STANDARD OPERATING PROCEDURE 35

Handling Requests for Information

Version:	2.0	Effective Date:	8 March 2022
Issue Date:	22 February 2022	Review Date:	8 March 2024
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Revision Chronology:	Effective date:	Reason for change:
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.
Version 1.0	8 December 2014	

STANDARD OPERATING PROCEDURE 35
Handling Requests for Information

1. Purpose and Scope

This Standard Operating Procedure (SOP) provides information on procedures for dealing with requests for information.

Requests may come from study participants, members of the public, or the media, and may be made in relation to the Freedom of Information Act 2000 (FOIA) for data held by the University, or the UK GDPR for personal data, in relation to study activity.

It is applicable to all staff working on University of Warwick sponsored research studies and for studies with external sponsors managed within the WCTU, where use of Warwick SOPs has been agreed, alongside any additional external sponsor requirements. For externally sponsored studies, teams should ensure the relevant sponsors office is kept informed of any request received.

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

Also refer to the University's Security and Information Management SOP: IMSOP 02: Handling Information Paper and Digital which classifies data types and provides guidance on data handling.

2. Definitions

Frequently asked questions (FAQs):	A list of questions and answers relating to a particular subject.
Positioning statement	A document to detail the core message to be delivered to internal/external audiences.
Briefing notes	A clear, concise paper to summarise all the relevant facts on a particular issue.
Personal Identifiable Data	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.

3. Background

Requests for information may be received by staff from individuals or the media who have interest in, or questions regarding, a study. This may also include calls or visits from concerned participants/relatives. Some studies may have potentially newsworthy aspects as part of their design or results, it is therefore worth considering liaising with the University's Press Office in such cases. See section 4.3.2 for further details of how to create a media strategy.

The UK GDPR makes provision for the regulation of the processing of information relating to individuals, including obtaining, holding, use or disclosure of such information. It gives individuals the right to request information on what **personal identifiable data** are held about them as a subject access request. See section 4.3.4 and Appendix 1 for further information.

The Freedom of Information Act 2000 provides public access to **information held by public authorities**. Individuals have the right to ask to see recorded information held by public authorities e.g., government departments, local authorities, the NHS, state schools and police forces. The general right of access ensures persons making a request to a public authority are entitled to be informed by the authority whether it holds the information described in the request, and if that is the case, that information should be communicated. See section 4.3.3 for further details.

4. Procedure

4.1 Responsibilities

Chief Investigator (CI)	• Responsible for ensuring that information on a study is publicly accessible e.g., on a research study registration database or the study's website. • Any requests for access to data or for further information are dealt with appropriately. • Responsible for ensuring that named contacts and any staff member who may receive requests for information are appropriately trained
University of Warwick Legal and Compliance team	• Handling data access requests and responding within the legally required timelines as applicable.

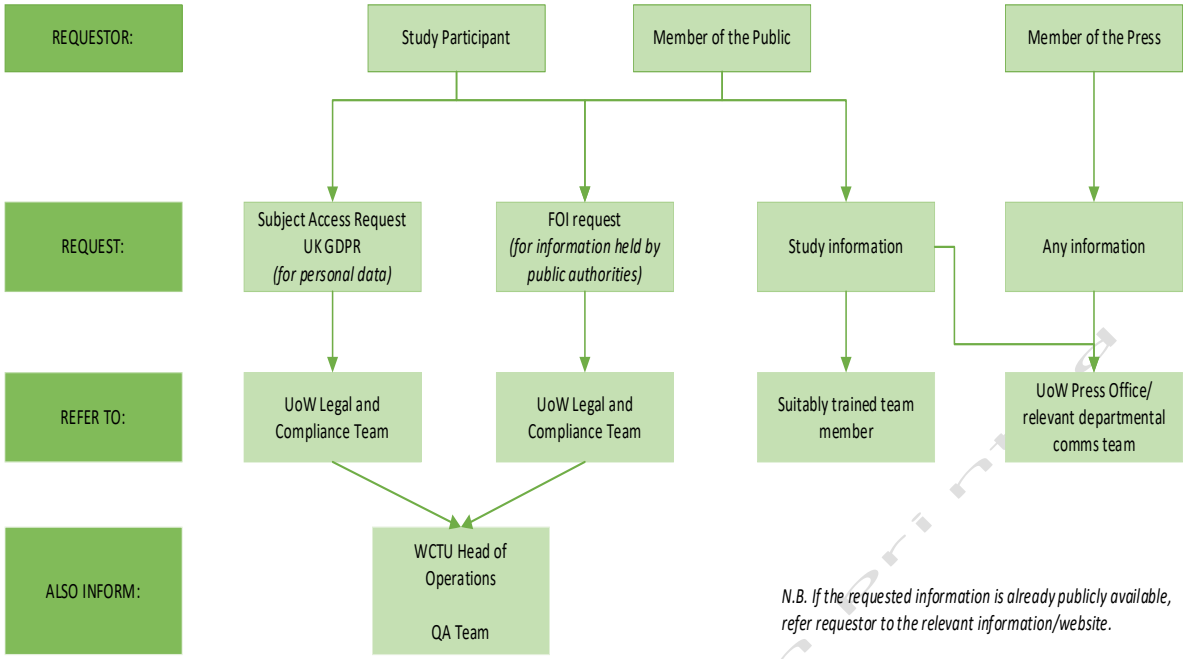
4.2 When?

When a grant for a new study has been awarded, a risk assessment should be undertaken as soon as possible, to include a focus on any aspects of the study's design which may generate interest from the press or public. The risk assessment should be regularly reviewed as new information may come to light which could change the level of interest to the media or members of the public.

4.3 How?

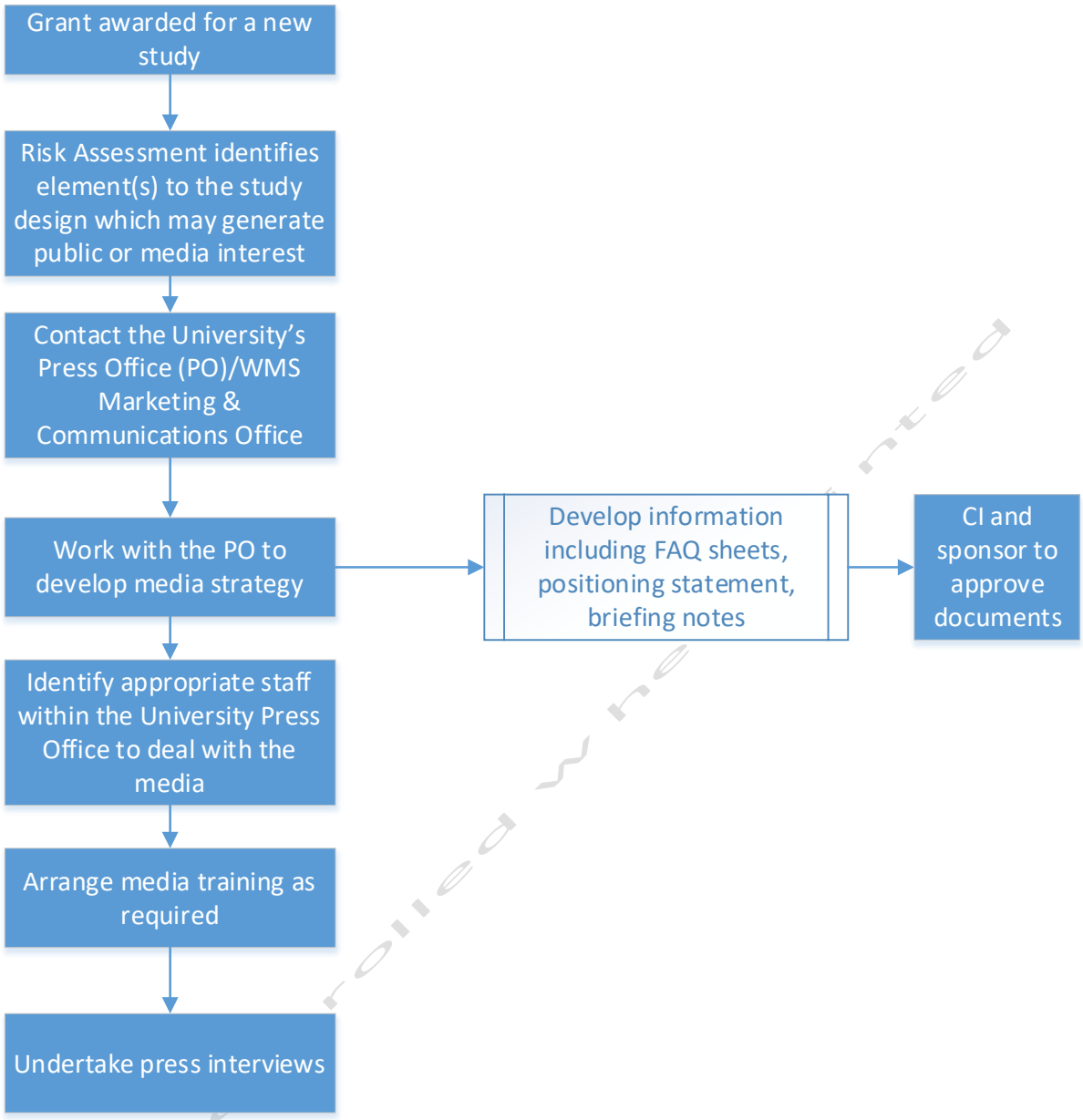
Procedures for staff to adhere to are described in the following sections. Consideration should be given to preparing a communication plan or guidance document. A template communications plan guidance document T02 is available on the WCTU website.

Process flow summary:



If the study risk assessment indicates that there may be elements in the design which have the potential to attract public or media attention, a strategy should be developed in collaboration with the University's Press Office (and the relevant department for any external/co-sponsor). The relevant departmental Marketing and Communications Office (or equivalent) should also be made aware of the situation. See the process flowchart on the next page.

Flowchart of procedure to produce a media strategy (if required by the study's risk assessment):



Information documents (FAQs etc.) should be prepared as soon as is practicable by staff with relevant knowledge of the study and approved by the CI. See SOP 34 'Generation, Review and Approval of Trial Specific Working Instructions' for further details.

The University's Legal and Compliance team have produced guidance for staff to refer to on what to do if a request is received:
https://warwick.ac.uk/services/legalandcomplianceservices/freedomofinformation/staffguidance/

4.3.1 Dealing with requests for information from study participants/members of the public

Study staff may receive requests for information from participants or members of the public with general enquiries, these may include questions about the NHS National Opt-outs and studies where consent isn't taken. Requests for information may be received via telephone, email, social media, or an unannounced visit in person by the individual.

If the request is in relation to an access rights request in accordance with the UK GDPR (see section 4.3.4) or FOIA (see section 4.3.3), contact the Legal and Compliance team for them to handle, but if the request is in relation to a study specific query, then this may be dealt with by a suitably trained staff member.

Staff should only deal with requests they feel adequately trained for and confident to handle. If a staff member is not confident that they can deal with a particular request, they should pass it on to a more experienced or qualified team member. Appropriately qualified team members should be identified at study set-up so that it is clear who requests can be passed to in such situations.

Study staff may receive a request from a distressed or angry participant/member of the public, this may be by telephone or a person coming onto university premises wishing to speak directly to a member of staff. Training on dealing with sensitive conversations is available to staff as required. Guidance will be provided on a study-by-study basis to train staff on how to deal with study specific circumstances, and who and where to go to for assistance. Line managers should ensure appropriate training is in place for all relevant staff.

No member of staff should be handling a request unless they are trained and confident with dealing with the person who is making contact (either face-to-face or via other methods). If any member of staff feels they were at risk at any point when dealing with a request for information, an incident report form should be completed and sent to the Health and Safety Department via: https://warwick.ac.uk/services/healthsafetywellbeing/incidents

Staff with appropriate experience and training may be approached to take over calls/specific requests where this is deemed necessary (e.g., a clinical query). An alert for assistance can be made by using a red card which will flag to other staff members that the person taking the call requires help or someone to take over the call.

All staff handling such calls/requests should act in a listening and referral role only and must not offer clinical advice (unless it is their specific role to do so). Where there is concern for the safety of the caller/person requesting the information, details should be passed on immediately to the caller's GP, appropriate clinical care team or emergency services. A list of staff with appropriate clinical experience and training who can be available to deal with calls, personal requests or face-to face visits is available alongside this SOP on the WCTU website. Where a call to a participant is being made by a staff member remotely/working from home and any issue occurs or the conversation becomes difficult to manage, end the call as quickly as possible and inform the caller that another person with more knowledge and/or experience to deal with the issue will call them back. Use the list of clinical staff available to assist to find the most appropriate person to contact and ask for help.

4.3.2 Dealing with requests for information from the Press

If a journalist or other member of the media contacts a member of staff, they should be referred immediately to the University's Press Office and the relevant departmental Communications Office (or equivalent) should also be informed – contact details can be found via their respective websites.

Study staff should not engage or attempt to answer any questions.

Contact details for the University Press Office are available here

Contact details for Warwick Medical School (WMS) Marketing & Communications Office can be found here

Individuals requiring media training should contact a Media Relations Manager from the University's Press Office

4.3.3 Dealing with requests relating to the Freedom of Information Act (FOIA) 2000

The FOIA gives members of the public "right of access" to information held by public authorities. Where such a request is made, contact the Legal and Compliance team via email: infocompliance@warwick.ac.uk providing full details of the request made. Ensure the WCTU QA team and/or Head of Operations are made aware of any requests as they will oversee progress and ensure responses are completed appropriately.

The exception to this would be if the information requested is otherwise publicly available or has been made publicly available previously (i.e., is or has been available on the study website, or it is information which the WCTU/relevant department would ordinarily provide to any enquirer.) Where this is the case, refer the requestor to the relevant information/website.

Requests received by Legal and Compliance Services are carefully assessed by the team. The FOIA includes some exemptions and should there be a valid reason/exemption the University can legally withhold disclosure. Examples of exemptions can be found here.

The University's FOI team have advised that requests should be reviewed as quickly as possible (on the day received it at all possible), and to let the team know:

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

When CTU staff reply, the FOIA team will draft the response using their own standard text, describe any exemption and send on to the Press Office team for review, and then send to the original

requester themselves. All responses should be shared with the WCTU Head of Operations (or delegate) to ensure responses are appropriate.

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 requests **must** be made within **20 working days**.

4.3.4 Dealing with subject access requests relating to the UK GDPR

A Subject Access Request (SAR) is a request made by or on behalf of an individual for the **personal identifiable data** information which they are entitled to ask for under Article 15 of the UK GDPR, see Appendix 1 for further details.

The UK GDPR does not set out formal requirements for a valid request. Therefore, an individual can make a SAR verbally or in writing, including by social media. 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.

A request does not have to include the phrases 'subject access request', 'right of access' or 'Article 15 of the UK GDPR'. It just needs to be clear that the individual is asking for their own personal data.

Requests for access to personal data received by staff should be referred to the Administrative Officer (Compliance) via infocompliance@warwick.ac.uk who will process the request. By law, requests must be responded to within 40 calendar days (unless an extension is required).

If a request is received from an individual to gain access to their personal data or that of a third party held by the University, it is not usually appropriate to provide those data yourself.

Details of the process can be found on the Legal and Compliance team website.

All rights requests will be dealt with without undue delay and at the latest **within one month**. That period may be extended by two further months if a request is complicated, or a number of requests are received from the same individual. If the University proposes to extend the time, the individual will be informed, within one month of receiving a request, why the extension is necessary and when it will be dealt with.

All members of staff who handle or process personal data must be aware of the Data Protection principles and how they should be applied. The Information Commissioners Office (ICO) state that it is good practice to have a policy/guidance or strategy for recording details of the requests received, particularly those made by telephone or in person, to check with the requester that you have understood their request and to avoid any confusion later in the process. The General Data Protection Regulation (GDPR) guidelines require that the information provided to an individual is in a concise, transparent, intelligible and easily accessible form, using clear and plain language.

Online training modules are available. All new staff must complete the Information Security Smart module during their induction period https://moodle.warwick.ac.uk/course/view.php?id=49636 and The Data Protection (UK GDPR) and Information Security Refresher module is the compulsory annual refresher for all staff: https://moodle.warwick.ac.uk/course/view.php?id=44635

Appendix 1

Art. 15 GDPR Right of access by the data subject

1. The data subject shall have the right to obtain from the controller confirmation as to whether or not personal data concerning him or her are being processed, and, where that is the case, access to the personal data and the following information:

    1. the purposes of the processing;

    2. the categories of personal data concerned;

    3. the recipients or categories of recipient to whom the personal data have been or will be disclosed, in particular recipients in third countries or international organisations;

    4. where possible, the envisaged period for which the personal data will be stored, or, if not possible, the criteria used to determine that period;

    5. the existence of the right to request from the controller rectification or erasure of personal data or restriction of processing of personal data concerning the data subject or to object to such processing;

    6. the right to lodge a complaint with a supervisory authority;

    7. where the personal data are not collected from the data subject, any available information as to their source;

    8. the existence of automated decision-making, including profiling, referred to in Article 22(1) and (4) and, at least in those cases, meaningful information about the logic involved, as well as the significance and the envisaged consequences of such processing for the data subject.
2. Where personal data are transferred to a third country or to an international organisation, the data subject shall have the right to be informed of the appropriate safeguards pursuant to Article 46 relating to the transfer.
3. 1The controller shall provide a copy of the personal data undergoing processing. 2For any further copies requested by the data subject, the controller may charge a reasonable fee based on administrative costs. 3Where the data subject makes the request by electronic means, and unless otherwise requested by the data subject, the information shall be provided in a commonly used electronic form.

4. The right to obtain a copy referred to in paragraph 3 shall not adversely affect the rights and freedoms of others.

List of Abbreviations

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

Associated Documents

Risk Assessment and Monitoring Plan spreadsheet (available from WCTU QA team on request)
Template Communications Plan Guidance Document (T02)
List of clinical staff available for phone call support (available on SOP webpage next to this SOP)