NDoH 2024 Version 3.2:

Key Changes and What They May Mean For Stakeholders

By Karen Cloete, TASK Research Academy

This guide summarises the amendments introduced in Version 3.2 of the NDoH 2024 Ethics Guidelines. Rather than simply restating the changes, it explores why they were likely introduced, what they may mean in practice, and how they could influence researchers, sponsors and Research Ethics Committees (RECs).

How this Guide is Organised

Rather than following the order of the NDoH 2024 Ethics Guidelines, this guide groups the Version 3.2 amendments according to the **research and ethics review lifecycle**. This approach is intended to make the updates easier to navigate and to highlight how related changes work together in practice.

For each amendment, I explore:

- **What changed?** - A concise summary of the amendment.
- **Why was it updated?** - A balanced interpretation of the likely intent behind the amendment.
- **What may this mean in practice?** - Considerations for researchers, sponsors, institutions and Research Ethics Committees (RECs).
- **Practical takeaway** - Suggested actions to help prepare for or respond to the change.

Disclaimer:

This guide is my personal review and interpretation of the amendments introduced in NDoH 2024 Version 3.2. It is intended as an educational resource to help researchers understand the changes and consider their potential practical implications. It does not represent the views of the National Department of Health, the NHREC, or any Research Ethics Committee (REC), nor should it be regarded as legal or regulatory advice. Throughout this guide, I intentionally use terms such as "may," "could," "is likely intended to," and "possible implications" to distinguish my interpretation from the wording of the guideline itself. Where uncertainty exists, readers should refer to the official guideline and seek guidance from their institutional REC or the appropriate regulatory authority.

Quick Reference Guide:

The table below provides a quick reference to the amendments discussed in this guide.

Part	Research lifecycle stage	NDoH Sections	Key amendments	Primary stakeholders
1.	**Entering the Ethics Review Process**	1.1	Observational research in public (including virtual) spaces	Researchers, RECs
		3.1.1	Scientific review process, conditional approvals, and SAHPRA wording	Researchers, Sponsors, RECs
2.	**How Ethics Applications Are Reviewed**	5.5.1.2	Ethics application content and moving beyond a "tick-box" approach	Researchers, RECs
		5.5.1.6	Rapid reviews and reciprocal recognition of NHREC-registered REC reviews	Researchers, Sponsors, RECs
		5.5.1.3	REC decision-making, narrative feedback, applicant response timelines	Researchers, Sponsors, RECs
		5.5.1.14	Complaints and queries through institutional processes before NHREC	Researchers, RECs, Institutions
3.	**Strengthening REC Governance**	5.2.2	Terms of Reference and SOPs	RECs, Institutions
		5.2.3.2	Administrative support	RECs, Institutions
		5.3.1	REC membership	RECs, Institutions
		5.3.2 & 5.3.2.2	Chairperson appointments	RECs, Institutions
		5.5.1.8	Archiving and record management	RECs
		5.6	NHREC reporting	RECs
4.	**Building Ethics Review Competency**	5.4	Ongoing education and training	REC Members, Researchers
		5.4.2	**AREC-specific:** Competency expectations and animal welfare considerations	AREC Members, Animal Researchers
		5.4.2.1	International collaborators and South African regulatory orientation	International Collaborators, Sponsors, Local PIs
5.	**Clinical Trial Governance**	6.5.2	SANCTR registration responsibilities	Sponsors, Researchers, RECs
		3.1.1	Scientific review and conditional approval pathways	Researchers, Sponsors, RECs

Part 1: Entering the Ethics Review Process

This part explores amendments that influence how research enters the ethics review system. Collectively, the changes appear intended to support a more proportionate, flexible and efficient approval pathway while maintaining appropriate ethical oversight.

Observational Research in Public Spaces (Section 1.1)

What Changed

The list of provisions for observational research in public spaces (including virtual spaces) not requiring a formal ethics review, has been updated. Version 3.2 clarifies that observational research in public (including virtual environments) may be exempt from ethics review, provided **no audio or visual recordings** of individuals are made.

Why It Was Updated

This clarification is likely intended to reduce unnecessary ethics review burden for low-risk observational studies. It also reflects the growing recognition that "public space" now includes digital environments, which previously lacked clear ethical boundaries.

What It May Mean In Practice

This may result in more consistent exemption decisions across Research Ethics Committees (RECs). However, researchers may still need to carefully consider whether individuals could be indirectly identified, particularly in online settings where data can be re-aggregated or traced.

Practical Takeaway

Researchers may wish to:

- Review whether observational protocols genuinely meet exemption criteria.
- Seek REC confirmation where digital or hybrid environments introduce ambiguity.

Scientific Design, Aims and Objectives (Section 3.1.1)

What Changed

Version 3.2 of the guideline removes the previous recommendation that Research Ethics Committees (RECs) delay ethics approval until completion of the scientific review (for SAHPRA-regulated clinical trials, this would generally be SAHPRA's review).

Instead, the updated guideline supports **parallel regulatory** and **ethics review** and clarifies that, where the scientific review is not yet available, a REC may grant **conditional ethics approval**, with final approval issued, where justified, once the scientific review has been received.

Why It Was Updated

This may reflect an effort to streamline approvals and reduce delays in study start-up. It also suggests a shift toward allowing parallel review processes rather than strictly sequential regulatory pathways, maintaining the requirement under SA GCP (2020) that both SAHPRA authorisation (where applicable) and REC approval must be in place before a clinical trial is initiated.

What It May Mean In Practice

RECs may now **grant conditional approval** where scientific review is still pending, if justified. This could improve efficiency in study activation timelines. RECs may increasingly rely on conditional approvals with defined outstanding requirements. However, this also places greater emphasis on tracking conditions post-approval.

Practical Takeaway

Researchers may wish to:

- Clearly separate scientific and ethics review components in submissions.
- Ensure robust tracking of outstanding approval conditions.

Part 2: How Ethics Applications Are Reviewed

This part focuses on the ethics review process itself—from the information researchers submit, to how applications are reviewed, decisions are documented, and complaints are managed. Together, the amendments may promote greater transparency, consistency and accountability throughout the review lifecycle.

Application for Ethics Review (Section 5.5.1.2)

What Changed

Version 3.2 provides additional guidance on the design and content of ethics review application forms.

The guidelines emphasise that application forms should move beyond a simple **"tick-box" approach** and instead encourage applicants to explain **how** ethical principles will be implemented in practice.

- For example, rather than simply indicating that participants will be protected, applicants should describe **how participant rights, safety and welfare will be safeguarded** throughout the study.
- For animal research, the guidance has also been strengthened to explicitly state that the welfare of animals should always take precedence over scientific interest. Applications should therefore provide a comprehensive explanation of how animal welfare will be protected throughout the research.

Why Was It Updated

These amendments are likely intended to improve the quality of ethics review by encouraging applicants to **demonstrate their ethical reasoning** rather than simply confirming compliance.

The revised wording suggests a move away from assessing whether ethical safeguards merely exist, towards evaluating **how they will be implemented in practice.**

For animal research, the additional wording reinforces an established ethical principle by making it explicit that scientific objectives should never override animal welfare considerations.

What May This Mean In Practice

Researchers may need to **prepare more detailed ethics applications** that clearly explain the practical implementation of ethical safeguards rather than relying on brief affirmative responses.

For RECs, this may facilitate a more meaningful assessment of ethical conduct by providing richer information on which to base their decisions.

Application forms themselves may also evolve over time, with institutions revising templates to encourage narrative responses rather than predominantly closed-ended questions.

For animal research, applicants may also need to provide stronger justification and documentation demonstrating how animal welfare has been prioritised throughout the study.

Practical Takeaway

RECs may wish to:

- Review ethics application forms to ensure they encourage explanatory responses rather than simple yes/no answers.
- Consider whether application templates adequately support assessment of ethical reasoning and implementation.

Researchers may wish to:

- Focus on explaining *how* ethical safeguards will be implemented, not simply confirming that they are in place.
- For animal research, clearly demonstrate how animal welfare has been prioritised throughout the study and justify any procedures that may impact animal wellbeing.

Rapid Reviews (Section 5.5.1.6)

What Changed

Version 3.2 introduces two clarifications relating to rapid ethics reviews.

Firstly, the example of a circumstance that may justify an accelerated review has been refined from a "major incident" to a "major incident of significant, wider impact."

Secondly, the guidelines now clarify that reciprocal recognition of an ethics review is acceptable where the review has been conducted by an NHREC-registered REC.

Why Was It Updated

These amendments are likely intended to improve consistency in the application of rapid review processes.

The refinement of the "major incident" example may help prevent accelerated review pathways from being used too broadly by making it clearer that rapid review is intended for exceptional circumstances with a broader public impact.

The clarification regarding reciprocal recognition may also support greater efficiency by reducing unnecessary duplication of ethics review between institutions, while maintaining confidence in reviews conducted by NHREC-registered RECs.

What may this mean in practice

Researchers requesting a rapid review may need to provide stronger justification that their study genuinely meets the threshold for accelerated review.

RECs may also apply more consistent criteria when determining whether a rapid review is appropriate.

The clarification on reciprocal recognition could facilitate more efficient multicentre research by allowing institutions to place greater reliance on reviews already completed by another NHREC-registered REC, where appropriate and in accordance with institutional policy.

While this may reduce duplication, RECs will likely continue to determine whether any local considerations still require review before accepting reciprocal recognition.

Practical Takeaway

RECs may wish to:

- Review their SOPs to ensure criteria for rapid reviews align with the updated guidance.
- Clarify how reciprocal recognition of reviews conducted by NHREC-registered RECs will be implemented within their institution.
- Continue documenting the rationale for accepting or declining reciprocal recognition.

Researchers and **sponsors** may wish to:

- Ensure requests for rapid review clearly justify why the study meets the criteria for accelerated review.
- Confirm with participating institutions whether reciprocal recognition of ethics review is accepted before assuming that duplicate submissions can be avoided.

REC Decision-Making (Section 5.5.1.3)

What Changed

Clarification has been added regarding quorum, decision thresholds, and documentation requirements.

RECs are now expected to provide more detailed feedback when:

- Requesting amendments, or
- Rejecting a research proposal

Importantly, decisions must be supported by narrative meeting minutes, not only a final outcome. This includes **recording the reasons behind decisions**, ensuring that feedback to applicants is sufficiently detailed and actionable.

In addition, the guidance on application timelines has been strengthened. Where **applicants exceed the stipulated timeframe** for responding to REC comments without communication, **the application may be removed from the agenda**.

If the study is still to proceed, a new application would need to be submitted. If not, the REC may require the researcher to formally withdraw the application.

Why It Was Updated

This update is likely intended to improve both **consistency and accountability** in REC decision-making.

It may also reflect a response to a practical operational challenge—namely, delays caused when applicants do not respond within agreed timelines, which can impact REC workflow efficiency and overall review turnaround times.

This may improve consistency and defensibility of REC decisions across institutions.

What It May Mean In Practice

This change may introduce a more structured and time-bound approach to REC–applicant engagement.

For applicants, this could mean:

- A stronger expectation to adhere strictly to response timelines
- Reduced flexibility once deadlines for feedback responses have passed
- A higher likelihood that inactive applications may be formally closed or removed from review cycles

For RECs, this may result in:

- More formalised documentation of decision rationale
- Increased emphasis on tracking applicant response timelines
- Greater procedural consistency when managing overdue responses

Overall, this may represent a shift toward **more disciplined lifecycle management of ethics applications.**

Greater emphasis may be placed on detailed minutes and traceability of decisions.

Practical Takeaway

RECs may wish to:

- Standardise decision documentation templates to ensure narrative justification is consistently captured
- Strengthen quorum verification and minute-taking processes

Applicants may wish to:

- Strictly adhere to REC feedback response timelines as specified in correspondence.
- Maintain proactive communication with the REC if delays are anticipated
- Treat response deadlines as procedural requirements that may affect the continuation of the application process

Queries & Complaints (Section 5.5.1.14)

What Changed

More structured guidance has been introduced for managing complaints related to REC decisions or processes. In the updated guidelines, text has been added to this section to reiterate that, typically, the NHREC should be approached after all internal processes, as per institutional policy, have been exhausted.

This reinforces a clear escalation pathway:

- Institutional REC processes must be followed first
- Internal resolution mechanisms should be used before external escalation to NHREC

Why It Was Updated

While framed as a procedural clarification, this update may also reflect an operational reality: NHREC may have been receiving a growing number of complaints or queries that have not first been addressed through the relevant institutional REC or internal ethics governance structures.

As a result, this clarification is likely intended to reinforce the role of RECs and institutions as the **primary point of resolution**, ensuring that NHREC is approached only when local processes have been fully applied.

In this sense, it may also encourage institutions to ensure they have **clear internal complaint handling policies and escalation pathways**, effectively acting as a structured "filter" before issues reach national level oversight.

What It May Mean In Practice

This may strengthen the expectation that complaints are first managed at institutional level before escalation to NHREC.

For RECs and institutions, this could mean:

- Greater responsibility to resolve queries and complaints internally and systematically
- Increased need for clearly documented escalation procedures
- A stronger emphasis on demonstrating that due process has been followed before external referral

For researchers and complainants, this may mean:

- A requirement to engage with institutional REC processes first
- Potential delays in accessing NHREC intervention unless internal pathways have been completed
- Greater importance of understanding institutional complaint procedures upfront

Overall, this may reinforce a **tiered governance approach**, where NHREC functions primarily as an oversight and escalation body rather than a first point-of-contact for disputes.

Practical Takeaway

RECs and **institutions** may wish to:

- Ensure formal complaint and query SOPs are in place and clearly communicated
- Define and document internal escalation pathways before NHREC referral
- Train staff and committee members on managing complaints consistently at institutional level.

Researchers may wish to:

- Familiarise themselves with institutional REC complaint procedures before escalating concerns externally
- Ensure all REC-related disputes are first addressed through formal internal channels

Part 3: Strengthening REC Governance

This part examines amendments that appear intended to strengthen the governance framework within which Research Ethics Committees operate, with greater emphasis on clear governance structures, defined responsibilities, operational consistency and effective oversight.

Terms of Reference & SOPs (Section 5.2.2)

What Changed

RECs are expected to maintain updated Terms of Reference (ToR) and SOPs aligned with current national guidelines.

Guidance now states that the ToR document for an REC must be in a **proper format**, as per institutional policy, and **contain at least**:

- A descriptive title
- Institutions name and logo
- An approval and revision date version control and history
- Signatures authorising the approval at the appropriate level
- Appropriate subheadings or content, which may include:
    - Purpose
    - Scope
    - Authority and accountability of the REC
    - REC's relationship to the institution
    - Administrative, financial, and other support
    - Training-related matters
    - Communication and reporting channels
    - Reference to code of conduct
    - REC composition and appointments
    - Procedures and resources
    - Compliance of the REC with national legislature and relevant regulatory documents
    - Reference to resources.

Similarly, guidance now states that SOP documents must be in a suitable SOP format, as per institutional policy, and contain at least:

- A descriptive title
- Institutions name and logo
- An approval and revision date version control and history (although it may be a living document)
- Signatures authorising the approval at the appropriate level
- Appropriate subheadings or content, which may include:
    - Purpose
    - Scope
    - Responsibilities

- Procedures
- Reference to resources.

Why It Was Updated

This likely aims to reduce variability in REC processes and ensure consistent ethical oversight across institutions.

What It May Mean In Practice

RECs may need more frequent SOP reviews and formal documentation demonstrating alignment with national standards.

Practical Takeaway

RECs may wish to:

- Conduct structured SOP gap analyses against Version 3.2.
- Implement scheduled SOP review cycles.

Administrative Support (Section 5.2.3.2)

What Changed

The guidelines strengthen expectations for adequate administrative support for REC functioning.

The responsibilities for REC administrative personnel now include **providing support for other processes and activities from the REC**, in addition to:

- Managing the office administration required to process research ethics applications,
- Organising and servicing REC meetings
- Regular record-keeping and reporting tasks expected of RECs.

Why It Was Updated

Administrative inefficiencies can directly impact ethics review timelines, so this update may aim to improve operational reliability.

What It May Mean In Practice

Institutions may need to reassess staffing models, workload distribution, and submission management systems.

Practical Takeaway

RECs may wish to:

- Define minimum administrative support requirements.
- Map and optimise workflow processes.

REC Membership (Section 5.3.1)

What Changed

Clarification has been added regarding REC composition, with emphasis on ensuring members have the requisite training, skills, expertise and diversity to review clinical studies. Furthermore, their members should understand the **local context of the participant community** as well as the **capacity for post-approval monitoring**.

Why It Was Updated

This may aim to strengthen multidisciplinary review capacity and reduce gaps in expertise during ethical evaluation.

What It May Mean In Practice

Institutions may need to reassess whether REC membership adequately reflects required scientific, ethical, and community perspectives.

Practical Takeaway

RECs may wish to:

- Review membership composition against updated expectations.
- Address identified expertise gaps.

Chairperson and Member Appointments (Sections 5.3.2. 5.3.2.1 & 5.3.2.2)

What Changed

- Chairperson appointment

Stronger guidance has been introduced on appointment processes, tenure, and independence safeguards for REC Chairpersons. In the latest update, guidance has been amended to provide clarity on the term of office of the Chairperson of the REC. The Chairperson may serve for a period of **three to five years, renewable once**, in addition to the terms served as a member of the REC.

- Additional Considerations for AREC Chairperson

As per NDoH 2024 v3.2, an Animal-REC Chairperson is now expected to either have relevant experience in research and training in animal research ethics or have been a member of an AREC for **at least two years**, rather than the one year previously stipulated.

- Appointment of REC members

REC members should be formally appointed for periods of **three to five years, renewable once as ordinary members**, after which the member should step down for at least one term. In addition to the terms served as an ordinary member, an REC member may serve a **three-to-five-year term** as a chairperson (or Vice Chairperson), **renewable once**, and a member may not serve more than two terms as a Chairperson (or Vice Chairperson).

However, a motivation can be made to the institutional authority for further renewal of membership.

Why It Was Updated

This likely reinforces governance independence and reduces potential institutional influence over REC decision-making.

What It May Mean In Practice

Chair and member appointments may require more formalised, transparent processes with documented independence criteria.

Practical Takeaway

RECs may wish to:

- Formalise Chair and member appointment procedures.
- Document conflict-of-interest safeguards.

Archiving and Record Keeping (Section 5.5.1.8)

What Changed

Stricter expectations for secure and structured REC record keeping and archiving of REC records have been introduced.

REC records of protocols received for review should include, at least:

- Names of Principal, Co, and Sub Investigators
- Names of all Sponsors, collaborators, and other team members, including students.
- Protocol identification number
- Title of the project
- Date of approval or rejection
- Duration of approval period (maximum 12 months, renewable)
- Conditions of approval, if applicable
- Whether approval was via normal process, reciprocal, expedited, rapid, or joint review.
- Copy of the signed final protocol
- Site or facilities where the research will be conducted
- Whether and how consultation occurred
- Records of protocol deviations
- Records of amendments
- Reports of adverse and serious adverse events, and all incidents, as well as the action taken
- Other relevant information, including complaints from participants

Why It Was Updated

This may reflect increased expectations around audit readiness and long-term accountability.

What It May Mean In Practice

Institutions may need to upgrade archiving systems and ensure defined retention policies are implemented.

Practical Takeaway

RECs may wish to:

- Review digital and physical archiving systems.
- Define and enforce retention schedules.

Compliance Reporting to NHREC(Section 5.6)

What Changed

Guidance on requirements for **RECs' annual reporting on their activities** to the NHREC has been updated in NDoH 2024 v3.2.

RECs are now required to report on the following activities:

- Membership and membership changes
- The number of meetings held
- Confirmation of participation by required categories of members
- The number of protocols presented, the number approved, and the number rejected
- Monitoring and related matters
- Complaints received and actions taken
- Any other matters regarded as important to promote REC functioning and compliance.

Furthermore, annual REC reports are now also used to gather information on the **national status of all registered RECs.**

Why It Was Updated

This may enhance national oversight and improve consistency in REC performance monitoring.

What It May Mean In Practice

RECs may need more structured reporting systems and scheduled submission processes.

Practical Takeaway

RECs may wish to:

- Align internal reporting with NHREC requirements.
- Assign accountability for reporting compliance.

Part 4: Training and Competency

This part highlights amendments that clarify and strengthen the competencies expected of those involved in ethics review. While some changes apply broadly to REC members, researchers and students, others are specific to Animal Research Ethics Committees (ARECs) and international collaborators conducting research in South Africa.

Education and Training (Section 5.4)

What Changed

Stronger emphasis has been placed on ongoing training requirements for REC members and researchers. Guidance now explicitly states that **researchers** and **students** have to undertake **ethics training at least every three years**.

Why It Was Updated

This may reflect the increasing complexity of clinical research and the need for continuous professional development.

What It May Mean In Practice

Training may shift from informal participation to structured, recurring programmes.

Practical Takeaway

- Implement formal annual training plans.
- Track training completion systematically.

Training Outcomes (Section 5.4.2)

Note: *The following amendments apply specifically to* ***Animal Research Ethics Committees (ARECs)*** *and researchers conducting animal research.*

What Changed

Version 3.2 expands and clarifies the knowledge expected of **Animal Research Ethics Committee (AREC) members** when reviewing animal research protocols.

The updated guidance includes greater emphasis on understanding:

- Analysis of the degree (magnitude and likelihood) of harm
- Justification of harm
- Identification of aggravating factors

The guidelines also broaden the options that should be considered for the fate of animals at the completion or termination of a study. In addition to euthanasia, these may include:

- Rehoming
- Introduction into breeding programmes
- Re-use, where appropriate
- Transfer to other facilities

- Public adoption

In addition, the guidance relating to euthanasia has been expanded to include knowledge of acceptable methods, legal requirements, ethical considerations, and emergency procedures.

Why It Was Updated

These amendments are likely intended to provide greater clarity regarding the competencies expected of AREC members when evaluating animal research.

The revisions also appear to encourage a broader ethical assessment that considers the entire lifecycle of research animals—not only the scientific justification for their use, but also their welfare during and after the study.

What It May Mean In Practice

AREC members may be expected to apply a more comprehensive and consistent approach when reviewing animal research proposals.

Researchers submitting animal research protocols may also need to provide more detailed justification regarding:

- The anticipated harms to animals
- Measures to minimise those harms
- The proposed fate of animals following study completion or termination

This could result in more robust ethical review and more detailed committee discussions around animal welfare considerations.

Practical Takeaway

AREC members may wish to:

- Review the updated competency expectations outlined in Version 3.2.
- Ensure they are familiar with the revised terminology and ethical considerations relating to harm assessment and animal welfare.

Researchers conducting **animal research** may wish to:

- Review animal research protocols to ensure they address the revised expectations regarding harm justification and post-study animal care.
- Provide sufficient detail to support AREC review of animal welfare throughout the research lifecycle.

International Collaborators with Existing Training in Research Ethics (Section 5.4.2.1)

What Changed

Clarification has been added regarding training expectations for international collaborators conducting research in South Africa.

In addition to demonstrating recent research ethics training (and GCP training where applicable), international collaborators are now expected to have a **basic understanding of the South African legislative and regulatory framework**, including the NDoH 2024 Ethics Guidelines.

The updated guidance also clarifies that:

- Human research conducted in South Africa must have at least a local Principal Investigator (PI) or research supervisor.
- International collaborators involved in animal research should also receive training or orientation on SANS 10386:2021 (or the latest version).

Why It Was Updated

These amendments are likely intended to strengthen local ethical oversight in internationally collaborative research.

Rather than assuming that research ethics training obtained elsewhere is sufficient, the updated guidance recognises that researchers also need an understanding of the **South African ethical, legal and regulatory environment** in which the research will be conducted.

The clarification regarding a local PI or research supervisor may also be intended to ensure there is clear local accountability, oversight and familiarity with national requirements throughout the conduct of the study.

This may support harmonisation of ethical standards in multinational research.

What It May Mean In Practice

International sponsors and collaborating institutions may need to include **South African regulatory orientation** as part of investigator onboarding, rather than relying solely on generic GCP or international ethics training.

Research teams may also need to demonstrate that:

- International collaborators understand the local regulatory framework;
- An appropriately qualified local PI or research supervisor has been appointed for South African studies; and
- Where animal research is involved, collaborators are familiar with the applicable South African animal research standards.

This could lead to more consistent application of South African ethical requirements across multinational research projects.

Practical Takeaway

International collaborators may wish to:

- Familiarise themselves with the NDoH 2024 Ethics Guidelines and other applicable South African legislation before commencing research.
- Ensure their research ethics and GCP training is current and appropriate for their role.

Sponsors and research institutions may wish to:

- Include South African regulatory and ethics orientation as part of investigator onboarding.
- Confirm that every South Africa-based study has an appropriately qualified local PI or research supervisor.
- For animal research, ensure collaborators receive orientation on SANS 10386:2021 (or the latest version).

Part 5: Clinical Trial Governance

This part explores amendments relating to the governance and oversight of clinical trials. The updates appear intended to clarify national responsibilities and processes that support transparency, accountability and the effective conduct of clinical research.

SANCTR registration responsibilities (Section 6.5.2)

What Changed

Clarification has been added regarding clinical trial registration and oversight through SANCTR.

Why It Was Updated

This may improve transparency and ensure all trials are properly registered and traceable at national level.

What It May Mean In Practice

There may be stronger enforcement of trial registration prior to participant enrolment.

Practical Takeaway

- Complete SANCTR registration early in the trial lifecycle.
- Confirm registration before first participant recruitment.

Scientific Review Integration (Section 3.1.1)

What Changed

Scientific review is more explicitly integrated into ethics approval processes, including conditional approval pathways.

Why It Was Updated

This may reduce duplication and streamline approval workflows.

What It May Mean In Practice

RECs may adopt a more integrated view of scientific validity within ethics review.

Practical Takeaway

- Clearly document scientific review status in submissions.
- Align institutional processes to avoid duplication.

Final Thoughts: From Compliance to Implementation

Viewed individually, many of the Version 3.2 amendments appear modest—clarifying wording, refining processes, or expanding existing guidance. However, when considered together, they reveal several consistent themes.

Many of the updates appear to encourage:

- **Greater clarity** in ethical expectations and regulatory responsibilities.
- **More consistent and transparent decision-making** by RECs.
- **Stronger governance and accountability** across ethics review processes.
- **A shift from demonstrating compliance to demonstrating implementation**, with greater emphasis on explaining *how* ethical principles will be applied in practice rather than simply confirming that they will.

The amendments also reinforce the importance of local oversight, whether through institutional complaint processes, the appointment of local Principal Investigators for international studies, or clearer delineation of responsibilities between researchers, RECs, institutions and national oversight bodies.

While some of these changes may require updates to application forms, SOPs, training programmes or internal processes, they also present an opportunity for researchers and RECs to strengthen the quality and consistency of ethics review.

Ultimately, Version 3.2 appears less about introducing new ethical principles and more about **clarifying expectations, strengthening governance, and supporting a more transparent and effective ethics review system**.

Author's Note

This guide reflects my personal review and interpretation of the amendments introduced in Version 3.2 of the NDoH 2024 Ethics Guidelines. It is intended to support discussion and understanding of the changes and should not be regarded as official guidance or legal advice. I am not affiliated with the National Department of Health, the National Health Research Ethics Council (NHREC), or any Research Ethics Committee in relation to this publication. Readers should always refer to the official guidelines and consult their own institution or REC where clarification is required.