How your health and safety is protected when you participate in vaccine and other research in South Africa

In South Africa, all health research involving the participation of any person is strictly regulated by legislation, regulations and guidelines. Such research, including those studying vaccines, are carefully reviewed by research ethics committees (RECs) who consider your safety and protection from exploitation and who monitors proper execution and management of all studies. The high norms and standards that these RECs follow, meeting international standards, have been set by the National Health Research Ethics Council (NHREC). The NHREC also audit the RECs to ensure compliance. This creates a national research environment that safeguards your participation, should you choose to take part in research.

The questions and answers below will provide more details and clarity for you to explore.

Who ensures that the vaccine trials conducted in South Africa are safe and ethical?

Vaccine trials fall under health research. We know that health research is vital for the advancement of health care services for the people and for proposing solutions to health care problems. But how does South Africa ensure that health research is conducted in an ethical manner that is both respectful and protective of its people?

To ensure that South Africa's people are fully protected against harm, fairly and respectfully treated by researchers, and that all health research conducted in the country stands up to ethical scrutiny, South Africa has established:

- A robust research ethics system and infrastructure, which are updated and strengthened regularly.
- Structures at Institutional, Provincial, and National level, which assist with ensuring that health research is conducted in accordance with the highest ethical norms and standards, and that core ethical principles of respect, protection of participants, scientific merit of studies, research integrity, beneficence, distributive justice- apply to all forms of research that involve living persons.
- The research ethics committees that review and approve health research studies, and monitors approved studies to ensure that all safety and privacy measures are followed.

What and who governs health research in South Africa?

There are statutory infrastructure and systems designed to regulate and oversee health research in South Africa. The framework includes

- The National Health Act 61 of 2003,
- Regulations on research involving human participants promulgated in 2018,
- The Health Research Policy, and
- The Department of Health Ethics in Health Research*, Principles, Processes, and Structures* guidelines of 2015 (DoH 2015), which contain the national policy for conducting research responsibly and ethically, tailored to South Africa's needs and context.

The documents above form the guiding legislative framework upon which the health research ethics infrastructure in South Africa is established and operates.

Which structures are involved in governance of health research in SA?

At a national level, the National Health Act of 2003 (NHA) authorizes the appointment of the National Health Research Ethics Council (**NHREC**). The **NHREC**'s core responsibilities are to;

- Advise the Minister of Health on health research ethics and related matters,
- Set and describe the minimum national benchmark of norms and standards in ethical research,
- Provide explication of the processes of ethics review of research studies, outline the expectations and standards for Research Ethics Committees (RECs),
- To advance research ethics in South Africa by promoting compliance by researchers and RECs using existing and new regulations and guidelines.
- To register and audit the NHREC-registered RECs

The NHREC produced the national guidelines for health research (DoH 2015).

These guidelines are for use by the Research Ethic Committees, researchers who involve human participants in their research, health care practitioners, health facility administrators, policy makers in government departments, and community representatives.

The NHA further requires every institution, health agency, and health establishment at which health research is conducted to establish or have access to an NHREC-registered Research Ethics Committee (NHA s 73). The primary role of the **RECs** is

to conduct rigorous review research study proposals (including clinical trials) to ensure that the welfare, safety, and other interests of participants in the research are properly protected, and that the research will be conducted in accordance with the required ethical norms and standards. It is only the **REC** that is authorized to grant **ethics approval** where research proposal and protocols meet the ethical standards.

You will typically find an ethics approval number from the REC in the informed consent form that you sign when agreeing to participate in a study, with contact details of both the researcher and REC, in case you have any questions or complaints. The REC's foremost responsibility is to protect you, above the importance of the research.

No research study should commence without ethics approval in place i.e., no advertising of the study or recruiting of participants before ethics review and approval.

What has been the contribution of the NHREC on Health during the COVID-19 pandemic?

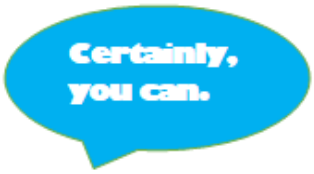
Following the appointment of a new Council by the Minister of Health in December 2020, Council promptly held a national stakeholder meeting with the RECs to understand challenges imposed by the pandemic, challenges that RECs experienced in reviewing he COVID-19- related studies, and what measures needed to be in place to assist the RECs in fulfilling their mandate to protect participants. The NHREC quickly embarked on a process of drafting guidelines for conduct of research under pandemic, to address new challenges, elaborate further on how the existing guidelines can be applied in the unique context of the pandemic. The draft guidelines were circulated to the research community for comments. Another stakeholder engagement meeting was held on the 29 November to consolidate inputs and clarify lingering points of concern. In the process, the country stayed abreast with the latest challenges, implemented urgent measures, and ensured proper ethical conduct of research. Although measures were swiftly implemented, the official publication of these guidelines is aimed for early 2022.

Can I have confidence in the National Ethics Infrastructure?

One of the key goals of the **NHREC** is to achieve, maintain and build the research ethics system that adheres to high ethical standards across South Africa, in line with international criteria, so that South Africans can rightfully be confident that the health ethics infrastructure conducts itself with integrity, according to the highest ethical standards.

The **NHREC** achieves this through its robust **REC** registration process, and capacity building within RECs, as well as through the audit process where **RECs** are assessed for compliance to national guidelines, their policies and Standard Operating Procedures, and other essential requirements such as evidence of proper training of their ethics committee members. Every five years an audit is done to review the capacity status quo of each **REC**.

Can I complain to the NHREC in a case of research misconduct?



- The **NHREC** has published a process through which the public, the researchers, and the **RECs** can report issues of alleged misconduct or request advice.
- If you are a participant in a research study, you are advised to raise any concerning issues with the study investigator, the ethics committee that approved the study, then the **NHREC** or South African Health Products Regulatory Authority (for clinical trials), in this order.
- The contact details of the investigator(s), ethics committee(s) and regulatory authority should be in the informed consent document(s) which you should be provided with before agreeing to participate in a research study.
- PROCESS IN A NUTSHELL: If you have a query or wish to lodge a complaint about your participation in research, the normal route is to first contact the researcher or REC indicated in the informed consent form. If you do not get a satisfactory response from both, you may then lodge your complaints with the NHREC, using the contact details below.

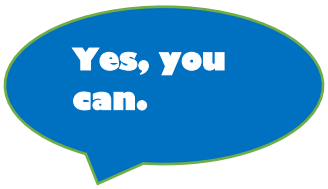
What is the informed consent document?

- The informed consent document is the paper with research information and your agreement, that you receive before you participate in the study. It contains detailed information about the study; the health condition being studied, the risks involved, potential benefits if any, the process and procedures of the study, the

expectations of the investigators about your involvement, the duration of the study, the available alternatives to the intervention provided in the study, and the contact details of the Investigators and **REC** that approved the study.

- Why is this necessary? Participating in health research is voluntary, based on your proper understanding of what the research entails, your rights and any risks associated with your participation. A research study is different from a health service, and this difference should always be made vividly clear to potential participants by the investigators. No one should be forced or be expected to participate in a research study.
- The signed informed consent form is usually evidence of your agreement to participate in the study.

Can I refuse to participate in a research study even if it happens at my workplace?



- Participation in a research study is on a voluntary basis and should be free from any undue influence.
- You can refuse to participate and/or withdraw your participation at any stage of the research should you wish, and both these decisions can be made without any fear of prejudice.
- If you decide to stop participation, you may in no way be discriminated against, and will still receive the same professional medical care. If any of your collected data are identifiable, these may be omitted from the study.

How can I get hold of the NHREC?

You can write an email to the NHREC secretariat: nhrec@health.gov.za. You will get a response within two working days (i.e., longer time over weekends and public holidays).