

Voice Study Centre: Monitoring and Auditing Policy

1. Purpose:

This policy establishes the framework for monitoring and auditing research activities conducted at the Voice Study Centre. The purpose is to:

- Ensure adherence to ethical principles, legal requirements, and institutional policies.
- Verify the accuracy and reliability of research data.
- Identify and mitigate potential risks.
- Promote continuous improvement in research quality.

2. Scope:

This policy applies to all research projects conducted under the auspices of the Voice Study Centre, including:

- Clinical trials.
- Observational studies.
- Qualitative research.
- Data analysis projects.

3. Monitoring Procedures:

- **Ongoing Monitoring:**
 - Principal investigators are responsible for ongoing monitoring of their research projects.
 - This includes:
 - Regular review of data collection and management.
 - Verification of informed consent procedures.
 - Monitoring of adverse events (if applicable).
 - Maintaining accurate and complete research records.
- **Risk-Based Monitoring:**
 - The Research Governance Committee will implement a risk-based monitoring approach.
 - Projects with higher risk profiles (e.g., clinical trials, studies involving vulnerable populations) will undergo more frequent and intensive monitoring.
 - Monitoring will focus on key risk areas, such as data integrity, participant safety, and regulatory compliance.
- **Monitoring Visits:**
 - The Research Governance Committee or designated monitors may conduct on-site monitoring visits.
 - These visits may include:
 - Review of research records.

- Interviews with researchers and staff.
- Verification of data collection procedures.

4. Auditing Procedures:

- **Internal Audits:**
 - The Research Governance Committee will conduct periodic internal audits of research activities.
 - Audits will assess compliance with policies, procedures, and regulations.
 - Audits will focus on key areas, such as:
 - Data management and security.
 - Informed consent processes.
 - Adverse event reporting.
 - Financial management.
- **External Audits:**
 - Research projects may be subject to external audits by regulatory authorities or funding agencies.
 - The Voice Study Centre will cooperate fully with external audits.
- **Audit Reports:**
 - Audit findings will be documented in audit reports.
 - Reports will include recommendations for corrective actions.
 - Reports will be submitted to the Research Governance Committee and relevant stakeholders.

5. Corrective and Preventive Actions:

- Any identified deviations or non-compliance issues will be addressed promptly.
- Corrective actions will be implemented to rectify existing problems.
- Preventive actions will be taken to prevent future occurrences.
- Corrective and preventive actions will be documented.

6. Confidentiality:

- All monitoring and audit activities will be conducted in a confidential manner.
- Access to research data and records will be restricted to authorized personnel.

7. Record Keeping:

- All monitoring and audit records will be maintained in accordance with applicable regulations and institutional policies.
- Records will be retained for a specified period.

8. Responsibilities:

- **Research Governance Committee:**
 - Oversee the monitoring and auditing program.

- Develop and implement monitoring and audit procedures.
 - Review audit reports and recommend corrective actions.
- **Principal Investigators:**
 - Comply with monitoring and auditing requirements.
 - Maintain accurate and complete research records.
 - Implement corrective actions as required.
- **Monitors and Auditors:**
 - Conduct monitoring and audit activities in accordance with established procedures.
 - Document findings accurately and completely.

9. Review and Updates:

- This policy will be reviewed and updated periodically to ensure its effectiveness and compliance with current regulations.

By implementing this Monitoring and Auditing Policy, the Voice Study Centre can ensure that its research is conducted to the highest standards of quality and integrity.