

Involving adults who lack capacity in research and the Mental Capacity Act 2005

The [Mental Capacity Act \(MCA\) 2005](#) provides the legal, ethical, and regulatory framework for working with adults (aged 16+) who lack capacity in England and Wales. Separate legislation applies in Scotland and Northern Ireland. All three frameworks have provisions for research involving adults lacking capacity and provide several [codes of practice](#).

MCA (2005) Key Research Provisions

Sections 30–33 of the MCA outline:

- What qualifies as an *appropriate body* for review and approval;
- criteria that must be met for approval; and
- requirements for involving a *consultee* and ensuring ethical safeguards throughout the study

Researchers must ensure their study design complies with the act before seeking approvals. For detailed guidance, we strongly recommend reviewing the [Health Research Authority \(HRA\) guidance](#).

Does the MCA (2005) apply to my research?

The Mental Capacity Act (MCA) 2005 applies to research conducted in England and Wales involving adults (16+) who lack capacity, and where the research is classed as intrusive under the act's definition.

Scotland and Northern Ireland have their own legislation that applies, so the MCA (2005) doesn't apply to research taking place at sites outside of England or Wales.

What is classed as Intrusive?

Intrusive research is research that would legally require consent if it involved people with capacity. Intrusive research is not limited to trials of clinical interventions or invasive procedures and could be any type of research.

Examples of intrusive research include:

- Research involving the processing of personal data;
- the administration of questionnaires, interviews or observations.

Non-intrusive research would be research that does not legally require consent to take place, for example research using only secondary anonymised data or fully anonymised human tissue samples.

What is an appropriate body?

An appropriate body is an authorised committee that reviews and approves intrusive research involving adults who lack capacity. Without approval from an appropriate body, this type of research is unlawful.

Their role is to ensure the study meets all legal and ethical criteria under the legislation in the country the research is taking place within; this includes checking safeguards are in place, such as the involvement of a consultee.

There are specific NHS Research Ethics Committees (NHS REC) in England, Wales, Northern Ireland and Scotland that are 'flagged' to review this type of research and act as an appropriate body.

How do I apply for approval to undertake my research?

An application to the correct NHS REC must be made via the [Integrated Research Application System](#).

Upon submission, an appointment with a 'flagged' NHS REC in the correct country must be booked. A list of flagged NHS RECs can be found [here](#).

This requirement applies regardless of whether your study involves NHS research sites.

What country should the REC I apply to be based in?

Research with sites in England and/or Wales only → Submit one IRAS application. Select a flagged NHS REC in England or Wales.

Research with sites in Northern Ireland and England/Wales → Submit one IRAS application. Choose a flagged REC in any of these three nations, as a mutual recognition agreement is in place.

Research with sites in Scotland only → Submit one IRAS application. Book a review with Scotland A REC - this is the only committee in Scotland authorised to review such research.

Research with Sites in Scotland AND any other UK nation → Submit two separate IRAS applications. Book two NHS REC reviews:

- Application 1: book a review with 'Scotland A REC' only.
- Application 2: book a review with any *flagged REC* in England, Wales or Northern Ireland.

Important Note: Even if your study does not involve NHS sites, you must still apply for NHS REC approval to conduct intrusive research involving adults lacking capacity. These studies may be exempt from HRA approval but still require ethical review and an application via IRAS.

HSCR-FLOW009 Identifying approvals required for involving adults lacking capacity in research

