

# Voice Study Centre: Compliance with International and National Research Standards Policy

## 1. Purpose:

This policy establishes the Voice Study Centre's commitment to conducting research in accordance with the highest ethical, legal, and scientific standards, encompassing both international and national regulations. It aims to:

- Safeguard the rights, safety, and well-being of research participants.
- Ensure the integrity and quality of research.
- Maintain public trust in the Centre's research activities.
- Facilitate international collaboration.
- Uphold the principles of the Concordat to Support Research Integrity.

## 2. Scope:

This policy applies to all research activities conducted under the auspices of the Voice Study Centre, regardless of funding source or location.

## 3. Core Principles:

- **Ethical Conduct:** Adherence to the principles of the Declaration of Helsinki, Belmont Report, and other relevant international ethical guidelines.
- **Legal Compliance:** Compliance with all applicable national laws and regulations, including but not limited to GDPR, the Data Protection Act 2018, the Human Tissue Act 2004, and the Medicines for Human Use (Clinical Trials) Regulations 2004 (if applicable).
- **Scientific Rigor:** Implementation of robust research methodologies, data management practices, and quality assurance procedures.
- **Transparency and Accountability:** Open communication about research activities and responsible management of research funds.
- **Respect for Diversity and Inclusion:** Ensuring research is conducted in a manner that respects the rights and dignity of all participants, regardless of their background.
- **Research Integrity:** Adherence to the principles and responsibilities outlined in the Concordat to Support Research Integrity.

## 4. Key Standards and Guidelines:

### International Standards:

- Declaration of Helsinki (World Medical Association).
- Good Clinical Practice (GCP) (ICH).
- General Data Protection Regulation (GDPR) (European Union).
- ISO Standards (e.g., ISO 27001 for information security).

- UNESCO Universal Declaration on Bioethics and Human Rights.

### **National Standards (United Kingdom):**

- Health Research Authority (HRA) guidelines.
- Medicines and Healthcare products Regulatory Agency (MHRA) regulations.
- Information Commissioner's Office (ICO) guidelines.
- Relevant legislation (e.g., Data Protection Act 2018, Human Tissue Act 2004, Equality Act 2010).
- UKRI policies and guidelines.
- The Concordat to Support Research Integrity.

## **5. The Concordat to Support Research Integrity:**

The Voice Study Centre is committed to upholding the five commitments of the Concordat:

- Upholding high standards of rigour and integrity in all aspects of research.
- Ensuring that research is conducted ethically and responsibly.
- Supporting a research environment that is conducive to research integrity.
- Employing transparent, robust, and fair processes for dealing with allegations of research misconduct.
- Working together to strengthen the integrity of research and to address research misconduct.

The Centre will take proactive steps to promote a culture of research integrity, including providing training, fostering open communication, and implementing clear procedures for reporting and investigating research misconduct.

## **6. Compliance Mechanisms:**

- **Ethical Review:** All research projects involving human participants must undergo ethical review by an appropriately constituted ethics committee.
- **Standard Operating Procedures (SOPs):** Development and implementation of SOPs for key research activities, including data collection, data management, and adverse event reporting.
- **Training and Education:** Provision of regular training to researchers and staff on ethical principles, legal requirements, and best practices, and the concordat.
- **Monitoring and Auditing:** Implementation of a robust monitoring and auditing program to ensure compliance with standards and guidelines.
- **Data Management:** Adherence to data management principles, including data security, confidentiality, and integrity.
- **Record Keeping:** Maintenance of accurate and complete research records in accordance with applicable regulations.
- **International Collaboration:** When engaging in international research collaborations, ensure that all activities comply with both UK and relevant international standards.

- **Continual Improvement:** Regular review and updating of policies and procedures to reflect changes in standards and best practices.

## **7. Responsibilities:**

- **Principal Investigators:** Responsible for ensuring that their research complies with all applicable standards and guidelines, including the concordat.
- **Research Governance Committee:** Responsible for overseeing research compliance and providing guidance to researchers.
- **Voice Study Centre Management:** Responsible for providing adequate resources and support for research compliance and research integrity.

## **8. Reporting Non-Compliance:**

Any suspected or actual non-compliance with standards or guidelines, or any concerns regarding research integrity, must be reported immediately to the Research Governance Committee.

## **9. Review and Updates:**

This policy will be reviewed and updated regularly to ensure its continued effectiveness and compliance with evolving standards, including the Concordat to Support Research Integrity.