News story: Improving how we collect and document consent

The statement confirms that electronic methods may be used for seeking, confirming and documenting informed consent for participation in research and is supported and endorsed by the UK health departments in Northern Ireland, Scotland and Wales.

It also sets out the legal and ethical requirements for eConsent, and joint expectations regarding the use of electronic signatures in Clinical Trials of Investigational Medicinal Products (CTIMPS).

eConsent enables potential research participants to be provided with the information they need to make an informed decision via a tablet, smartphone or digital multimedia. It also enables their informed consent to be documented using electronic signatures.

This approach can supplement the traditional paper-based approach or, where appropriate, replace it.

Using eConsent offers a number of potential benefits, such as:

- improving understanding
- testing and reinforcing participant comprehension
- providing feedback on how consent materials could be improved
- improving patient recruitment process and reducing dropout rates
- enabling process efficiencies

While the statement focuses primarily on clinical trials, the basic principles can be applied to all research conducted within the UK where consent is sought.

Dr Samantha Atkinson, Director Inspection, Enforcement and Standards Division at MHRA, said:

> We are committed to protecting public health, and research and clinical trials form a key part of this commitment.
>
> That’s why we are continuing to innovate and improve the methods by which consent and feedback are sought from potential research participants.
>
> This guidance aims to promote best practice where eConsent is used for clinical trials, ensuring continued provision of key information in a clear way to trial participants.
>
> We continue to support the appropriate implementation of new technologies in clinical research, safeguarding vital and safe health research which benefits us all.

Amanda Hunn, Joint Head Policy at HRA, said:

> Our joint statement clarifies HRA and MHRA expectations with regards to the use of electronic methods for seeking, confirming and documenting informed consent for participation in research.
>
> The use of eConsent has the potential to improve participants' understanding of what is involved in taking part in research and to make recruitment and consent procedures more efficient.
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> This clarification forms part of our ongoing work to encourage researchers to take a more proportionate approach to the process of seeking consent from research participants and will support them in implementing eConsent procedures.