALITY

Participants have a right to privacy and confidentiality. This right is backed by the General Data Protection Regulation (GDPR). The GDPR is a legal framework that imposes obligations on organizations collecting data of individuals residing in the European Union (EU). Failure to adhere to the GDPR guidelines results in harsh fines and penalties. Researchers must protect participants' personal information from unauthorized disclosure, this includes following strict security protocols.

RIGHT TO INFORMED CONSENT

Clinical trial participants have a right to informed consent. This means researchers must provide participants with information about the study. This information includes the study's purpose, risks, and benefits. Clinical investigators must allow participants to make an informed decision about whether they want to participate in the study or not.

RIGHT TO WITHDRAW FROM THE TRIAL

Patients have a right to withdraw from the trial at any time without penalty. Researchers must inform the participants of this right at the start of the study. They must communicate this to the participants in a way they can easily understand.

RIGHT TO COMPENSATION FOR INJURY OR HARM

Patients have a right to compensation for any injury or harm that may occur due to their participation in the clinical trial. This includes compensation for medical expenses, lost wages, and other damages. From the start of the trials, researchers must inform participants where they can receive treatment if they have a research-related injury. They should also communicate clearly who will pay for research-related treatment.

RIGHT TO ACCESS TRIAL-RELATED INFORMATION

Patients have a right to access information related to the clinical trial. This includes the results of the study. Researchers and clinical investigators must provide participants with the result of the study in a timely and transparent manner.

Clinical researchers can ensure they treat research participants with respect, fairness, and honesty by protecting their rights. This will help ensure that the research is conducted in an open way and that the participants' well-being is safeguarded.

CHAPTER 4

PRACTICAL CONSIDERATIONS FOR CONDUCTING
ETHICAL CLINICAL TRIALS

Conducting ethical clinical trials involve much more than simply following the regulations and guidelines set forth by regulatory agencies. It requires a deep understanding of the ethical principles and practical considerations that guide clinical research. In this chapter, we will discuss practical considerations for conducting ethical clinical trials.

COLLABORATIVE DECISION-MAKING

In ethical clinical trials, principal investigators should ensure everyone's voice is heard. This means allowing participants to share their thoughts and ideas about how the study should be run. Researchers may need to work with healthcare providers and stakeholders to make sure that everyone's needs and concerns are taken into account.

Collaboration in clinical trials can help ensure that the study is designed to meet everyone's needs. This can make participants feel comfortable sharing their thoughts and ideas and can lead to the development of new treatments and interventions.

ADHERENCE TO ICH-GCP

ICH-GCP means the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Guideline for Good Clinical Practice (GCP). Adhering to ICH-GCP guidelines is essential for conducting ethical clinical trials. GCP is a set of international standards that help make sure that clinical trials are designed, conducted, and reported in an ethical and scientifically valid way. Adhering to GCP guidelines can help ensure that the study is being done in a way that's both fair and scientifically accurate.

TRAINING AND EDUCATION OF TRIAL PERSONNEL

Before conducting ethical clinical trials, everyone involved in the study must receive adequate training and education. This includes the principal investigators, study coordinators or nurses, and other staff members. They need to understand the ethical principles that guide clinical research and be familiar with the study protocol and procedures. When everyone is aware of the importance of ethics and rights, it ensures that the study is conducted with the participant's best interests in mind.

EFFECTIVE COMMUNICATION WITH PARTICIPANTS

When running clinical trials, it's really important to communicate clearly with the individuals voluntarily participating. This means making sure that they understand what the study is all about, including any risks or benefits that might be involved.

Communication with participants must happen throughout the study, not just at the beginning. This way, they can be updated about any changes to the study or if there's any new information that could affect their decision to continue participating.

ETHICS COMMITTEE (EC) / INSTITUTIONAL REVIEW BOARD (IRB) APPROVAL PROCESS

Getting approval from the EC or IRB is essential when conducting ethical clinical trials. An EC/ IRB is responsible for reviewing and approving research protocols to make sure that they're ethical. Researchers must work closely with the EC/IRB to ensure the study protocol is scientifically sound and in line with all the applicable laws and regulations. This kind of collaboration can help make sure that the study is being conducted in a way that's safe for everyone involved.

CONCLUSION

Conducting ethical clinical trials is essential to protect research participants' rights and welfare while advancing medical knowledge. This practical handbook provides an overview of the ethical and practical considerations involved in clinical trial conduct.

By incorporating these principles into every aspect of clinical trial conduct, we can ensure that research is conducted safely. Researchers, sponsors, ECs/IRBs, and regulatory bodies all have a role in prioritizing ethics and patient rights in clinical trials. By prioritizing ethics and patient rights, we can ensure that clinical research continues to improve patient outcomes while upholding ethical standards.

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SETTING MISTRUST IN A HISTORICAL CONTEXT

We entrust the recognition of the FDA of mistrust amongst the underrepresented population in the clinical study via this declaration: "In addition, distrust of the clinical trial system might come from past events, which unfavorably impacted racial as well as ethnic minorities, which takes account of the unprincipled Tuskegee experiments." On the other hand, we are concerned that a reference to Tuskegee alone could have a harmful and even reductionist influence by casing a long narration of unethical trial practices toward many underserved subpopulations, such as the Indigenous, Latinx or Hispanic communities through one egregious study. It is vital for today's research populations to understand the various historical origins which have generated distrust, in order to pave more diverse trails to inclusive clinical research.

Developing trust and improving opportunities for various individuals to participate in clinical studies are key steps in improving medical equity.

WHY LACK OF DIVERSITY MAY
LEAD TO CLINICAL FAILURE

Lack of diversity in clinical trials is a scientific, moral, ethical, and medical issue. A new report from the commission shines heavily on the "critical shortcomings" in clinical trial studies conducted in the U.S; therefore, a lack of representation in clinical studies. While diversity has become increasingly crucial in clinical trials, ethnic and racial minority populations continue to be left out. However, progression has been made in the scope of integrating a better balance of women to men ratio in clinical research.

The degree of (unknown) heterogeneity in the target patient population is one of the major challenges with clinical development in rare diseases. In fact, it is a common case in many clinical trial development programs. Often, this becomes the root cause for why studies may fail, especially during the later stages, where a more general patient population tends to be enrolled to meet guidelines. In addition to the FDA's guidance for the industry, we underscored that understanding the target patient population in all its heterogeneity and being able to target populations living with the disease earlier may help de-risk late-stage clinical development studies.

We postulated that state-of-the-art artificial intelligence (AI) can be used to inform a better, more targeted selection of patient populations to consider in clinical development programs.

COULD AFRICA BE A POWERHOUSE
IN CLINICAL TRIALS ?

At this point, the majority of the African geography is made up of more than 1.34 billion individuals, and it's expected to increase to 2 billion people by the year 2038. By the year 2050, the anticipated population will be 2.5 billion.

Consisting of more than 17% of the global population with a high range of diversity and extensive disease burden at approximately 25%, the African continent can provide unique conditions suitable to conduct clinical studies.

Notably, several illnesses – particularly those described as tropical and deserted – are widespread in the developing world, including Africa. Despite the clinical advantages, this continent adds to less than 2% of the total number of clinical studies.

CHALLENGES OF CONDUCTING

CLINICAL STUDIES IN AFRICA

There is ongoing investment and development in the there is ongoing investment and development within the logistics segment of Africa that is actively supported by local influences. There are national healthcare organizations, extremely motivated, skilled, there are national healthcare organizations, extremely motivated and skilled investigators, and remarkable clinical trial facilities that can be held up as opposed to the best in class worldwide.

From a lab perspective, some clinical tests are conducted overseas in central laboratories when there is, in fact, the ability to complete lab work in a variety of local nations. Central laboratory hubs placed deliberately in Africa can assist scientific overall progress and improve the skill pool around understanding illnesses.

CHALLENGES OF CONDUCTING

CLINICAL STUDIES IN MIDDLE EAST

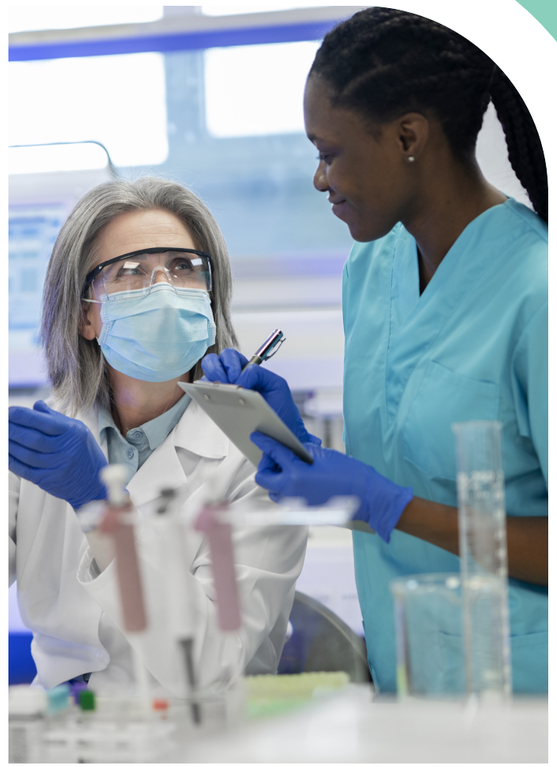
The Middle East region comprises 17 UN-recognized countries and a British Overseas Territory. However, it only contributes little to efforts in clinical studies. Reports show that the region only hosts 6 percent of the worldwide registered trials[1]

In terms of interventional clinical trials, reports also show that more than 76 percent of interventional studies occuring in UAE are sponsored by the pharmaceutical industry [1].

UAE, especially it's capital is well positioned to becoming the head in clinical trials in the Middle East. Abu Dhabi is specifically suited to attract international life sciences corporations. According to news reports, the UAE was also one of the first countries to engage in clinical trials of coronavirus vaccines and Abu Dhabi made over 300,000 Covid-19 RNA extraction solution samples [2].

With a large population treatment-naive and increased diversity in the Middle East, there can be a wide range of individuals from Middle Eastern countries participating in clinical trials contributing to the graal of diversity. This diversity would also promote health equity, produce more innovative science, and reduce biases in clinical trials [3].

To promote diversity of clinical trials in the Middle East, Zanteris supports diversity-focused public policies, encourages investing in communities, and builds a diverse pool of staff. Zanteris is also in support of the diversity in the Middle East and promotes pharma and biotech clinical trials from diverse backgrounds.



UNDOING UNDERREPRESENTATION

IN CLINICAL TRIALS

When participants choose to engage in a clinical trial, they are serving as representatives of the community in which they come from. The decision to join in clinical research is personal and must be made in discussion with a professional health provider and their internal support network.

Advancing inclusive clinical trials or research is multifaceted and involves genomic particulars, as well as the interconnected social drivers of wellbeing. Achieving a wider range diversity, equity, and inclusion in clinical trials needs nothing less than a worldwide commitment to varied, equitable, and inclusive research, which can result in enhanced medical intervention or treatments for various communities.

CLINICAL TRIAL SITES IN UNDERSERVED GROUPS

Establishing research sites where participants presently receive medical attention, considering non-traditional locations such as community health centers and pharmacies, can also assist in improving diversity in a clinical trial.

CREATE A DIFFERENT POOL OF STAFF AND INVESTIGATORS

Ethnically and racially supportive staff and investigators who represent the group or community in which they serve are key ambassadors for clinical studies. They can assist in ensuring trials are ethnically competent and mindful of implicit and unconscious bias.

CREATE LONG-TERM CONNECTIONS AND INVEST IN THE PEOPLE

Community-based clinical trial infrastructure stakeholders must prioritize sustainable and long-term community-building efforts, such as investing in health learning or building the next generation of health investigators and practitioners.