

STANDARD OPERATING PROCEDURE 35

Handling Requests for Information

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Version 4.0	14 Oct 2026	Biennial review: Updated template, streamlined content, removed flowchart, and introduced study-specific risk-based escalation arrangements for distressed participants.
Version 3.0	16 May 2024	Biennial review: Update to process flowchart for handling requests. Minor amends to text.
Version 2.0	8 March 2022	Biennial review: Change to new format. Minor amends to text.
Version 1.2	23 December 2019	Biennial review: Change to new format. Minor updates to text throughout.
Version 1.1	24 October 2017	Change to new format. Web links updated, minor amends to text and flowchart.
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1 Purpose and Scope

This SOP describes the process for dealing with requests for information relating to research studies.

This SOP applies to all staff working on University of Warwick sponsored research studies and to externally sponsored studies managed by WCTU where use of Warwick SOPs has been agreed. Any additional sponsor-specific requirements must also be followed. For externally sponsored studies, the sponsor should be informed of requests where appropriate and as outlined in relevant delegation of responsibilities. All requests for information should be documented and managed in accordance with this SOP.

Requests to share data generated from studies are covered in SOP 15 part 3 'Information Handling: Sharing Data'.

This SOP should be read in conjunction with guidance and procedures on the UoW Legal and Compliance services website: <https://warwick.ac.uk/services/legalandcomplianceservices/>

2 Acronyms

CI	Chief Investigator
GDPR	General Data Protection Regulation
FAQ	Frequently Asked Questions
FOIA	Freedom of Information Act
ICO	Information Commissioners Office
QA	Quality Assurance
R&IS	Research and Impact Services
SAR	Subject Access Request
SOP	Standard Operating Procedure
WCTU	Warwick Clinical Trials Unit

3 Definitions

SAR	A request made by an individual to obtain access to their personal data held by an organisation and to receive information about how that personal data is being processed. A SAR may be made verbally or in writing and does not need to refer to UK GDPR to be valid.
FOIA Request	A request for recorded information held by a public authority under the Freedom of Information Act 2000. Requests can generally be made by any person and may be submitted in writing, including by email.
Personal Data	Any information relating to an identified or identifiable living individual. An identifiable individual is one who can be identified directly or indirectly from that information.

4 Background

Research study staff may receive requests for information from study participants, members of the public, the media, or other organisations. Requests may be received by telephone, email, social media, post, or in person. Some studies may attract public or media interest due to their design conduct, or results. Where this is anticipated, consideration should be given to developing a media strategy in collaboration with the University's Press Office (contact details in section 7.2) .

The UK GDPR regulates processing of personal data, including its collection, storage, use and disclosure. Individuals have the right to request access to their personal data by making a subject access request (SAR). Some rights requests may be subject to applicable research exemptions under data protection legislation. UoW Legal & Compliance will advise where relevant.

The Freedom of Information Act 2000 provides right of access to recorded information held by public authorities. Individuals may request information held by public authorities. Public authorities are required to confirm whether requested information is held and, where appropriate, provide that information. However, FOIA contains a number of exemptions which may permit information to be withheld and, in certain circumstances, allow an authority to neither confirm nor deny whether information is held.

5 Responsibilities

Chief Investigator (CI)	- Ensure that information on a study is publicly accessible e.g. on a research study registration database or the study's website. - Ensure requests for access to data or for further information are dealt with appropriately.
University of Warwick Legal and Compliance team	Handle data access requests and responding within the legally required timelines as applicable.

6 When

A study risk assessment should be completed during study set-up and reviewed throughout the study lifecycle. The assessment should consider whether any aspect of the study design, conduct, or results may generate significant public or media interest. Where potential risk is identified, appropriate communication and media management arrangements should be put in place. The assessment should be documented using the study risk assessment process (**T19** Risk Assessment and Monitoring Plan).

7 How

All requests for information must be reported to the WCTU Head of Operations and QA team as soon as possible and no later than the next working day. Requests should be documented and managed in accordance with this SOP. Where there is uncertainty regarding the nature of a request or the action required, advice should be sought from the WCTU Head of Operations, QA team or Legal and Compliance as appropriate.

Where a study may attract significant public or media interest, a communication plan should be developed. Template **T02** is available on the WCTU website. Supporting materials, such as FAQs, positioning statement and briefing notes, should be approved by the Chief Investigator.

7.1 Requests from study participants and members of the public

General study enquiries may be managed by appropriately trained study staff. Requests relating to FOIA or UK GDPR rights must be referred to Legal and Compliance after informing the WCTU Head of Operations and QA team.

Staff should only respond to requests within their area of competence and should seek assistance where required. Individuals who are distressed, dissatisfied or raise welfare concerns should be referred to an appropriate colleague or service.

During study set-up, the study team must assess the potential for participant distress, safeguarding concerns, complaints, or other challenging interactions, taking into account the nature of the study population and procedures. Where a risk is identified, documented arrangements must be established to ensure staff have access to appropriate support, escalation routes, and subject matter expertise. These arrangements should be proportionate to the identified risks and communicated to all relevant study staff.

Staff working remotely/working from home who encounter a situation they are unable to manage safely or confidently should bring the interaction to an appropriate close and inform the individual that the matter will be escalated to a suitable qualified colleague. The staff member should then follow the study-specific escalation arrangements and seek assistance in accordance with the documented study procedures.

Staff must not provide clinical advice unless authorised to do so as part of their role. Any incident where a member of staff feels threatened or at risk must be reported in accordance with University Health and Safety procedures: <https://warwick.ac.uk/services/healthsafetywellbeing/incidents>.

7.2 Requests from the Press

Media enquiries must be referred immediately to the WCTU Head of Operations and QA team and the University Press Office. Staff must not provide comments to the media unless authorised to do so.

Contact details for the University Press Office are available [here](#).

7.3 Freedom of Information Act (FOIA) Requests

Any FOIA request must be reported to the WCTU Head of Operations and QA team and forwarded to Legal and Compliance as soon as possible, ideally on the day of receipt using the address outlined below:

infocompliance@warwick.ac.uk. Legal and Compliance will coordinate the University's response, including consideration of any applicable exemptions and consultation with relevant third parties. WCTU Head of Operations and/or QA Manager should be kept involved in communication.

The University's Legal and Compliance Team have advised that the following should be included in initial notification to them if it is applicable:

1. If we require further clarity on what is being asked
2. Whether or not we hold the info requested
3. Whether we feel it is ok to share the information and if not, why not.
4. To flag if any third parties should be consulted and send to them in parallel (e.g. if info related to the trial which is sponsored by another University etc.), although Warwick would have the final say.

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5. To send to sponsors office if it relates to a Warwick sponsored trial and keep them informed.
6. Be clear in the email to the FOI team that any delays would need to be reported to NHS England due to the terms of our DSTP toolkit, as this should help ensure the FOI team prioritise it accordingly.

All responses should be shared with the WCTU Head of Operations (or delegate) to ensure responses are appropriate. When WCTU staff reply, the Legal & Compliance team will draft the response and describe any exemptions as necessary, they will also communicate with the requestor directly with the response.

Requests made under the FOIA can be responded to in various ways under the law depending upon the nature of the request. However, a final response to any request must be made within **20 working days**.

7.4 Subject Access Requests under UK GDPR

A SAR is a request by an individual for access to their own personal data. A SAR may be made verbally or in writing (inc. social media) and does not need to refer to UK GDPR to be valid.

They can make it to any part of an organisation, and they do not have to direct it to a specific person or contact point. Any SAR must be reported to the WCTU Head of Operations and QA team and forwarded to Legal and Compliance (infocompliance@warwick.ac.uk) as soon as possible. Staff must not disclose personal data directly unless authorised to do so. The list of rights to access can be located on the ICO website: <https://ico.org.uk/for-organisations/uk-gdpr-guidance-and-resources/individual-rights/individual-rights/>.

By law, requests must be responded to within **1 month**, although this can be extended to up to 2 further months for complex requests.

8 Associated Templates and Documents

T19	Risk Assessment and Monitoring Plan spreadsheet (available from WCTU QA team on request)
T02	Template Communications Plan Guidance Document