Research Governance Standard Operating Procedure 2 – Triaging new studies

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Owner	Research Governance Team (research-governance@bristol.ac.uk)	
Originally Prepared by	Matt Hewson, Research Quality Officer (matt.hewson@bristol.ac.uk)	
Reviewed by	*Adam Taylor, Head of Research Governance, adam.taylor@bristol.ac.uk*	
Approved by	*Adam Taylor, Head of Research Governance, adam.taylor@bristol.ac.uk*	DocuSigned by: A6FCBDDBFE914CD...
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1. Glossary

Terminology is explained in the Research Governance Glossary, the most recent version of which can be found **on the Research Governance webpages.**

2. Background

The RGT receives information about studies being conducted by University of Bristol researchers from a variety of sources. For example: a researcher may write directly to a shared mailbox managed by the RGT (research-governance@bristol.ac.uk, research-ethics@bristol.ac.uk or research-safeguarding@bristol.ac.uk); they may complete the Research Registration Checklist (RRC); a researcher may write directly to a member of the RGT, especially if they have corresponded previously; a member of another University department (e.g. Research Contracts, Insurance or DREI Operations) may pass details of a study to the RGT.

This SOP describes how new studies should be triaged; that is, how the RGT goes from being made aware of a (prospective) new study, to that new study being passed to a member of the RGT for more detailed assessment and support. It also helps to ensure researchers have their queries responded to in a timely manner. Because triage is managed through F2, this SOP refers to email enquiries as *records,* per the F2 user guide. Collections of records and associated data are described as *cases*. The reader should refer to the RGT F2 user guide section 1.1 for more details.

3. Scope

This SOP specifically refers to information about new studies sent to research-governance@bristol.ac.uk, but no other member of the RGT. It does not advise on the standard procedures these queries might raise (e.g. issues around sponsorship, amendments, etc.), only their triage. Nor does it advise on whether a new study should be sponsored, registered or neither; this is handled in **RGT SOP 3 – Deciding on Sponsorship, Registration or Neither**. Records sent to individual team members are not in scope, and it is left otherwise tacit that if triage is required in this case, the **RGT member** should contact the **RGC** asking them to create a pre-checklist case and send a holding email, or otherwise, as appropriate. Similarly, where records are sent to both **a member of the RGT** and research-governance@bristol.ac.uk, that **member of the RGT** and the **RGC** should correspond on how to proceed. Lastly, more detailed assessment of study information may reveal that a study has not been triaged to the correct **RGT member.** In this scenario, **RGT members** should correspond among themselves to reassign the study, or discuss with the **HoRG**.

4. Responsibilities

This SOP describes how the **RGC** should handle records concerning new studies sent to research-governance@bristol.ac.uk, or how **other members of the RGT** may cover for the **RGC** in their absence. For initial applications and enquiries, it describes how the **RGC** should decide whether a record requires the assignment of a case number and case guide. It describes how the **RGC** should decide to which **member of the RGT** the record should be forwarded.

Individuals using this SOP should be familiar with the RGT F2 user guide (v4); all references to the user guide below are to this version.

5. Procedure

At a ‘macro’ level, the procedure for triage is straightforward: the **RGC** performs a preliminary assessment of the information about the new study; assigns to a relevant team member where there is sufficient information to do so, and solicits further information where there is not.

At points, references are made to the 'appropriate team member', and their corresponding colour flags in F2. These are determined as follows:

- If the record concerns a new study or a study in setup, and that study involves human tissue, a CTIMP, or a CIMD, the appropriate team member is an **RHTM**.
- If the record concerns a new study or a study in setup involving humans or their data but not human tissue, a CTIMP, or a CIMD, the appropriate team member is an **RGO**.
- In all other cases, or in cases where the nature of the study is unclear, the **RGC** should judge which member of the team is appropriate, seeking advice if needed.

5.1 Confirm that the record concerns a new study

First, the **RGC** should confirm that the record concerns a new study. In confirming this, there are some general principles they may apply, such as searching the name of the emailing party or other keywords within F2, or consulting members of the RGT referred to in the record.

They may also search the following pieces of information in F2 and the Expected RRCs2 spreadsheet (which is used by members of the RGT to log studies for which they are anticipating an RRC submission) to learn if it is pre-existing:

- The case number, if quoted.
- '[CI name] – Sponsor'.
- The short title.
- The long title.
- Key sections of the long title (for instance, intervention descriptions).
- The name(s) of the researchers involved.

The **RGC** may also search for the study in Worktribe or OREMS, which can raise more pertinent information allowing one to search within F2 or the Expected RRCs2 spreadsheet..

If the study does not yet have a submitted RRC, the RGC should request this now. If the RRC and declaration therein wasn't completed by the CI, the output of the RRC email should be sent to the CI by the **RGC** with a link to the standalone declaration form and a request to complete. The **RGC** should monitor this to ensure its completion, and file all records/outputs related to the above on the case.

5.2 When the record relates to a new study likely to require sponsorship or registration

The **RGC** should create a new case, without a case guide, per the instructions in F2 user guide section 5.1; the case guide can be created and populated by the **RGC** upon receipt of the RRC and/or IRAS form.

The **RGC** should name the case according to the conventions in the F2 user guide (section 5).

The **RGC** should colour flag the record and then pass the record to the appropriate **RGT** member(s) using the 'chat' function in F2 (see section 2.7 of the F2 user guide).

Where necessary, this **RGT member** should request an RRC from the researcher, or ask the **RGC** to do so. Where necessary, this **RGT member** should request completion of the

standalone declaration form from the CI, or ask the **RGC** to do so.

The **RGC** should populate the case guide with all information contained in the record (for instance, the output of the RRC). Instructions on how to use the case guide are in the F2 user guide section 5.3.

5.3 When the email relates to a study in early setup (i.e. pre-checklist study record or grant application)
The **RGC** should create a new case, without a case guide, per the instructions in the F2 user guide section 5.1.

The **RGC** should name the case according to the conventions in the F2 user guide section 5.

The **RGC** should colour flag the case and then pass the case to the appropriate **RGT** member using the 'chat' function in F2 (see section 2.7 of the F2 user guide).

Where necessary, this **RGT member** should request an RRC from the researcher, or ask the **RGC** to do so. Where necessary, this **RGT member** should request completion of the standalone declaration form from the CI in line with section 5.5, or ask the **RGC** to do this.

5.4 When the record relates to a project which will not require formal Sponsorship (as defined in the Policy Framework), for instance an audit or service evaluation
The **RGC** should create a new case, without a case guide, per the instructions in F2 user guide section 5.1.

The **RGC** should name the case guide according to the conventions in the F2 user guide section 5.
The **RGC** should colour flag the case and then pass the case to the appropriate **RGT** member(s) using the 'chat' function in F2 (see section 2.7 of the F2 user guide).

5.5 When the record has been triaged to the appropriate RGT member
Where necessary, the **RGC** should request completion of the RRC by a member of the research team. The output of this should be filed to the case. If a member of the research team besides the CI completed the form, the **RGC** should send the CI both the output of the RRC, and the standalone declaration form, to ensure that this has been completed by the CI. The output of the completed standalone declaration form should be filed to the case. The **RGC** should follow up with the CI until this declaration has been completed and filed on the case.

The **RGT member** who has received the triaged study should refer to SOP 3 – Deciding on Sponsorship, Registration or Neither.

6. Related documents
Internal documents
F2 user guide v4.

Expected RRCs spreadsheet.

Research Registration Checklist

Research Registration Checklist – CI Declaration

RGT SOP 3 – Deciding on Sponsorship, Registration or Neither

External documents

N/A