UNIVERSITY OF WARWICK

STANDARD OPERATING PROCEDURE 43

Seeking and Maintaining Approval from the Confidentiality Advisory Committee (CAG)

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Sponsor approval:	Carole Harris, Assistant Director Research Culture, Governance and Compliance, R&IS

Revision Chronology:	**Effective date:**	**Reason for change:**
Version 3.0	12 June 2026	Biennial Review: Change to updated template, Multiple minor clarifications throughout text.
Version 2.0	04 March 2024	Biennial Review: Changed all references from NHS Digital to NHS England. Detail added on annual reporting, section 251 support closure and the requirement for applicants to attend meetings where applications will be reviewed.
Version 1.0	13 December 2021	**N/A new SOP**

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CONTENTS

1 Purpose and Scope

This SOP describes the process for applying for and maintaining support under section 251 and NHS Act 2006 from the Confidentiality Advisory Group (CAG) where there is a justification to process confidential data without consent from research participants in England and Wales.

This SOP applies to all UoW sponsored studies managed by WCTU or externally sponsored studies managed by WCTU that require a CAG application. For studies not managed by WCTU that require a CAG application, advice must be sought from the Sponsor's Office via sponsorship@warwick.ac.uk.

2 Acronyms

CAG	Confidentiality Advisory Group
CI	Chief Investigator
DPIA	Data Protection Impact Assessment
DPO	Data Protection Officer
DSPT	Data Security and Protection Toolkit
UK GDPR	UK General Data Protection Regulation
HRA	Health Research Authority
IAR	Information Asset Register
IG	Information Governance
IRAS	Integrated Research Application System
PID	Personal Identifiable Data
QA	Quality Assurance
R&IS	Research & Impact Services
ROPA	Record of Processing Activities
SPM	Senior Project Manager
SOP	Standard Operating Procedure
S/TMF	Study/Trial Master File
TM/TC	Trial Manager/Trial Coordinator
UoW	University of Warwick
WCTU	Warwick Clinical Trials Unit

3 Definitions

Personal Identifiable Data (PID)	Any information relating to an identified or identifiable natural person ('data subject'); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.
Special Category Data	This is PID related to: Racial or ethnic origin, political opinions, religious or philosophical beliefs, trade union membership, genetic data, biometric data, data concerning health or data concerning a person's sex life or sexual orientation.
Confidential data	Information that is given with the expectation that it is kept confidential. It is not always, but in most cases likely to be related to an individual. Unlike personal

	data, confidential data are always sensitive and never in the public domain and is applicable to data subjects that are both living or deceased.
Information Guardian	To provide CAG, on request, with evidence that the organisation works within the conditions for processing identifiable patient data under the Data Protection Act (DPA) and Section 251. This role is delegated to the WCTU Head of Operations.
Data Custodian	The person who will be responsible for the use, security, and management of all data generated by a study. This role is delegated to the study CI.
Data Controller	Organisation that determines the purpose and means of data processing.
Data Processor	Follows instructions for processing of data on behalf of an organisation but do not determine the purpose or means.
Data Security and Protection Toolkit (DSPT)	An online self-assessment tool that allows organisations to measure their performance against the National Data Guardian's 10 data security standards. All organisations that have access to NHS patient data and systems can use the DSPT to provide assurance that they are practicing appropriate data security, and that personal information is handled correctly. In WCTU this is maintained on an annual basis by the Information Governance (IG) Working Group.
ROPA	Internal record of information on all personal data processing activities carried out by WCTU.

4 Background

Where identifiable confidential patient information is processed without informed consent, additional legal approvals are required. Confidential patient information is governed by the Common Law Duty of Confidentiality, while personal data (including special category data) is regulated under the UK GDPR.

The preferred legal basis for accessing confidential patient information is informed consent. Where consent is not practicable, and where there is a clear public interest justification, processing may be permitted under Section 251 of the NHS Act 2006, subject to support from HRA and CAG.

Processing of personal data must also meet UK GDPR requirements, including identification of an appropriate lawful basis under Article 6 and a condition for processing under Article 9, supported by ethical approval and appropriate technical and organisational safeguards.

As a condition of Section 251 support, organisations must demonstrate robust data protection and information security arrangements. WCTU meets this requirement through maintenance of a compliant DSPT.

5 Responsibilities

Programming Team Manager	• Named IG Lead on WCTU DSPT submission • Chair of WCTU IG Working Group
WCTU Head of Operations	• Named **Information Guardian** on applications to CAG
IG Working Group	• Oversight and submission of WCTU's DSPT
CI	• Ensure all relevant approvals in place prior to any trial specific activities taking place

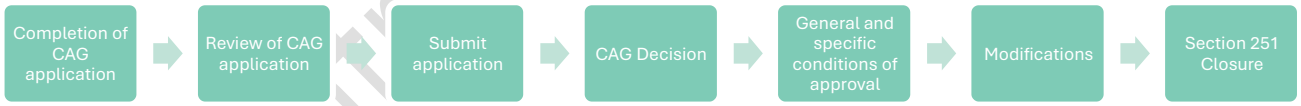
	• Act as **Data Custodian** for all study data and named on applications to CAG
QA Manager	• Review of applications in line with this SOP and the DSPT
TM/TC	• Coordination of applications to CAG under supervision of the CI
SPM	• Review applications • Review and ensure teams are aware of any contractual or legal obligations • Ensure the ROPA)contains the detail of the data WCTU holds and processes and the legal basis under which it is being processed
Statistician	• Review the application and ongoing compliance with the rest of the team
Governance Committee	• Oversight of compliance with training requirements for Information Governance & Security in line with the DSPT training needs assessment
Data Protection Officer (DPO)	• Responsible for overseeing UoW data protection strategy and its implementation to ensure compliance with UK GDPR requirements • UoW's DPO sits in Legal and Compliance Services and is responsible for signing letters of support for CAG applications where CAG authority sits with the University.

6 When

Sufficient time should be given for preparation and review of the application. In some circumstances, this process can take up to a year. All approvals and relevant data protection processing safeguards must be in place before any data are received and processed. In addition, there is an expectation of early Patient and Public Involvement to assess the acceptability of using confidential information without consent. Time for this activity should be built into the project plan.

7 How

The process for applying for section 251 approval and for maintaining approval from the CAG is outlined below. Further information on each of the required steps is provided in the subsequent sections.



When processing confidential data for the purposes of research, consent must be obtained from the research participant or a legal/consultee on their behalf. Where consent cannot be obtained, researchers will need to apply to the HRA CAG for approval. The applicants must clearly explain why these data are needed considering the public interest case. The CAG will consider the application request to determine whether the processing is in the public interest and that the processing organisation has sufficient data security and protection measures in place.

7.1 Completion of the CAG application

Applications to the CAG must be submitted via IRAS, which will generate a CAG form based on responses to initial filter questions. Applicants should follow IRAS guidance, CAG guidance, and guidance document **G31**. See here for frequently asked questions: https://www.hra.nhs.uk/about-us/committees-and-services/confidentiality-advisory-group/guidance-cag-applicants/.

Named individuals responsible for data security must be identified, using the roles defined in this SOP. The WCTU DPIA must be reviewed to confirm coverage of the proposed processing; where necessary, a study specific DPIA should be completed.

Supporting documentation required for approval is listed in IRAS and includes a letter of support. Where the University of Warwick is the data controller, this must be signed by the University DPO. Requests should be submitted early and sent to GDPR@warwick.ac.uk, Sponsorship@warwick.ac.uk, copying in the DPO or their Deputy. Where controllers are joint, letters are required from both organisations.

7.1.1 Precedent-set pathway

Whilst preparing a CAG application, consideration should be given to whether it is eligible for the Precedent Set review pathway. This pathway applies to defined, commonly occurring scenarios that have previously been considered and approved by CAG and offers a streamlined review process. Where an application meets the Precedent Set criteria, applicants may use this pathway to support a more timely review. Eligibility criteria, examples and exclusions are available here: CAG - Precedent Set Pathway.

7.2 Review of CAG application

Internal organisational review of the CAG application should be performed prior to submission by:

- SPM
- CI
- QA Manager
- Any collaborators named on the application
- Sponsor
- Representative of the DPO in the Legal and Compliance Team (for letter of support as described in section 7.1)

CAG provides a pre-assessment service for further review to help applicants identify any potential issues with the application prior to submission. Details on this process can be found here: CAG - Pre-assessment.

7.3 Submit application

Details of the submission process and CAG meeting dates can be found here: https://www.hra.nhs.uk/about-us/committees-and-services/confidentiality-advisory-group/guidance-cag-applicants/. Dates for CAG meetings (full or Precedent Set), application submission deadlines, and outcome notifications are published on the HRA CAG Meetings and Minutes webpage. An applicant representative is expected to attend the meeting at which the application is reviewed.

7.4 CAG Decision

Following CAG review, any queries will be addressed to the named person on the application. Subject to satisfactory responses, CAG will issue an approval or rejection letter. Study activities relating to the application must not commence until written approval has been received.

Where CAG approval is granted, data collection may commence or applications for data access may be submitted to NHS England or relevant third-party data providers. For data accessed via NHS England, refer to SOP 44 (NHS England: Applications, Receipt of Data and Compliance).

Decisions on initial applications or amendments may be dependent on NHS England reviewing evidence items from the DSPT. If this is requested by CAG, then instructions on how to initiate this process can be

found in **G31**. While G31 focuses on the Sponsor/WCTU DSPT, CAG may also require NHS England to review DSPT assurances for other organisations named in the application. Guidance on updating DSPT assurances in England is available on the HRA website: https://www.hra.nhs.uk/about-us/committees-and-services/confidentiality-advisory-group/guidance-confidentiality-advisory-group-applicants/update-dspt-assurances-england/.

7.5 General and Specific Conditions of Approval

The CAG standard conditions of support are published on the HRA website: CAG - Standard Conditions of Support. These include requirements relating to training, publication, compliance with UK GDPR, management of confidentiality breaches and submission of annual reports. Evidence of compliance, including submission of annual reports should be stored in the TMF. Failure to comply with the standard conditions may result in suspension or termination of CAG support. The TMG should review and document ongoing compliance with the conditions at regular intervals while section 251 approval remains in place.

In addition to the standard conditions, CAG may impose study-specific conditions of support. These conditions may require the submission of additional evidence or confirmation that actions have been completed within defined timeframes. Where applicable, applicants should prepare a written response addressing each condition, clearly describing how it has been met, and cross-referencing supporting documentation where required.

Confirmation that specific conditions have been satisfied may be provided by CAG via email rather than through a revised approval letter. Evidence of sign-off and all associated correspondence should be retained in the TMF. Specific conditions, particularly those with deadlines, should be actively monitored by the Study Management Group (SMG) and/or TMG to ensure timely compliance.

7.6 Modifications

As set out in the standard CAG conditions of support, any substantive changes to the activity approved under section 251 must be submitted to CAG for approval before the changes are implemented. Modifications are submitted using the CAG amendment form and are normally submitted by email to CAG. Guidance on when and how to submit modifications and access to the relevant forms, is available via IRAS: https://www.myresearchproject.org.uk/help/hlpconfidentiality580.aspx

A modification should be submitted if any of the following change:

- Data flows
- Data items
- Data sources
- Purpose of application
- Data controller (please note that an amended application form and supporting documents setting out the new data controller arrangements will be required, you are advised to contact the Confidentiality Advice Team via email: cag@hra.nhs.uk prior to submission)
- Data processor
- Duration of data processing.

Where changes to the study do not directly impact the information provided to CAG, then these may be notified to CAG for information. The next time a substantial modification is made to CAG, the ethical approval for any changes since the initial CAG applications should be supplied.

Applicants should note that, where CAG approval is obtained part-way through a study, any required substantial modification to the REC approval and/or protocol must be completed **before** submitting the CAG application.

CAG may request that NHS England review the security assurances prior to approving the modification. If this is requested, please follow the guidance in **G31**.

7.7 End of CAG support – Section 251 Closure

Once the approved period of Section 251 support has ended and all processing of confidential patient information has ceased, a section 251 closure report should be submitted to CAG. Until this is submitted, annual reporting should continue. A link to the Section 251 Closure Report along with supporting guidance can be found in IRAS: https://www.myresearchproject.org.uk/help/hlpconfidentiality581.aspx.

7.8 Training requirements for staff

Staff who are involved in applications to use data under section 251 should ensure that their Information Governance and Information Security training is up to date. For WCTU staff, this can be checked using the competency tab inside your Personal Development Log. Up to date training is a key part of the DSPT security assurance process and one of the terms of CAG support.

8 Associated Templates and Documents

G31	CAG Application Guidance