SONIC HEALTHCARE

July 2026

Clinical Research Policy

sonichealthcare.com

Contents

SHL-PO-0028-00

Purpose and principles

Sonic Healthcare (Sonic[1]) is a multinational healthcare company focused on delivering quality healthcare services in laboratory medicine/pathology, radiology/diagnostic imaging and primary care medical services. Sonic, together with all its subsidiaries, is committed to advancing patient care and public health, including through supporting ethical, high-quality clinical research.

This Policy sets the minimum requirements for governance of research involving human participants, human data and/or human biological materials across Sonic's federated operations globally.

Participant rights, safety, wellbeing and dignity are paramount and take precedence over scientific, operational or commercial interests. This Policy aligns with internationally recognised standards (including the Declaration of Helsinki and International Council for Harmonisation Good Clinical Practice guidelines (ICH GCP E6(R3)) where applicable.

1. 'Sonic' refers to Sonic Healthcare Limited and all its subsidiaries, being all companies within the Sonic Healthcare Group worldwide (including controlled joint ventures).

Scope and applicability

This Policy applies to activities involving human participants, human data (including identifiable, anonymised, pseudonymised and de-identified data), and/or human biological materials that are conducted by or on behalf of Sonic meeting the definition of clinical research (see below).

This Policy applies to any research activity (study), including where Sonic assumes the role of:

- **Sponsor:** Sonic initiates and is accountable for the study.
- **Co-Sponsor:** Sonic shares Sponsor responsibilities under a written co sponsorship agreement that allocates decision rights and duties.
- **Study site:** Sonic clinicians/staff conduct study procedures and manage participant care at a site.
- **Contract research organisation (CRO)**: Sonic is contracted or subcontracted to provide specialised clinical trial and related services by pharmaceutical, in-vitro diagnostic, biotechnology, medical device or other CRO companies.

This Policy excludes standard quality assurance, control, accreditation, audits, routine method validation/verification studies and internal service evaluations done solely for operational improvement – unless the activity aims to produce generalisable knowledge, is intended for publication, adds participant burden or risk, or includes randomisation or research-only procedures. For guidance on whether this Policy applies, please see Appendix A.

Definitions

Clinical research

A systematic study involving human participants, their data, and/or human biological materials designed to develop or contribute to generalisable knowledge relating to health, disease, diagnostics, prevention, or treatment. This includes interventional and non interventional studies (e.g., observational, epidemiological, registries, qualitative research).

Clinical trial

A study involving human participants that prospectively assigns one or more interventions to evaluate effects on health-related outcomes (including clinical, pharmacological, diagnostic or other outcomes), typically subject to ICH GCP and applicable regulatory requirements.

Ethics Committee

An independent committee that is formally constituted to review and approve research proposals to ensure the protection of research participants. Such committees may be referred to as Human Research Ethics Committees (HREC) in Australia, Institutional Review Boards (IRB) in the USA and Research Ethics Committees (REC) in Europe. All such committees are guided by core principles such as those in the Declaration of Helsinki.

- **Sponsor:** an individual, group or organisation that starts, supervises, directs, and often finances a clinical trial or clinical research project.
- **Co-Sponsor** an individual or organisation that shares Sponsor responsibilities with one or more other entities under a written agreement that allocates responsibilities, decision rights and oversight arrangements.
- **Principal Investigator (PI):** the person responsible for the conduct of the study at a study site and for protecting participant rights, safety and wellbeing; ensuring protocol adherence; and supervising delegated tasks.

Governance, accountability and quality system

Governance requirements for in-scope clinical research studies are summarised in the checklist in Appendix B.

Ethics, approvals and participant protection

All studies must be ethically justified, scientifically sound, and designed so that anticipated benefits justify foreseeable risks. Research must be conducted only after obtaining prior Ethics Committee approval (and any required regulatory authorisations) and must remain subject to ongoing oversight, including reporting of protocol deviations, safety events, required progress and final reports.

Informed consent must be obtained and documented before any study-specific procedures, unless a consent waiver is approved by an Ethics Committee and permitted by law. Consent processes must support participant comprehension (including language and accessibility needs) and include additional protections for vulnerable populations, consistent with applicable ethical guidelines.

Clinical trials must be conducted according to ICH GCP E6(R3) and all studies must comply with applicable ethical, legal, regulatory and institutional requirements. Where requirements differ, the more stringent standard applies unless prohibited by law.

Where emerging technologies or novel methodologies are used (e.g., AI-enabled decision support, digital endpoints, remote data capture), study teams must identify and mitigate associated ethical, safety, privacy and bias risks.

Accountability, delegations and escalation

For each study, the sponsor must ensure there is a documented study-specific accountability model specifying roles, responsibilities, decision rights, delegations, escalation contacts, and oversight arrangements for delegated activities.

Delegation of tasks does not transfer accountability unless explicitly agreed in writing and permitted by applicable standards and law.

Each study must define escalation contacts and timeframes. Urgent participant safety concerns and material compliance, integrity or privacy incidents must be escalated immediately to the PI and Sponsor and relevant Sonic risk incident reporting functions as required.

Sponsor and Co-Sponsor oversight, monitoring and reporting obligations

When Sonic acts as Sponsor or Co-Sponsor Sonic is accountable for end-to-end study governance and oversight, and must ensure the following obligations are defined, implemented, and evidenced (directly or through appropriately overseen delegation):

Accountabilities	Accountable role (defined per study)
Overall study governance and oversight	Sponsor / Co-Sponsor (as agreed)
Site conduct and participant safety at site	Principal Investigator
Risk-based quality oversight model	Sponsor
Privacy/security approvals and cross-border transfers (where applicable)	Local Privacy function / data protection lead (consult Sponsor)
Delegated activities (CRO/vendor/lab)	Delegating party retains accountability; vendor/lab responsible within scope
Escalation of material issues (safety, integrity, compliance)	Minimum escalation to Principal Investigator and Sponsor, Sonic Group Chief Medical Officer
Safety, adverse event, compliance reporting	Principal Investigator
Documentation & inspection readiness	Principal Investigator

Responsibilities as a CRO

When Sonic's role in a study is as a CRO, accountability for overall trial governance and oversight remains with the external Sponsor. Sonic is accountable under contract for performing delegated activities in accordance with the study protocol, ethics approvals, and applicable standards. Sonic will maintain data integrity and service quality within contract scope, ensure inspection readiness, and promptly escalate material issues, safety concerns, or compliance risks.

Principal Investigator and study site responsibilities

Responsibility for the conduct of a sponsored study at the study site rests with the Principal Investigator. The Principal Investigator may delegate study-related tasks to appropriately qualified personnel but retains responsibility for supervision of delegated activities, participant safety and wellbeing, protocol adherence, and the integrity of study conduct and data at the site and remains accountable to the Sponsor for these obligations.

Training, competency and resourcing

All personnel must be appropriately qualified by education, training and experience, and trained on the protocol and applicable requirements prior to performing delegated tasks. Sonic will maintain role-appropriate training and competency expectations, including GCP training where applicable.

Transparency, publication and results disclosure

Sonic is committed to the transparent and responsible dissemination of clinical research findings. Authorship must reflect substantial intellectual contribution and comply with recognised authorship standards. Each Sonic author must be acknowledged individually, with their consent and appropriate practice affiliation noted.

Where required, applicable clinical trials must be registered in a public registry before first participant enrolment (or within legally/ethically mandated timeframes) and summary results must be publicly disclosed within required timeframes. Sonic supports timely publication of results, including negative or inconclusive findings. Where mandated by law or ethics (and where feasible), Sonic will support the provision of plain-language results summaries to participants.

Data governance, privacy and information security

Study data and biospecimens must be governed across their lifecycle (collection, processing, analysis, sharing, retention and destruction) in accordance with applicable privacy laws, ethics approvals, participant consent, contractual requirements, and Sonic policies (including Privacy and Information Security requirements). Study planning and documentation will address the following:

- Access and minimisation: restrict access to authorised personnel; use de-identified/coded data where practicable and safeguard re-identification keys.
- Integrity and auditability: maintain data integrity and audit trails, with appropriate change control.
- Systems assurance: use fit-for-purpose, appropriately assured/validated systems with security and backup/recovery controls.
- Secondary use and sharing: Secondary use and the sharing of data or specimens, including cross-border transfers, must comply with consent, ethical approvals or waivers, and legal requirements. Appropriate agreements and safeguards are necessary to ensure adherence to these obligations.
- Retention: retain and securely dispose/archive records and specimens in accordance with legal/regulatory, ethics and contractual requirements.

Complaints, concerns and whistleblowing

Participants, investigators and other stakeholders may raise concerns through study contacts, the overseeing Ethics Committee, or via Sonic's whistleblower mechanisms. Concerns may be raised without fear of retaliation.

Each study must provide participants with clear contact details for questions and complaints, including an independent pathway (e.g., Ethics Committee contact) where required.

Complaints and concerns must be logged, triaged, investigated proportionately, and responded to in a timely manner.

Material concerns (e.g., participant safety, serious non-compliance, privacy incidents) must be escalated according to the study escalation pathway and managed through issue management/CAPA where applicable.

Whistleblower reports are managed under the Sonic Whistleblower Policy.

Compliance and enforcement

Compliance with this Policy is mandatory. Breaches may result in corrective action, disciplinary action, termination of contracts, and/or notification to Ethics Committees and regulators where required. Suspected serious non-compliance must be escalated promptly in accordance with the study escalation pathway and Sonic governance requirements.

Related policies

This Clinical Research and Clinical Trials Governance Policy works in concert with other Sonic Healthcare policies and standards. The following are particularly relevant and should be consulted as needed:

- Privacy Policy
- Global Whistleblower Policy
- Code of Conduct and Ethics

Review and updates

This Policy will be reviewed at least annually and whenever there are material changes to applicable laws/regulations, ICH guidance, organisational structure, or significant findings from audits/inspections or incident trends. Current versions must be available to personnel performing research-related activities.

Policy owner: Group Chief Medical Officer, Sonic Healthcare

Appendix A: Is this clinical research under this Policy?

Answer the questions below. This Policy applies if you answered 'Yes' to one or more questions. If you are unsure, seek advice before commencing.

Question Checklist item	YES	NO	N/A
Is the primary intent to develop or contribute to **generalisable knowledge** (beyond local service improvement)?	☐	☐	☐
Is there an intent to **publish**, present externally, register or share findings outside Sonic (beyond internal QA reporting)?	☐	☐	☐
Is there a **systematic protocol** (prospective plan/objectives/endpoints/analysis plan) to answer a research question?	☐	☐	☐
Are participants **prospectively assigned** to an intervention/pathway (including randomisation) to evaluate effects on health-related outcomes?	☐	☐	☐
Does the activity involve **research-only procedures** or additional participant burden (extra samples, visits, questionnaires, or data collection not required for routine care/operations)?	☐	☐	☐
Are you creating/adding to a **registry**, biobank or dataset intended for future research use?	☐	☐	☐

Appendix B: Governance checklist for research under this Policy

Complete this checklist for any activity that meets the definition of clinical research under this Policy (including clinical trial) to ensure you have met the requirements of this policy. Retain the completed checklist in the study file along with supporting documentation.

Question Checklist item	YES	N/A
Sonic role and accountabilities		
Have you confirmed Sonic's role for this activity (Sponsor / Co-Sponsor / Study site / CRO) and documented the accountable role(s) for governance and oversight?	☐	☐
Where Sonic is a co-sponsor or performing services as a CRO, have you documented (including in contracts) the respective governance roles of Sonic and other parties?	☐	☐
Is there a documented delegation, supervision and escalation pathway (including urgent escalation for safety, integrity, compliance and privacy incidents)?	☐	☐
Ethics, approvals and participant protection		
Do you have documented Ethics Committee determination/approval before commencing any study-specific activity?	☐	☐
Is informed consent required, and if so, is the consent process and documentation in place before any study-specific procedure?	☐	☐
If consent is waived: is there documented Ethics Committee approval for a waiver and confirmation that it is permitted by law and local requirements?	☐	☐
Are additional protections in place for vulnerable participants (where applicable) and are participant contact/complaints pathways documented?	☐	☐
Data governance, privacy and security		
Have you confirmed the lawful basis/consent/ethics authority for collection, use, linkage and any secondary use of participant data/ specimens?	☐	☐
Are access controls and minimisation in place (need-to-know access; de-identified data where practicable; secure management of re-identification keys)?	☐	☐
Are study systems fit-for-purpose with appropriate assurance/ validation, audit trails, backup and recovery controls?	☐	☐
Are cross-border transfers and external sharing (including vendors/ partners) permitted by consent/ethics/law and covered by appropriate agreements and safeguards?	☐	☐
Are retention, archiving and secure disposal arrangements defined and consistent with legal, ethics and contractual requirements?	☐	☐

Question Checklist item	YES	N/A
Quality system, training, monitoring and reporting		
Have all personnel completed role-appropriate training (including GCP where applicable) and been delegated tasks commensurate with competency?	☐	☐
Is there an appropriate risk-based quality oversight and monitoring approach for the study and role (Sponsor/Co-Sponsor/Site/CRO)?	☐	☐
Are processes in place for safety event reporting, protocol deviations, serious non-compliance, and CAPA (as applicable)?	☐	☐
Are essential documents and records maintained to support inspection readiness and to evidence compliance with approvals and this Policy?	☐	☐
Transparency and dissemination		
If a clinical trial: have you assessed whether trial registration and results disclosure obligations apply and who is responsible for them?	☐	☐
Are publication/authorship arrangements documented and consistent with recognised authorship standards and Sonic expectations?	☐	☐

Note: Even where an activity is classified as QA/internal service evaluation (and therefore out of scope of this Policy), it must still comply with applicable privacy, information security, accreditation and local governance requirements. If unsure, seek advice before commencing.