Wessex SECURE DATA ENVIRONMENT

Part of the NHS Research Secure Data Environment Network

NHS

# HRA Governance and Approvals

## Wessex SDE approvals and amendments

*March 2026*

# Contents



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# Background to the Health Research Authority

The Health Research Authority, or HRA for short, is one of a number of organisations that work together in the UK to regulate and approve different aspects of health and social care research.

Most of their functions apply to research undertaken in England but they also work closely with the other countries in the UK to provide a UK-wide system.

## What is health and social care research?

Health and social care research aim to find out new knowledge that could lead to changes to health treatments, policies or care. Without health and social care research, clinicians (doctors, nurses, dentists, social workers, and other health professionals) would continue to carry out their work the same way without knowing if a new treatment or approach would be more effective for the person they are supporting or treating.

## How is health and social care research funded?

Research can be funded through the NHS itself (commonly through the National Institute of Health Research (NIHR) which is the research arm of the Department of Health and Social Care), commercial organisations (for example, drug companies), universities, research councils, health organisations and charities.

## How does research get approved?

Before a research study can start; it needs to be approved first by the relevant bodies and health regulatory organisations.

Research Ethics Committees (REC) are independent groups of people who review certain types of research to assess whether studies are ethical. The Confidentiality Advisory Group (CAG) provides advice on specific projects that will be using confidential medical information.

Our staff also assesses research in the NHS to make sure that studies comply with relevant legislation and guidelines (such as Clinical Trials Regulations, the Human Tissue Act and the Data Protection Act).

There are other specialist approvals provided by other organisations for some types of research.

## Where is research carried out and by whom?

With all the relevant approvals in place, health and social care research is carried out in a number of locations including NHS hospitals, doctors/GP surgeries, dentists, care homes or residential care services with patients and service users. Some health

research testing new medicines involves healthy volunteers and takes place in universities or in commercial research centres. In health and social care research, these are called the research sites.

There will be someone responsible for the overall research study called a chief investigator. Usually, this is someone who works directly with patients such as a doctor, dentist, nurse, social worker or a university researcher. The principal investigator is the person responsible for the conduct and day to day running of a study at each research site and will lead a team to carry out the research.

# Section 251 and how it is used

### What is confidential patient information and why is it used?

Confidential patient information is a legal term defined in Section 251 of the NHS Act 2006. It applies to both living and deceased patients and meets the definition if all of the following apply:

- The information is identifiable or likely to be identifiable - this is determined on a case-by-case basis but can include identifiers such as:
    - NHS number, name, address and date of birth, or
    - Where the activity requires information on rare illnesses that could potentially identify a patient or
    - Where the patient could be identified from other data likely to be held by the person or organisation receiving the data
- The information was provided under circumstances where the individual is owed an obligation of confidence
- Conveys information about the physical or mental health or condition of an individual, a diagnosis of their condition, or information on their care or treatment

Under the common law duty of confidentiality, if information is given in circumstances where it is expected that a duty of confidence applies, that information cannot normally be disclosed without patient consent.

However, there are certain circumstances when confidential patient information can be used for the benefit of research and other important activities without patient consent. An alternative legal basis is required which is commonly Section 251 support. You can find examples of activities relying on Section 251 support in our registers of approved applications.

### What is Section 251?

This is a shorthand term and refers to section 251 of the National Health Service Act 2006 and its current Regulations, the Health Service (Control of Patient Information) Regulations 2002.

Section 251 was established as it was recognised that there were essential activities of the NHS, and important medical research, that required the use of confidential patient information where it was not possible to use anonymised information and obtaining consent was not practical.

Section 251 allows the common law duty of confidentiality to be lifted temporarily to enable disclosure of confidential patient information for medical purposes. Whilst it is commonly referred to as 'Section 251' support, support is actually given under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002. Therefore, they are same thing.

### What does Section 251 support mean?

CAG reviews research and non-research applications and advises under the framework of the Health Service (Control of Patient Information) Regulations 2002. They will consider whether there is sufficient public interest to temporarily lift the common law duty of confidentiality and enable access to the requested confidential patient information. Using the CAG advice as a basis for their consideration, the following bodies act as the decision maker on whether Section 251 support can be provided by:

- The Health Research Authority (HRA) – for research applications
- The Secretary of State for Health – for non-research applications
- NHS England – in relation to data dissemination.

## Wessex SDE's HRA approval

The Wessex SDE requires HRA Section 251 Approval to link together data from different places. This is crucial for creating the big datasets that researchers need. Personal information is always removed or disguised before it is made available to researchers. Researchers never see confidential patient information.

The Wessex SDE first obtained its approval in February 2024 and is required to provide annual returns to the HRA to revalidate and provide ongoing permission to use confidential information without individual consent.

Wessex SDE's CAG Reference is: 24/CAG/0013. A copy of our approval can be found in the CAG register – April 2013 onward approved research applications line 886.

Data can only be used for approved purposes as defined in the Wessex SDE's HRA approval as listed below, or via an amendment. Any amendments are captured and summarised within this document for public visibility purposes.

- New approaches to diagnosis, making better use of blood tests, medical images, and other information already in patient records.
- New approaches to treatment, including changes to clinical pathways, better support for clinical decisions, and the introduction of new therapies.
- New approaches to patient records, improving the accuracy and relevance of the data recorded and the management of patients across services.
- Clinical trial feasibility using previously collected clinical and operational data. Identification of potentially eligible trial subjects would take place using pseudonymised data within the SDE DPE but communication with subjects would only be via their care provider (GP, hospital consultant etc) - SDE staff would not approach subjects directly.
- Population health research to identify factors to aid understanding of health outcomes of a group of individuals including the distribution of such outcomes within groups including study of health determinants, health behaviours and the impact of health policies and interventions.
- Operational healthcare research using health and social care data to improve decision making, efficiency, and effectiveness in health services and systems.

**The Wessex SDE HRA has now been updated and approved for 2026.**

**Personal information is always removed or disguised before it is made available to researchers. Researchers never see confidential patient information.**

## Wessex SDE HRA amendments

As described above, the Wessex SDE was first approved by the HRA in February 2024. This was based on a detailed description of how the SDE would work and handle identifiable patient information, known as a protocol.

As the Wessex SDE matures over time, it may be necessary to rethink or reevaluate how we do things and to make changes that will ensure that we work efficiently and effectively, and deliver best value to the public and the NHS. These changes are called “amendments”.

An HRA amendment specifically is a change to a research study after it has already been approved. This could be something small (like correcting a document) or something more significant (like changing how patients take part). Important changes must be reviewed and approved to make sure the study remains safe, ethical and in the public interest.

Below we set out the amendments that have been submitted by the SDE to the HRA along with their relevant approvals.

## No amendments were made to the Wessex SDE's HRA in 2024

### Amendment 1: 25 July 2025 – adding new datasets

We sought CAG approval to add National NHSE Datasets for:

- National Cancer Registration and Analysis Service (NCRAS)
- GP Prescribing

This was in addition to our original CAG protocol approval which only listed Hospital Episode Statistics (HES) / Secondary Uses Service (SU)S datasets. This was in support of an NHSE Data Access Request Service (DARS) process requesting the Wessex slice of the National Data Assets.

REC approval received: 01/09/25.

CAG approval received: 10/11/25.

### Amendment 2: 25 July 2025 – adding other SDEs as providers to Wessex

We are seeking CAG approval to add multiple sub national SDEs as Providers to our existing approvals.

This is to enable pseudonymised datasets, with opt-out applied, to flow between the SDEs in preparation for requests from users to access de-identified extracts for approved purposes within the Connect-D Dementia study.

For specific projects in a controlled way, SDEs will share data with other SDEs for approved research databases or projects. An SDE will act as the "Lead SDE" for these purposes. The amendment is sought in order to link dementia data across five SDEs: Wessex (Host/Lead for Dementia), Kent Medway & Sussex, Thames Valley & Surrey, Great/South Western, and the West Midlands.

**This amendment is currently being discussed with the HRA.**

### Amendment 3: 19 December 2025 – changes to our Data Processing Environment and bringing in data

After one year of operations for the Wessex SDE, we have learned a lot about the practical day-to-day running of an SDE.

In order to be able to continue to deliver valuable research across multiple complex research use cases for patients and public in Wessex, we need more flexibility in our Data Processing Environments (DPE). *[Our DPE is the backend, private, area of the Wessex SDE which is used to pull in and link data that is provided to the SDE for research. It is only accessible to SDE staff, not by researchers.]*

The changes requested in our amendment will allow us to improve the ways in which we bring in new datasets; in a way that is more precise, minimises unnecessary data flows, and reduces administrative burden.

**This amendment is currently being discussed with the HRA.**