Research Governance Awareness For Ambulance Personnel
Objective

To develop an understanding of clinical research processes and the standards which serve to protect patients and promote scientific quality
In this first section you will gain an appreciation of the purpose behind health research; steps in the research process; people involved and key terminology
Purpose of research

Research is an integral part of NHS activity:

1. It identifies **innovative** ways of preventing, diagnosing and treating illness;

2. Provides the **evidence base** for the organisation, management and delivery of healthcare services **to increase the quality of patient care**, ensuring **better patient outcomes** and contributes towards population health;

3. Provides information on the **costs, effectiveness and broader impact** of health technologies;

4. **Is important to the public** [97% express support and 72% indicate a willingness to participate - Mori poll 2011]

5. **Is supported by the HCPC** as contributory to patient care.
What is health research?

Health research can take many forms, from quantitative studies such as clinical trials of drugs through to qualitative studies which explore clinician and patient attitudes; preferences and experiences:

- Randomised Controlled Trials [RCT]
- Case control studies
- Cohort studies
- Surveys
- Qualitative studies
- Case studies
But it does not include:

- Service Improvement – designed and conducted solely to improve current care
- Clinical Audit – designed and conducted to collect information against existing standards and improve delivery of best care
# The Clinical Research Process

<table>
<thead>
<tr>
<th>Before</th>
<th>Study</th>
<th>After</th>
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<tbody>
<tr>
<td></td>
<td>1. Research idea</td>
<td>8. Data analysis</td>
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<td></td>
<td>2. Design, feasibility, funding &amp; sponsorship</td>
<td>9. Publication of results</td>
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<td></td>
<td>3. Regulatory approvals [MHRA; NRES; Local R&amp;D]</td>
<td>10. Implementation of changes based on outcomes</td>
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<td>4. Protocol, training, release of IMP for CTIMP study</td>
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<td>5. Identifying and enrolling patients</td>
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<td>6. Taking consent if appropriate for the study</td>
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<td>7. Data gathering; Intervention; Safety reporting</td>
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NIHR
Study Roles and responsibilities

• **Sponsor**: An individual, company, institution, or organisation which takes **overall responsibility** for the initiation, management, and/ or financing of a clinical trial (legal duty under UK Regulations).

• **Chief Investigator**: Authorised health professional who takes **primary responsibility** for the conduct of the trial.

• **Local / Principal Investigator [PI]**: Authorised health professional responsible for the conduct of the trial at the **trial site**.

• **Local research support**: Authorised clinician or NHS research staff helping with a study during the delivery of clinical care according to the duties **delegated by the PI** and responsible for monitoring the patient during that time.
All clinical studies/trials involving human subjects in which an intervention is investigated to establish both its efficacy and safety is classed as either CTIMP or Non-CTIMP.

**CTIMP** - Clinical Trial of an Investigational Medicinal Product fall within the scope of the UK Medicines for Human Use [clinical trials] Regulations 2004

e.g. Blood pressure medication

**Non-CTIMP** studies do not use any type of medically active agent and fall outside of those regulations

e.g. new clinical assessment process
Understanding Terminology 2

**Protocol**
an official document describing the study objective(s), design, methodology, statistical considerations and organisation

**Randomisation**
the process of assigning trial subjects to treatment or control groups using an element of chance in order to reduce bias

**Blinding**
one or more parties to the trial are kept unaware of the treatment assignments.
Research Governance

In this section you will gain an appreciation of the legislation and standards that apply to all clinical studies.
Purpose of Standards

- Protection of patient health and rights
- Reduction of the risk of harm
- Quality data and reliable outcomes
- Credibility
## Legislation

<table>
<thead>
<tr>
<th>Year</th>
<th>Legislation</th>
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<tbody>
<tr>
<td>2010</td>
<td>Advanced therapy Products e.g., genes, cells &amp; tissues [MHUR SI 2010/1882]</td>
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<tr>
<td>2009</td>
<td>Rapid response to public health threats/ pandemics [MHUR SI 2010/1882]</td>
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<tr>
<td>2008</td>
<td>Minors in urgent situations [MHUR SI 2008/941]</td>
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<tr>
<td>2006</td>
<td>Incapacitated adults in urgent situations [MHUR SI 2006/2984]</td>
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<tr>
<td>2005</td>
<td>EU GCP Directive, Mental Capacity Act, DH Research Governance Framework</td>
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<tr>
<td>2004</td>
<td>UK Medicines for Human Use (Clinical trial) Regulations [MHUR], Human Tissue Act</td>
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<tr>
<td>2001</td>
<td>EU Clinical Trials Directive, Misuse of Drugs Regulations</td>
</tr>
<tr>
<td>1998</td>
<td>Human Rights Act, Data Protection Act</td>
</tr>
<tr>
<td>1996</td>
<td>International Conference on Harmonisation [ICH], Technical Requirements for Registration of Pharmaceuticals for Human Use</td>
</tr>
<tr>
<td>1964</td>
<td>Declaration of Helsinki, Guidance to physicians and other participants in medical research involving human subjects</td>
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UK Guidance

- DH Research Governance Framework sets out the broad principles of good research governance in NHS

- Separate frameworks for England, Scotland, Wales and NI
  www.hra.nhs.uk/resources/research-legislation-and-governance-frameworks
Good Clinical Practice [GCP]

Clinical studies in the NHS are required to comply with the International Conference on Harmonisation [ICH] Good Clinical Practice [GCP] standards

GCP represents the international ethical & scientific quality standard for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of clinical trials that provides assurances that the data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial subjects are protected

ICH 1.24
1. Ethical principles govern the conduct of trials.

2. Anticipated benefits justify the risks.

3. Rights, safety and well-being of trial subjects prevail over the interests of science and society.

4. Information on any medicinal intervention should be adequate to support the trial.

5. Clinical trials should be scientifically sound, and described in a clear, detailed protocol.
6. A trial should be conducted in compliance with the approved protocol.

7. Medical care given to, and medical decisions made on behalf of, patients are the responsibility of a qualified practitioner.

8. Each individual involved in conducting a trial should be qualified by education, training, and experience to perform their tasks.

9. Freely given informed consent should be obtained from every patient unless exceptions apply.
10. All trial information should be recorded, handled and stored to ensure accurate reporting, interpretation and verification.

11. The confidentiality of records must be protected.

12. Study drugs must be used in accordance with the protocol.

13. All systems and procedures should assure the quality of the trial.
Ethics Committee Approval

• Research in or through the NHS is reviewed by NHS Research Ethics Committees (RECs) to ensure it is both ethical and worthwhile.

• Each regional committee consists of up to 18 members comprising both members of the public and registered healthcare professionals.

• Each year, RECs review around 6,000 research applications across the UK.

• REC’s assess whether anticipated risks, burdens or intrusions will be minimised and justified by expected benefits.

• They are required to give their opinion within 60 days.

• Research activities requiring REC approval must not begin without a favourable opinion being secured.
In this section you will gain an appreciation of what constitutes informed consent; how it is taken and the exceptions which apply in the prehospital environment.
What is informed consent?

Informed consent is a process by which a subject voluntarily confirms his or her willingness to participate in a particular clinical trial, after having been informed of all the aspects of the trial that are relevant to the subjects decision to participate.

ICH-GCP 1.28
Obtaining Consent for Research

- Patient Information Sheet and Consent Form must have been approved by a Research Ethics Committee [REC]
- There should be no coercion to enter the study/trial
- The information must be presented to the patient in the most appropriate way using non-technical language and/or pictures
- The patient or their representative must be allowed appropriate time to consider their decision according to the circumstances and the urgency of care
- Consent form must be signed and dated by the patient or their representative as well as the practitioner and the process documented in NHS records
Patients Lacking Capacity

The Mental Capacity Act 2005 states: A person must be assumed to have capacity unless it is established that he/she lacks capacity. Capacity must be assessed in terms of a person’s ability to make a decision at the point when it is required.

Assessing the patient’s ability to make a decision:

- Do they understand what decision they need to make and why
- Do they understand the consequences [risks and benefits]
- Are they able to weigh up and retain relevant information
- Can they communicate their decision

Studies may use standard scripts and questions to assess capacity.

A legal, personal or professional consultee can represent the patient during a research decision if the patient does not have capacity.
Exceptions in Pre-hospital Research

No time to consult a third party

- Alternative arrangements must be made and documented subsequent to treatment e.g., consultation with an identified member of staff independent of the research

[MHUR/SI/2004/1031]

Waiver of consent on the basis of futility

- Only if agreed by REC and documented in Protocol

[MHUR/SI/2006/2984]
In this section you will gain an appreciation of the requirement for accurate data collection.
Why have research documentation?

- **Compliance**
  - with protocol, standards, regulations
- **Transparency**

Protocols may include a Case Report Form [CRF] which is a printed, optical or electronic document designed to record the research information required by the Sponsor for each participant.

The clinical record must be complete and accurate. It should also document the trial name, trial number if known and randomisation group if appropriate.
CRF Completion

- Records should be accurate, complete, legible and timely
- Data should be consistent with source documents (or discrepancies explained)
- Any changes should be initialled and dated – do not obliterate the original entry
- CRFs are the official documentation of the trial for Sponsors and regulatory authorities, and together with source documents will be closely examined during audits and inspections.
Safety Reporting

In this section you will gain an appreciation of safety reporting requirements and associated terminology.
What is Safety Reporting?

- It monitors the effects of the intervention on patients
- Serves to protect current and future patients
- Ensures benefits outweigh risks & side effects before any new treatment becomes standard practice

**Adverse Event [AE]**

- Any untoward medical occurrence in a subject to whom a research intervention has been administered
- Is not necessarily related to the treatment
- Reporting requirements are described in the study protocol

ICH-GCP 1.2

In urgent situations your first priority is always: **protect the patient**
Clinical research takes many forms but each trial/study is broadly classified as either a CTIMP or Non-CTIMP.

Research is an integral part of the NHS constitution and your involvement is supported by the HCPC.

All studies are subject to regulations and standards which are encapsulated in the principles of Good Clinical Practice [GCP].

Patients must voluntarily consent to participate unless they lack capacity [for which alternate arrangements apply] or consent has been waived because of the study design.

Accurate and full documentation is important.

Patients’ rights, dignity and safety must be the priority.
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Further information and advice regarding research in the NHS may be obtained from

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