NHS
Health Research Authority

Future Focus on GCP Training and e-consent

R&D Forum

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Policy guidance:

New statements forthcoming on:

- Joint HRA/MHRA* statement on GCP and training
- Joint HRA/MHRA statement on e-consent

* Medicines & Healthcare products Regulatory Agency

What do we mean by e-consent/ e-studies?

Includes

- Electronic consent
- Electronic Participant Information Sheet (PIS) as videos

Not:

- Use of consent4consent databases/registers
- Not real world data as outcomes or
- Outcome data extracted from patient notes.

Joint HRA/MHRA statement on e-consent

- **Information about the trial can be provided to potential participants by any method including the use of electronic methods; it does not have to be in writing**
- **Electronic methods to provide information will not always be appropriate and special attention should be paid to the information needs of specific patient populations and those of individual subjects**
- **The *prior interview* should involve *two-way audio or audiovisual communication in real time* and allow confirmation of the participant's identity**
- **Informed consent must always be recorded *in writing, signed and dated* by the participant (or, where applicable, their legal representative)**
- **Electronic methods for documenting consent will be considered to be 'in writing'**

e-signatures

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The Medicines for Human Use (Clinical Trials) Regulations 2004 specifically allows for the use of electronic signatures as a method of signing documents referred to in the Regulations.

An electronic signature can include any of the following forms:

- Typewritten
- Scanned
- An electronic representation of a handwritten signature
- A unique representation of characters
- A digital representation of characteristics, for example, fingerprint, retina
- An advanced electronic signature

e-consent

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- What are the implications for e-consent for researchers, sponsors and RECs?

Consider:

- Electronic versions of patient information sheet - videos
  - version control
  - Internet access?

- Electronic consent
  - What issues does this raise?

Questions?

Joint HRA/MHRA statement on Good Clinical Practice (GCP) and training

- GCP applies in full to those undertaking Clinical Trials of Investigational Medicinal products (CTIMPS) for licensing purposes
- Sponsors of CTIMPs which are not seeking a marketing authorisation application can choose to comply with ICH GCP as a standard in full or they can just follow principles
- There is no set frequency for the training in GCP
- Those undertaking research which is not a CTIMP should not be required to undertake GCP training.

Examples of inappropriate GCP training

- Patients sitting on PPI group to inform trial
- Members of Data Safety Monitoring Committee
- Researchers conducting observational or qualitative studies required to follow GCP and undertake training
- Practice nurses taking blood samples in simple pragmatic trials of existing licensed treatments required to undertake GCP training.

- How does this statement impact on your organisation?
- What problems if any do you forsee?
- How can we help you with this?