

# UK Legislative Compliance Policy

## 1. Introduction:

The Voice Study Centre is committed to conducting research in full compliance with all applicable UK legislation and regulations. This document provides an overview of key legal areas relevant to our research activities.

## 2. Key Legislative Areas:

### Data Protection:

- **General Data Protection Regulation (GDPR) and Data Protection Act 2018:**
  - Ensures the lawful, fair, and transparent processing of personal data.
  - Requires obtaining informed consent for data collection and processing.
  - Mandates appropriate data security measures.
  - Covers data storage, retention, and destruction.
  - Requires implementing a data management plan.
- The voice is considered biometric data, and therefore special category data, and needs extra protection.

### Research Ethics:

- **Declaration of Helsinki:**
  - International ethical principles for medical research involving human subjects.
- **Health Research Authority (HRA) Guidance:**
  - Provides guidance on ethical approval and governance for health and social care research.
  - Requires ethical review of research involving human participants.
- **Mental Capacity Act 2005:**
  - If research involves people who may lack capacity, this act must be adhered to.

### Clinical Trials (if applicable):

- **Medicines for Human Use (Clinical Trials) Regulations 2004:**
  - Regulates the conduct of clinical trials involving medicinal products.
  - Requires obtaining Clinical Trials Authorisation (CTA) from the Medicines and Healthcare products Regulatory Agency (MHRA).
- **Good Clinical Practice (GCP):**
  - International ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve the participation of human subjects.

### Human Tissue Act 2004:

- Regulates the storage and use of human tissue for research.
- Requires obtaining appropriate consent for tissue use.

## **Intellectual Property (IP):**

- **Patents Act 1977, Copyright, Designs and Patents Act 1988:**
  - Protects intellectual property rights, including patents, copyrights, and designs.
  - Requires careful management of IP generated during research.

## **Equality Act 2010:**

- Prohibits discrimination based on protected characteristics (e.g., age, disability, gender).
- Requires ensuring research is inclusive and accessible.

## **Health and Safety at Work etc. Act 1974:**

- Requires employers to ensure the health, safety, and welfare of employees and others affected by their work.
- Risk assessments are required.

## **3. Responsibilities:**

### **Principal Investigators:**

- Responsible for ensuring that their research complies with all relevant legislation and regulations.
- Must obtain necessary ethical approvals and consents.
- Must maintain accurate and complete research records.

### **Research Governance Committee:**

- Responsible for overseeing research governance and ensuring compliance.
- Must provide guidance and support to researchers.
- Must monitor research activities.

### **Voice Study Centre Management:**

- Responsible for providing adequate resources and support for research compliance.
- Must ensure that appropriate policies and procedures are in place.

## **4. Compliance Procedures:**

- Researchers must complete appropriate ethics training.
- All research protocols must be reviewed and approved by the Research Governance Committee.
- Informed consent must be obtained from all research participants.
- Data must be stored and managed in accordance with GDPR and the Data Protection Act 2018.
- Any adverse events or breaches of compliance must be reported immediately.

## **5. Review and Updates:**

- This document will be reviewed and updated regularly to reflect changes in legislation and best practice.

## **6. Further Information:**

- For further information on UK research legislation, please refer to the following resources:
  - Health Research Authority (HRA)
  - Medicines and Healthcare products Regulatory Agency (MHRA)
  - Information Commissioner's Office (ICO)