**FOI 23/848**

Dear

Many thanks for your request for information, dated 06 November, where you asked the following:
*The guidance on using human materials is under the Nuremberg agreement, but only offers guidance. What statutory regulations is the MHRA using to provide direction on this matter, please?*

**Our response:**

The use of human material is under the remit of the Human Tissue Authority and is covered by the Human Tissue Act 2004. Please refer to the links below.
Home | Human Tissue Authority (hta.gov.uk)
Human Tissue Act 2004 (legislation.gov.uk)

The reference to the Nuremberg agreement in your request suggests that you may be interested in clinical trials subjects. Clinical trials in humans are conducted in accordance with Good Clinical Practice (CGP) requirements.

Good clinical practice (GCP) is a set of internationally-recognised ethical and scientific quality requirements that must be followed when designing, conducting, recording and reporting clinical trials that involve people.
Organisations that may have to comply with GCP include:

- pharmaceutical companies
- contract research organisations
- universities
- NHS hospitals
- charities
- GP practices
- laboratories analysing samples originating from a clinical trial (including NHS, academic and commercial laboratories)

Guidance on good clinical practice has been produced by the International Conference on Harmonisation of technical requirements for registration of pharmaceuticals for human use (ICH).
To ensure compliance with GCP, MHRA:

- asks trial sites to notify them of serious breaches
- carries out inspections of trial sites where serious breaches are reported
- carries out inspections of trial sites that sponsor clinical trials, mostly based on a risk assessment
- carries out inspections of sites when companies apply for marketing authorisations

You can find the European Union directives, GCP and other guidance in Volume 10 of the rules governing medicinal products in the European Union
The key UK legislation and guidance which covers GCP inspections includes:

- The Medicines for Human Use (Clinical Trials) Regulations 2004

- The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006
- The Medicines(Advisory Bodies)(No. 2)Regulations 2005
- The Medicines (Marketing Authorisations Etc.) Amendment Regulations 2005
- The Medicines for Human Use (Clinical Trials) Amendment (No.2) Regulations 2006
- The Pharmacists and Pharmacy Technicians Order 2007
- The Medicines for Human Use (Clinical Trials) and Blood Safety and Quality (Amendment) Regulations 2008
- The Medicines for Human Use (Miscellaneous Amendments) Regulations 2009
- The Medicines for Human Use (Advanced Therapy Medicinal Products and Miscellaneous Amendments) Regulations 2010
- MHRA's guidance for clinical trial sponsors and host organisations on electronic health records

Schedule I, Part 2(6) of the UK SI 2004/1031 The Medicines for Human Use (Clinical Trials) Regulations (as amended), require for clinical trials to be conducted in accordance with the principles of the Declaration Helsinki.
https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/

We hope that the above information addresses your request.

If you are unhappy with our decision, you may ask for it to be reviewed. That review will be undertaken by a senior member of the Agency who has not previously been involved in your request. If you wish to pursue that option, please email: info@mhra.gov.uk

After that, if you remain dissatisfied, you may write to the Information Commissioner at;
The Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow

Cheshire
SK9 5AF