STANDARD OPERATING PROCEDURE 43
Seeking and Maintaining Approval from the Confidentiality Advisory Committee (CAG)

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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**

STANDARD OPERATING PROCEDURE 43
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1. Purpose and Scope

This Standard Operating Procedure (SOP) describes the steps required to apply for and maintain data in accordance with section 251 approval 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 is applicable to any staff working on University of Warwick (UoW) or externally sponsored studies that are managed by WCTU where applications to CAG are to be made. For studies that are not managed by WCTU that require a CAG application, the Sponsor's Office should be contacted for advice via sponsorship@warwick.ac.uk.

2. 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 Chief Investigator (CI).
Data Controller	Organisation who determines the purpose and the means of the data processing.
Data Processor	Follow 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 practising good 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.

3. Background

Where researchers intend to process identifiable and confidential data without informed consent from study participants, additional applications and approvals will be required. As part of the applications and approvals process, the stakeholders involved will want to be assured of WCTU's compliance with the appropriate UK Law that govern the processing of PID and confidential data. Confidential data and PID often overlap but are governed by two separate parts of UK law.

The Common Law Duty of Confidentiality applies to confidential information as defined in section 2 (above). To lawfully access confidential data for clinical research, the access must be in line with the reasonable expectation of the research participants. The best way for researchers to access this information is to describe the research to participants and **obtain informed consent**. Where obtaining informed consent is not practical, there is an alternative legal basis under the NHS Act 2006 Section 251. This allows processing of confidential data **without consent** from study participants under certain controlled circumstances where there is clearly justified public interest in the research outcomes. Approval for this can be only granted by the Health Research Authority (HRA) CAG.

The UK GDPR governs the processing of PID and any Special Categories of PID as defined in section 2 above. To process these data, a further legal basis is required, and this should be determined by the data controller. Typically for clinical research this will be under *Article 6(e) of the GDPR– Task in the public interest* for special categories (for PID) and *Article 9(j) of the GDPR – processing is necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article (89) (for special category PID)*. Any processing must be in the public interest, be protected by organisational and technical safeguards, approved by an ethics committee and be in line with transparency information provided to the data subjects.

Part of the conditions for processing confidential data without consent from the participant under section 251 is that there are robust data security and protection procedures in place by the processing organisation. The organisation needs to assure the CAG that they can keep these data safe and process them within the confines of the laws described above. WCTU does this by submitting and maintaining a DSPT.

4. Procedure

4.1 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

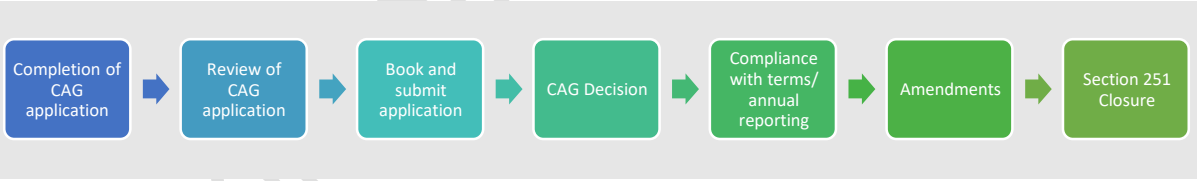
Trial Manager/Trial Coordinator (TM/TC)	• Coordination of applications to CAG under supervision of the CI
Senior Project Manager (SPM)	• Review applications • Review and ensure teams are aware of any contractual or legal obligations • Ensure the Information Asset Register (IAR) contains the detail of 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

4.2 When?

Sufficient time should be given for preparation and review of the application. In some circumstances this process can take up to 6 months. Approvals and all other necessary data protection processing safeguards must be in place before any data are received and processed.

4.3 How?

The process for applying for section 251 approval and the subsequent maintenance of approval from the CAG is outlined below. Detailed information on each of the required steps is described 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. There are some scenarios where consent cannot be obtained. In these circumstances, 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 the sufficient data security and protection measures in place.

4.3.1 Completion of the CAG application

An application to the CAG should be prepared via the Integrated Research Application System (IRAS). The CAG application form will be generated depending on the filter questions which are answered at the beginning of the IRAS process. For guidance on completion of the CAG application and the associated data protection assurances, please see associated guidance document (**G31**). The application process will require the applicant to name individuals responsible for data security and

protection. The responsibilities outlined in this SOP should be used to complete this. In addition to these assurances, it is expected that the WCTU Data Protection Impact Assessment (DPIA) is reviewed to ensure that the intended processing and risks are covered. If not, a study level DPIA should be considered to cover the processing.

A checklist of documentation that should be submitted with the application (or by the time of approval) is provided in IRAS. One of those items is a letter of support. Where the University of Warwick is the data controller, this letter will need to be signed by the DPO based in the University's Legal and Compliance Team. Requests for this must include a copy of the application and must flag this is part of a CAG application in the subject line of the email. Requests for letters of support should be emailed to GDPR@warwick.ac.uk, Sponsorship@warwick.ac.uk, and Karim.Kapadia@warwick.ac.uk should be copied in to ensure this is prioritised. Although not required for submission, this letter must be in place prior to approval so this should be initiated early in the application process.

4.3.1.1 Precedent-set pathway

Whilst preparing the CAG application, consideration should be made as to whether it could be submitted via the precedent-set pathway. This is a shorter pathway to approval in circumstances where commonly arising situations which have already been identified and discussed at previous meetings of the CAG and approval granted. If an application to CAG falls into one of the precedent set categories described on the HRA CAG website, applicants are able to use the CAG Precedent Set review pathway which has been developed to enable a more timely review process for these types of applications. More information with examples and relevant exclusions can be found here: CAG - Precedent Set Pathway.

4.3.2 Review of CAG application

Internal review of the CAG application should be performed by:

- SPM
- CI
- QA Manager
- Any collaborators named on the application
- Sponsor
- UoW Legal and Compliance Team (for letter of support as described in section 4.3.1)

CAG provide 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

4.3.3 Book and submit application

Applications to the CAG panel review must be booked for review **prior** to application submission. You should only contact the team to book once an application is ready for submission (with all necessary signatures in place) as the application must be submitted within 24 hours of booking. If the application is not submitted within 24 hours the booking will be cancelled. Details on how to book and submit are here: CAG - Book & Submit.

4.3.4 CAG Decision

Once the CAG has reviewed the application any queries will be addressed to the named person on the application. Subject to satisfactory responses to the queries, the CAG will issue an approval or rejection letter. It is only after receipt of an approval letter that activities can commence.

Meeting dates for full CAG or precedent set reviews, application submission deadlines and outcome dates are here: CAG - Meetings and Minutes

A representative of the application will be expected to attend the meeting at which the application is being reviewed at.

If CAG approval is granted, the data can be collected or the data application can be made to NHS England or relevant third-party data provider. If you will collect the data via NHS England, see SOP 44 (NHS England: Applications, Receipt of Data and Compliance).

CAG decision for initial applications or amendments to previous applications are likely to 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**.

4.3.5 Compliance with CAG terms and annual reporting

The standard conditions of support can be found here: CAG - Standard Conditions of Support. These include terms around training, publication, compliance with UK GDPR, handling breaches of confidentiality and the requirement to submit reports every 12 months. Evidence of submission should be stored on the Trial Master File(TMF)Non-compliance with these standard terms can lead to termination of support. The TMG should review and document their continued compliance with the conditions on a regular basis whilst the study is processing data under section 251 approval.

It is expected that any other parties who are processing the confidential data on behalf of the applicant also has appropriate security assurance in place (usually in the form of a DSPT self-assessment that reaches the required 'Standards Met' attainment level). The applicant is usually the party who is expected to check and monitor this. Current status of all organisations submitting a DSPT can be located here: https://www.dsptoolkit.nhs.uk/OrganisationSearch.

4.3.6 Amendments

Part of the standard support terms is that any significant changes must be approved via formal amendment prior to changes coming into effect, this can be done using the CAG Amendment Form, and can be emailed to CAG. Guidance of submission of amendments and the associated forms can be found in IRAS: https://www.myresearchproject.org.uk/help/hlpconfidentiality580.aspx#CAGamendments.
An amendment 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 changes

If an amendment is made to the study that does not directly impact the CAG approval, then this can be sent for information. The next time a substantial amendment is made to CAG, the ethical approval for any changes since the initial CAG applications should be supplied. You do not need to wait for approval from CAG each time you make a substantial amendment, unless it impacts the information provided to CAG on the initial application.

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

4.3.7 End of CAG support – Section 251 Closure

Once the period for which you had received section 251 support is complete and processing of the data has ceased. A section 251 closure report should be sent 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

4.3.8 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. 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.

List of abbreviations

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
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

Templates and Associated Guidance

G31 – CAG Application Crib Sheet