The parameters of the current legal framework for health research: Forms of health research which are regulated and obligations imposed on researchers

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On 1 March 2012, the South African Minister of Health operationalised section 71 of the National Health Act (NHA), ushering in a new phase of research regulation. When read with sections 1, 11 and 16 of the NHA, section 71 describes the legal norms for undertaking various forms of health research in South Africa. Three key terms used in the NHA now set the parameters of the legal framework for regulating health research: 'health research' (section 1), 'research or experimentation on a living person' (section 71), and the provision of a 'health service for research or experimental purposes' (section 11). Importantly, these three concepts delineate (*i*) what forms of health research are regulated by the legal framework, and (*ii*) the nature of the obligations placed on health researchers and others. Researchers and members of research ethics committees need to be aware that the NHA assigns different legal obligations to different forms of health research. This article describes the parameters of the new legal framework and the obligations that flow from each of the three categories of health research. It shows how the restrictions the framework imposes are not evenly spread across all forms of research, and concludes by identifying some of its strengths, weaknesses and anomalies. It further suggests that more conceptual elaboration is required to ascertain whether the differences are coherent and justified.

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On 1 March 2012, the Minister of Health ushered in a new phase of research regulation by operationalising – among others – section 71 of the National Health Act (NHA).[1] When read with sections 1, 11 and 16 of the NHA, section 71 describes the legal norms when undertaking health research in South Africa. These new norms have been widely criticised – with some arguing that they make the legal framework overprotective of human subjects, remove flexibility from research ethics committees (RECs), and create conflict as they are inconsistent with well-established ethical norms.[2-6] In this context, knowledge of the reach of the legal framework becomes particularly important, and RECs and researchers alike must be able to establish into which category their studies fall, to properly establish which obligations apply.

This article describes the parameters of the new legal framework and the obligations that flow from each of the three categories of health research. It shows how the restrictions this framework imposes are not evenly spread across all forms of research, and concludes by identifying some of the framework's strengths, weaknesses and anomalies.

Parameters of the legal framework

The parameters of the legal framework for regulating health research are set by three key terms used in the NHA:[1] 'health research' (section 1), 'research or experimentation on a living person' (section 71), and the provision of a 'health service for research or experimental purposes' (section 11) (Table 1).[1] Importantly, these three concepts delineate (*i*) what forms of health research are regulated by the legal framework, and (*ii*) the nature of the obligations placed on health researchers and others.

Health research

Health research is defined very broadly in section 1 of the NHA, as research which contributes to knowledge in various health-related fields. The first element of the definition covers any research which contributes to knowledge of:

- biological, clinical, psychological or social processes in human beings
- improved methods for the provision of healthcare services
- human pathology
- the cause of disease
- the effects of the environment on the human body
- the development or new application of pharmaceuticals, medicines and related substances
- the development of new applications of human technology.[1]

Second, the research activity must aim at knowledge production. While the NHA does not define 'research which contributes to knowledge', the national ethical guidelines issued by the Department of Health define research as a 'systematic investigation to establish facts, principles or knowledge'.[7] Furthermore, these ethical guidelines provide that the research may have a wide range of objectives. These range from 'understanding normal and abnormal physiological or psychological

Table 1. Obligations imposed by the NHA on various forms of health research

All health research must:	All health research with human subjects must ensure:	All health research which forms part of a health service at a health establishment can only be undertaken if:	If the health research is considered therapeutic and enrolls minors, it must:	If the health research is considered non-therapeutic and enrolls minors, it must:
• Fit within national health-research priorities (if undertaken by the public sector) • Comply with obligations set by the NHREC • Be submitted for ethical review	• Written consent • Adherence to prescribed obligations	• The user is informed that the health service is experimental • Authorisation has been obtained from the user, their healthcare provider, the head of the health establishment, and the REC	• Be in the minors' best interests • Include obtaining consent from a parent/guardian and the minors themselves, if they have understanding	• Obtain consent from the Minister of Health • Obtain consent from the minors' parents/guardians, and the minors themselves if they have understanding

NHA = National Health Act; NHREC = National Health Research Ethics Council.

functions or social phenomena, to evaluating diagnostic, therapeutic or preventive interventions and variations in services or practices. The activities or procedures involved in research may be invasive or non-intrusive and include surgical interventions; removal of body tissues or fluids; administration of chemical substances or forms of energy; modifications of diet; daily routine or service delivery; alteration of environment; observation, administration of questions or tests; randomisation; review of records; etc.'[7]

The term 'health' research is used in the following sections of the NHA, which deal with research regulation:

- sections 69 and 70 require the National Health Research Ethics Council (NHREC) to determine the health-research priorities for public sector or state-funded research
- section 72 describes the role and functions of the NHREC regarding the ethical issues involved in health research
- section 73 requires institutions conducting health research to set up or have access to a REC. This section must be read in concert with the NHREC guidelines, which set obligations for obtaining ethical approval.[7]

This means that the legislature intended all forms of health research to: (*i*) fall within national research priorities if being conducted by the public sector or with state funding, (*ii*) be regulated by the NHREC, and (*iii*) be submitted for ethical review. These obligations have been in place since 2005, and are considered some of the cornerstones of an effective legal framework for regulating health research.

Research or experimentation on a living person

The phrase 'research of experimentation on a living person' is used in section 71 of the NHA.[1] The Act does not define the term, but recently published draft regulations state that a 'human subject' is a 'living person about whom an investigator obtains data or specimens or identifiable private information through intervention or interaction with that person'.[8]

This definition suggests that section 71 only applies to studies that include an 'intervention or interaction' with a living person. This appears to limit these obligations to a sub-set of health research in which there is actual engagement with research participants.[2]

The normative obligations imposed by the NHA for health research with human subjects are:

- the obligations that apply generally to health research
- mandatory written consent
- compliance with prescribed norms
- ensuring that therapeutic research with minors is in their best interests
- obtaining consent from the minor's parents/legal guardians, from the minors if they have understanding, and the Minister of Health if the study is classified as non-therapeutic.[1]

Given the narrow definition of a human subject, the norms in section 71 of the NHA would not apply, for example, to epidemiological research.

Health services research at health establishments

The third key term is 'health service for research or experimental purposes'. Again, this is a particular type of health research, as it only refers to research which takes the form of an experimental health service at a health establishment.

Section 1 of the NHA defines a 'health service' as:

- healthcare services, including reproductive healthcare and emergency medical treatment, contemplated in section 27 of the Constitution
- basic nutrition and basic healthcare services, contemplated in section 28(l)(c) of the Constitution
- medical treatment contemplated in section 35(2)(e) of the Constitution
- municipal health services.[1]

Section 1 defines a health establishment as 'the whole or part of a public or private institution, facility, building or place, whether for profit or not, that is operated or designed to provide inpatient or outpatient treatment, diagnostic or therapeutic interventions, nursing, rehabilitative, palliative, convalescent, preventative or other health services'.[1]

To fall into this category of health research, the study must investigate an experimental health service such as a new TB drug.

This excludes studies of proven health services, such as evaluations of HIV-testing services. The study must also take place at a health establishment and not, for example, at a traditional male-circumcision school.

For this type of research, section 11 of the NHA and requires that:

- the obligations that apply generally to health research be met
- users be informed that the health service they are receiving is experimental
- prior authorisation is obtained from the user, their healthcare provider, the head of the healthcare establishment, the REC and any other person to whom this authority has been delegated.[1]

The provisions in section 11 of the NHA must be read with the draft regulations. In three instances, the draft regulations set out additional obligations on either researchers or RECs regarding related research. Regulation 4(3)(b) provides that RECs must pay special attention to persons in dependent situations, such as those in a healthcare worker/patient relationship.[8] Furthermore, regulation 5(3) requires researchers undertaking research involving 'innovative therapy or interventions' to make appropriate provision for long-term care and observation of participants.[8] Likewise, Regulation 6 requires researchers to ensure that the informed-consent process addresses users about certain issues which may affect their decision-making, such as: (*i*) 'the possibility of the random assignment of each treatment' (Regulation 6(b)); (*ii*) alternatives to participating in the study (Regulation 6(d)); and (*iii*) in clinical trials, the availability of treatment after the study (Regulation 6(k)).[8]

The obligations in section 11 have only been in place since March 2012.[8] The obligations in the regulations have yet to be finalised and implemented.

Strengths and weaknesses of the framework

The parameters of the legal framework are first established by the term 'health research', as this delineates the type of research to be regulated by the NHA. As stated above, this term is very broadly defined and appears to encompass a range of studies, including those on the social aspects of health such as teenager's TV-watching habits. The listed areas seem to cover most aspects of health research, except possibly studies into human rights or health law. It is submitted that this very broad definition is a key strength of the framework, as it ensures that a wide range of studies must focus on national research priorities, comply with ethical norms, and be submitted for ethical review. Furthermore, these obligations apply regardless of whether there are human subjects in the study. In line with international trends,[9] the framework strengthens RECs, which become the gatekeepers of all forms of health research, including studies that do not include human subjects.

The legislature has identified two types of health research that require further scrutiny: studies with human subjects, and those in which the human subjects receive an experimental health service. Thus, a graded system of regulation is established, in which different forms of health research must meet varying standards. Again this is a strength, as it recognises that not all forms of health research can be treated alike.

There are two major weaknesses within this conceptual framework. First, the excessive restrictions placed on research into experimental health services are out of step with international and local ethical norms. These types of studies offer the possibility of direct benefit to participants, and placing additional administrative burdens on researchers, such as obtaining institutional approval from both the user's healthcare provider and the head of the health establishment, simply results in the 'over-bureaucratisation' of ethics.[5] The reason for identifying this form of research as requiring the greatest protection is unclear. The second weakness in the conceptual framework is that, because some of the protections which section 71 offers are limited to research with human subjects, non-interactional research is not required to comply with certain legal norms, such as the privacy obligations in the draft regulations.

A key anomaly is that section 16 does not require healthcare workers to obtain ethical approval for record reviews, even though other researchers would be required to get authorisation from a REC.

Conclusions

The parameters of the legal framework have become particularly important since March 2012, when restrictive obligations were placed on researchers undertaking research with living human subjects (particularly where such a study involves the provision of a health service).

Researchers and REC members must be aware that different forms of health research have been assigned different legal obligations by the NHA, and further conceptual elaboration is required to ascertain whether the differences are coherent and justified.

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