

Irregular appointment of the NHREC: Implications for legitimacy and the path forward for South Africa's health research ethics guidelines

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Background. Transparency is a fundamental value in South Africa's constitutional and ethical framework, particularly in the appointment of statutory bodies such as the National Health Research Ethics Council (NHREC). The integrity of such appointments is crucial for maintaining public trust and ensuring that decisions are legally and ethically sound. An additional fundamental value is that those appointed be suitably qualified to perform their designated tasks. A transparent process alone is insufficient – the purpose of the process itself must also be respected. Transparency is directly linked to this second objective. The appointment of the NHREC has contravened the transparency of the process by not publishing the process and it has also circumvented the purpose of the process by appointing persons who have not been subjected to scrutiny.

Objectives. This article demonstrates that the NHREC was constituted in an irregular manner, with key procedural requirements, designed to promote transparency and the appropriateness of the appointees, being overlooked. The article also explores the possible impact of this irregular appointment on the authority and validity of the NHREC's decisions.

Methods. The article conducts a detailed analysis of the statutory requirements governing the appointment of the NHREC, followed by an examination of the irregularities in the appointment process. The prejudice to stakeholders and the broader implications for governance are also considered.

Results. The investigation found that the NHREC's appointment process did not follow statutory requirements, leading to a significant irregularity. This undermines the legitimacy of both the council and its decisions, as it denies stakeholders the right to participate in the nomination process, violating principles of participatory democracy. Additionally, the credentials and suitability of appointees were not properly evaluated. As a result, the third edition of the Ethics Guidelines (2024) is legally vulnerable and could face challenges.

Conclusion. Given these serious concerns about legitimacy, we recommend that the Minister of Health withdraws the third edition of the Ethics Guidelines and recommences the revision process once a properly constituted NHREC has been appointed. This approach restores the legitimacy of the NHREC and reaffirms the government's commitment to transparency, accountability and participatory democracy in the governance of health research ethics in South Africa.

Keywords. Health, transparency, public administration, governance.

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Transparency is a foundational pillar of South Africa's constitutional framework, as are the 'rule of law' and 'accountability ... and openness',^[1,2] and these are deeply embedded in the principles that guide public administration and governance. Section 195(1) entrenches this right by requiring, inter alia, that 'public administration must be accountable' and that 'transparency must be fostered by providing the public with timely, accessible, and accurate information'.^[3] It ensures that government actions are conducted openly, allowing the public to hold institutions accountable for their decisions. The Constitutional Court has repeatedly upheld the importance of these principles of administrative justice, emphasising that administrative decisions must be justifiable and procedurally fair, (*Bato Star Fishing (Pty) Ltd v Minister of Environmental Affairs and Tourism and Others* 2004 (4) SA 490 (CC)^[4] and *Minister of Health v New Clicks South Africa*

(*Pty*) Ltd 2006 (2) SA 311 (CC)^[5] and has affirmed the centrality of transparency to the administrative processes (*Brümmer v Minister for Social Development* 2009 (6) SA 323 (CC).^[6]) This commitment to transparency is not only a constitutional mandate but also an ethical imperative, particularly in areas such as health research and public policy, where the integrity of decision-making processes must be safeguarded.

As an ethical value, transparency is closely connected to the principles of accountability, trust and integrity. Further, legitimacy, in particular throughput legitimacy (procedural fairness, transparency and accountability) is dependent on, inter alia, the principle of trust.^[7] Society trusts the state to use its power for the common good, and if a perception is created that the state is not doing this, society's trust in the state is eroded, undermining the state's legitimacy. In fields

where decision-making has significant consequences for public welfare, such as bioethics and health policy, transparency ensures that stakeholders including the public, researchers and policymakers, can see and understand the processes behind decisions that affect them. This openness fosters trust in institutions and ensures that decisions are made in a manner that is fair, informed and free from undue influence or conflicts of interest. It also affords stakeholders an opportunity and the means to challenge any shortcomings in the process or the outcomes of flawed processes.

The ethical significance of transparency is well recognised in academic literature. For example, Virginia Sharpe argues that transparency in bioethics is essential for managing conflicts of interest and aligning the actions of professionals with the public interest.^[8] This underscores the dual function of transparency as both a constitutional and ethical safeguard, essential for maintaining the legitimacy of public institutions and the trust of the citizenry.

The present article shows that the National Health Research Ethics Council (NHREC) was appointed in an irregular manner, with key procedural requirements designed to promote transparency being overlooked. Specifically, the mandated process for appointment, which includes publicising a call for nominations in the Government Gazette, was not followed.

Problem statement and roadmap of analysis

The central issue explored in this article is the impact of the NHREC's irregular appointment on its authority and the validity of its decisions. The failure to adhere to the transparent procedures designed to ensure the NHREC's legitimacy and competence raises critical questions: Does this irregularity affect the legality of the NHREC's decisions, particularly the recently published third edition of its Ethics Guidelines?^[9] Can these decisions be considered valid, or are they voidable owing to the procedural flaws in the appointment process?

To address these questions, the article proceeds as follows:

- **Examination of the statutory requirements for the appointment of the NHREC:** This section outlines the statutory framework governing the appointment of the NHREC members, detailing the procedures that were intended to ensure transparency and legitimacy in the process.
- **Analysis of the irregular appointment of the NHREC:** This section details the irregularities in the NHREC's appointment process, showing how the failure to follow transparent procedures violates the principles intended to ensure the council's legitimacy.
- **Analysis of whether the NHREC's decisions are administrative decisions:** This brief section notes that decisions by the NHREC are subject to scrutiny in terms of the Promotion of Administrative Justice Act^[10] and the common law.
- **Impact on the legality of the NHREC's decisions:** This section assesses the legal implications of the NHREC's irregular appointment, focusing on the validity of its recent decisions.

Through this analysis, the article aims to highlight the critical importance of transparency in maintaining the legitimacy of public institutions and ensuring that their decisions are both legally and ethically sound.

Examination of the statutory requirements for appointment of the NHREC

The NHREC is a statutory body established under the National Health Act 61 of 2003^[11] (the NHA), which governs health research ethics in South Africa. The NHREC plays a pivotal role in ensuring that health research conducted in the country adheres to the highest ethical standards. Given the importance of its functions, the NHA and accompanying regulations^[11,12] set out specific statutory requirements for the appointment of its members, designed to ensure transparency, legitimacy, and public confidence in the council's decisions.

Specifically, the regulations^[12] set the following requirements for the composition of the NHREC:

'The members of the Council appointed by the Minister in terms of section 72 (2) (a)^[12] are constituted as follows:

- (a) Nine with extensive experience and knowledge in health research ethics;
- (b) A representative from the community;
- (c) A representative from the Department;
- (d) A representative of the pharmaceutical industry;
- (e) A representative from the Medicines Control Council;
- (f) A person with extensive knowledge in animal health research ethics; and
- (g) A person with extensive knowledge in law.'

The statutory requirements for the appointment of the NHREC members^[12] are intended to ensure that the process is conducted in a transparent and participatory manner. The key requirements include:

- The NHA and the regulations relating to the NHREC^[12] require that the Minister of Health must issue a public invitation for nominations for NHREC members. This invitation must be published in the Government Gazette.^[12] In addition, the regulations also require publication in at least one newspaper with nationwide circulation.^[13] The purpose of this requirement is to ensure that the nomination process is open to all qualified candidates and that the public has an opportunity to participate in the process.
- After the nomination process, the Minister is required to publish the names of the appointed NHREC members in the Government Gazette.^[14] This publication serves as a formal record of the appointments and ensures that the process is transparent and subject to public scrutiny.

The statutory requirements for the appointment of the NHREC are designed to promote transparency, accountability and public trust in the council's operations, as well as to ensure that suitable, qualified, candidates are selected and as such they are explicit in requiring that the call for nominations and the appointments must be gazetted. By mandating a public and open nomination process, the provisions aim to prevent the arbitrary appointment of members and ensure that the NHREC is composed of individuals who are both qualified and representative of the broader community. The publication of the appointments further reinforces the legitimacy of the process by allowing the public to verify that the proper procedures have been followed. They do not provide for an alternative mechanism to be used, such as internal advertising, or couch it in such terms as to allow

for any alternative interpretation of the requirements, and a diligent search also did not indicate that any Covid-related concessions were made in this regard.

Failure to adhere to these statutory requirements can have serious consequences for the legitimacy and legality of the NHREC and its decisions. Generally, in administrative proceedings, non-compliance with legislated procedural rules can render an administrative decision invalid; as such, decisions must be made in accordance with the right to just administrative action.^[11]

The Promotion of Access to Justice Act (PAJA)^[10] gives effect to this right. Specifically, with regard to any administrative action affecting the public (section 4), it provides that:

'4 (1) In cases where an administrative action materially and adversely affects the rights of the public, an administrator, in order to give effect to the right to procedurally fair administrative action, must ...
(d) where the administrator is empowered by any empowering provision to follow a procedure ... follow that procedure...'

Therefore, compliance with the procedures is not only required in terms of the NHA, but also explicitly required in terms of the PAJA.^[10] Accordingly, if the NHREC is not properly constituted, its authority to issue guidelines and make binding decisions may be called into question, as well as its competence. Moreover, any decisions made by an irregularly appointed NHREC could be challenged on the grounds that they lack legal validity, potentially leading to their nullification. Both such challenges, to the authority and competence of the NHREC and in respect of its decisions, may be brought by way of an application to the High Court for judicial review.

In the case of the NHREC, the failure to publish the call for nominations and the concomitant failure to publish the names of the appointed NHREC members, represents a significant breach of these statutory requirements. The following sections explore these issues in greater detail, examining the legal and ethical implications of the NHREC's seemingly irregular appointment.

Analysis of the irregular appointment of the NHREC

The term of office of the members of the NHREC is a period of three years, and serving members may be appointed for further terms, subject to a maximum of three consecutive terms.^[15] However, reappointment, though possible, is not exempt from compliance with due process as stipulated in the legislation.

In our search, the most recent call for nominations that complied with the statutory requirements appears to have been made in 2006. Thus, if any members appointed in terms of this nomination are still serving, they have exceeded the allowable three-term limit (effectively nine years) and are thus serving in breach of section 3.3 of the NHREC's own constitution.

To verify compliance, a comprehensive search was conducted of all Government Gazettes over the past five years using the Government Printing Works website, a reliable database and tool for accessing and searching Government Gazette records. The search terms used were 'NHREC'; and 'National Health Research Ethics Council', and ensuring that any mention of the council in the Government Gazettes would be identified. Despite the thorough nature of this search, no results were found that indicated the required publication of a call for nominations or the announcement of appointed members for the past five years.

To validate the effectiveness of the platform and the search function, control searches were conducted using the terms 'health', 'research ethics' and 'nominations'. These control searches revealed that between January 2019 and July 2024, the South African Pharmacy Council, the Health Professions Council of South Africa, the various professional boards under the Health Professions Council of South Africa, and the National Forensic Pathology Services Advisory Committee (NFPSC) issued calls for nominations and announced appointments.^[16] These control searches confirmed that the platform and its search function were operating correctly and effectively, as they successfully retrieved the expected records for these other statutory bodies.

The stark contrast between the results for the NHREC and those for the Health Professions Council of South Africa (for example) suggests that the issue is not with the search platform but rather with the absence of the required publications in the case of the NHREC. This indicates that the NHREC stands out as an exception, where the legally mandated transparency measures were not adhered to, leading to an irregular and potentially unlawful appointment process.

When the timeframe was broadened to include a period prior to the last five years, results were found that indicated that on a previous occasion, namely in 2006, a call for nominations was published by the NHREC.^[17] This is in compliance with the NHA^[18] and also sets a precedent that the law can be complied with. As it was possible that the call for nominations, notwithstanding our being unable to locate same, may have been made, and responded to by the current appointees, we also approached the current NHREC in writing on 25 June 2024 requesting it to provide us with a copy of (or reference to) the call for nominations to which they (presumably) responded. The NHREC acknowledged our request but has not provided the document nor a reference to it.

Furthermore, a formal appeal to the Department of Health, copied to the Information Regulator in terms of the Promotion of Access to Information Act No. 3 of 2000, asking, inter alia, for a reference to the relevant gazette/s and copies of the call for nominations in a newspaper of national circulation, was made in August 2024, by Esselaar Attorneys. While a response was received from the Department of Health, it was woefully inadequate. No references were provided to any Government Gazette in which a call for nominations was published, nor was any evidence provided of an advertisement having appeared in a national newspaper, as required by the regulations. In addition, no reference was provided to the publication of the official notice of appointment of the NHREC members in the Government Gazette, as is statutorily mandated. What was provided was a copy of an internal governmental notice or advertisement. It is unclear where or when this was published. An arbitrary web search revealed that this advertisement calling for nomination of candidates was published on the Department of Health's website^[18] in June 2023 and nowhere else.

Given the ease with which any one of these requests could have been complied with and the seriousness of the consequences if the NHREC has not been legally constituted, the conclusion must be that both the call for nominations and the appointments were not published in the Government Gazette.

The failure to follow the required statutory procedures has significant implications for the legitimacy of the NHREC. The absence of published records in the Government Gazette indicates a clear departure from

the transparent processes that are essential for maintaining public trust and confidence in the council's **decisions**. Section 3 (1) of PAJA^[10] specifies that 'Administrative action which materially and adversely affects the rights or legitimate expectations of any person must be procedurally fair' and PAJA^[10] goes on to stipulate in section 3 (5) that where the requirements of procedural fairness are stipulated in any specific legislation, in this case the NHA,^[11] then 'the administrator may act in accordance with that ... procedure.'

The irregular appointment not only violates the legal framework, including the Constitution,^[1] the NHA^[11] and PAJA,^[10] but also undermines the ethical standards expected of a body tasked with overseeing health research ethics in South Africa, which must of necessity include constitutional parameters such as transparency and the parameters it itself sets for others to follow. We thus have a situation where an illegally constituted body is purporting to regulate, illegitimately, in the specific field of ethical responsibility and regulations. This irony cannot go unmarked.

Impact on the legality of the NHREC's decisions

The irregular appointment of the NHREC raises significant legal questions regarding the validity of its decisions, especially the third edition of its Ethics Guidelines.^[9] In South African administrative law, the principle of legality requires that all exercises of public power must be conducted within the framework of the law. (Specifically, the right to just administrative action in the Constitution^[1] and its enabling legislation, the PAJA.^[10]) When a statutory body is not properly constituted according to the prescribed legal procedures, its authority to issue binding decisions is fundamentally compromised. However, the legality of these decisions is also subject to considerations of material irregularity and prejudice, as established by relevant case law.

Voidability of decisions and material irregularity

Are the decisions of the NHREC administrative decisions? There can be little doubt that they are, as they fall squarely within the definition in the PAJA,^[10] which defines an administrative decision to be: '... any decision taken, or any failure to take a decision, by-

(b) a natural or juristic person, ... when exercising a public power or performing a public function in terms of an empowering provision, which adversely affects the rights of any person and which has a direct, external legal effect ...'^[19]

The Constitution,¹ at section 33 (1), states that 'Everyone has the right to administrative action that is lawful, reasonable and procedurally fair ...' and the PAJA,^[10] at section 3 (1), gives effect to this, requiring that 'Administrative action ... must be procedurally fair.' The principle of legality, as emphasised in cases such as *Fedsure Life Assurance Ltd v Greater Johannesburg Transitional Metropolitan Council*^[20] and *Oudekraal Estates (Pty) Ltd v City of Cape Town*,^[21] dictates that administrative actions taken by public bodies must be lawful, reasonable and procedurally fair.

In *Fedsure*,^[20] the Constitutional Court underscored that all exercises of public power must be authorised by law, and any decision made without such legal authority is invalid.^[20]

However, for a decision to be set aside, the irregularity must be material. The *Oudekraal* case^[21] clarified that not every procedural flaw

will render a decision voidable. The irregularity must be significant enough to affect the decision's validity. In the case of the NHREC, the failure to follow the statutory requirements for appointment constitutes a material irregularity because it strikes at the heart of the council's legitimacy. The NHREC's very authority to issue guidelines is based on its proper constitution, and the deviation from mandated procedures materially undermines its ability to function as a legitimate regulatory body. The way in which the NHREC is supposed to be constituted is not merely a procedural formality but is intrinsically linked with the value of transparency. This connection to transparency further underscores the materiality of the irregularity, as transparency is essential for maintaining public trust and the integrity of the NHREC's decisions. Circumventing the primary purpose of the process, to scrutinise and appoint suitably qualified applicants, compounds this irregularity.

In addition, section 195 (1) of the Constitution, dealing specifically with public administration, stipulates that:^[3]

'Public administration must be governed by the democratic values and principles enshrined in the Constitution, including the following principles:

- (a) A high standard of professional ethics must be promoted and maintained.
- (b) Efficient, economic and effective use of resources must be promoted.
- (c) Public administration must be development oriented.
- (d) Services must be provided impartially, fairly, equitably and without bias.
- (e) People's needs must be responded to, and the public must be encouraged to participate in policymaking.
- (f) Public administration must be accountable.
- (g) Transparency must be fostered by providing the public with timely, accessible and accurate information.
- (h) Good human-resource management and career-development practices, to maximise human potential, must be cultivated.
- (i) Public administration must be broadly representative of the South African people, with employment and personnel management practices based on ability, objectivity, fairness and the need to redress the imbalances of the past to achieve broad representation.'

The significance of section 195 (1), specifically subsection (a), is addressed later in this article.

Prejudice and the potential for legal challenge

In addition to material irregularity, the concept of prejudice is also relevant when assessing the legality of the NHREC's decisions. Prejudice, in this context, refers to the extent to which the irregularity has adversely affected the rights or interests of stakeholders. According to the *Chairperson, Standing Tender Committee v JFE Sapela Electronics (Pty) Ltd*^[22] case, a court is more likely to set aside a decision if the procedural irregularity has caused prejudice to the parties involved.

For the NHREC, the irregular appointment process could be argued to have prejudiced various stakeholders, including researchers, institutions and participants in health research. These stakeholders should all have had the opportunity to nominate members for

the NHREC. By depriving them of this opportunity, the irregular appointment process has disregarded their rights and interests, effectively excluding them from participating in a critical aspect of health research governance. This exclusion is a slap in the face of the constitutional commitment to participatory democracy, where public involvement in decision-making processes is a fundamental principle.

Given the material irregularity in the NHREC's appointment and the prejudice to stakeholders in the South African research community, there is a strong case for challenging the legality of the third edition of its Ethics Guidelines^[9] and indeed other guidelines and decisions made by the NHREC. If a court were to find that the NHREC was not properly constituted, it could set aside the guidelines, thereby reinstating the second edition issued in 2015. It may be argued that although the NHREC was irregularly appointed and possibly functioned in breach of its own constitution, this has no impact on any guidelines it produced or any decisions it made. However, that the guidelines and decisions were produced or made by an NHREC that may not have been properly constituted (for example, if a suitably legally qualified person was not appointed), would be a significant piece of evidence in establishing that the guidelines, or any other decision, may be materially flawed. Further, as mentioned earlier, section 195 (1) (a) of the Constitution requires that 'A high standard of professional ethics must be promoted and maintained.'^[3] Any guidelines produced by an illegally or irregularly appointed NHREC that seek to implement section 195 (1) (a) must themselves comply with the 'high standard of professional ethics' that they are seeking to impose.

Conclusion

The irregular appointment of the NHREC has raised serious questions about the suitability of the appointees. Suitability here refers firstly to the lack of opportunity to scrutinise the skills requirements of the members and, secondly, to the willingness of the members to serve, knowing that their appointment is irregular. While doing so, they have produced guidelines holding others to account to ethical standards that they themselves have not observed. This failure to comply with a 'high standard of professional ethics' renders such members unsuitable, even if they are academically or professionally qualified.

It especially raises questions about the legality and legitimacy of its decisions, particularly the third edition of its Ethics Guidelines. Institutionally speaking, the NHREC must be above reproach as it is mandated to provide guidance to all research ethics committees (RECs) in South Africa. There are indeed rigorous standards and guidelines that RECs must comply with, with regard to appointments and performance. The implication is that the current situation may delegitimise the entire system. The failure to follow statutory requirements for the NHREC's constitution – requirements that are intrinsically linked to the constitutional value of transparency and participatory democracy – constitutes a material irregularity. This irregularity not only undermines the authority of the NHREC but also prejudices the stakeholders who were deprived of their rightful opportunity to participate in the nomination process. This exclusion strikes at the heart of South Africa's commitment to participatory democracy, a fundamental principle enshrined in the Constitution.

Given these significant concerns, the third edition of the Ethics Guidelines is on precarious legal footing. A challenge could be

mounted against the Minister's failure to follow proper legislated procedures in appointing the current NHREC as well as individual challenges to outcomes of the NHREC itself. The guidelines, therefore, are vulnerable to legal challenges that could lead to their being set aside. The PAJA allows for an application for the review of any decision by an administrative body to be brought before the High Court. This would allow for each decision of the NHREC, including the guidelines, to be individually challenged. If this occurs, the 2015 edition of the Ethics Guidelines would remain in force. This would ensure continuity in the ethical framework governing health research in South Africa, but it would also highlight the necessity of restoring the NHREC's legitimacy.

To address these concerns and to restore the integrity of the NHREC, it is recommended that the Minister of Health withdraw the third edition of the Ethics Guidelines and initiate a fresh process of revising the guidelines once a properly constituted NHREC has been appointed. This would not only ensure that the guidelines are developed in compliance with the law but also reaffirm the government's commitment to transparency, accountability and participatory democracy. By adhering to the proper legal procedures, the NHREC can regain its legitimacy and effectively fulfil its mandate to oversee health research ethics in South Africa. It would also avoid the possibility of a plethora of individual court applications in respect of the NHREC's decisions, which would only address the issue on a piecemeal basis. However, if no co-operative systemic action is taken, such applications for review will occur.

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