Research Governance Standard Operating Procedure 1 – Document Management

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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 Research Governance Team advises University of Bristol staff and students on how to set up and conduct research projects that involve human participants, their tissue, or their data. All such research requires ethical review; depending on the exact nature of the research, by either a University Research Ethics Committee, or an external body. All research must be conducted to the highest possible standards of Research Integrity.

The RGT documentation collectively captures substantial, coherent, and repeatable processes that contribute to the delivery of the RGT remit.

This SOP describes how version-controlled, team-wide RGT documentation – including, but not limited to, SOPs, guidance documentation and templates – should be managed. It describes the process for their preparation, approval, review, dissemination, and archiving.

The RGT documents ensure that the advice given to researchers is consistent and timely. They ensure that both the advice, and the projects being advised, are compliant with relevant regulatory and ethical requirements.

3. Scope

RGT documentation only covers processes surrounding the governance of research on humans, their tissue or their data, and matters relating to Research Integrity. Matters surrounding animal ethics are out of scope, and are ultimately the responsibility of the University Secretary, with support from the University's Animal Services Unit and AWERB. Matters concerning compliance belong to the Research Compliance team. Research contracts, procurement contracts and other legal contracts belong, respectively, to the Research Contracts Team, Procurement team and Secretary's Office.

4. Responsibilities

Documentation is prepared on an ad hoc basis by an RGT member, typically the **RQO**, at the request of the **HoRG**. The **HoRG** is responsible for the approval and reapproval of the documentation. The **HoRG** is ultimately responsible for their periodic review, though this will be delegated to the **RQO**, to organise in collaboration with other RGT members. The **RQO** is responsible for the dissemination and archiving of documentation.

5. Procedure

5.1 Writing documentation

Upon the possible identification of a substantial, coherent, and repeatable process that contributes to the delivery of the RGT remit, the identifying **RGT member** should raise this with the **HoRG** for their consideration. The **HoRG** should decide whether the process requires an SOP, guidance notes, a template, or some other form of documentation, and if so, assign an **RGT member,** typically the **RQO**, to complete this.

The responsible **RGT member** should gather information and map out the processes needed for the document, collaborating with colleagues as required.

Upon the completion of information-gathering and process-mapping, the responsible **RGT member** should draft the document, by means of populating a template if one exists (for instance, the SOP template). Upon the completion of this draft, the responsible **RGT member** should:

- Give the document a short name that succinctly captures its core purpose.
- Update the version to v0.1.
- Insert a 'DRAFT' watermark throughout.
- Save the file as RG [Document Type X] – [Name of Document] – DRAFT – v0.1.docx, where those variables are replaced with the relevant information.

Where the **RQO** was not responsible for preparing the draft, they should complete a first pass review, and ensure stylistic consistency and compliance with the template. After this first pass review is completed and any comments applied, the **RQO** should submit the document for review to the **HoRG**, the **Research Ethics and Integrity Manager**, or the **RQO**'s line manager, as appropriate. The responsible **RGT member** should then apply any comments, before sharing the draft with the **RGT** for further evaluation and comments. The responsible **RGT member** should make changes as required to address these comments.

5.2 Authorising a document

The responsible **RGT member** should now send the draft document to the **HoRG** for review.

Once the **HoRG** receives the draft document, they should verify that:

- The draft is accurate.
- The draft is readable.
- Any guidance in the draft complies with relevant regulations.
- Any guidance in the draft is sufficiently detailed that it may be used by a trained team member otherwise unfamiliar with the specific process(es) being documented.

If the draft document does not meet these criteria, the **HoRG** should return it with comments on the changes needed. The responsible **RGT member** should make these changes. At this point, the responsible **RGT member** and the **HoRG** should repeat the steps described in the first three paragraphs of this subsection.

If the draft document does meet these criteria, the **HoRG** may approve the document**.** The **HoRG**, or the responsible **RGT member** assigned by the **HoRG**, should now:

- Update the version number; to v1.0 for new documents, or by following the process for versioning substantial updates, described in section 5.3, if it is determined that this document will replace an existing one.
- Add an effective date in agreement with the **HoRG.**
- Add a review date, which should typically be two years after the effective date.
- Complete the document history table within the SOP in line with the above.
- Update the version information in the header.
- Remove the 'DRAFT' watermark throughout.
- Export the .doc file containing the documentation as a .pdf, by selecting File > Export > Create PDF/XPS > Options... > Create bookmarks using: Headings > OK > Publish.
- Pass the exported .pdf file to the **RQO** for filing and dissemination.

5.3 Reviewing a document

The **RQO** will agree a review schedule with the **HoRG.** The **RQO** is responsible for assigning SOPs to review to members of the **RGT** (including themselves).
Documents should be reviewed at least every two years, though they can be reviewed more frequently on an ad hoc basis to keep pace with changes in legislation and regulations, or due to the discovery of inadequacies within the existing document. The **RGT member** who identifies any of these conditions should refer them to the **HoRG** for a decision on whether an urgent review of the document is required. If the **HoRG** deems this necessary, the document will then be handed to the **RQO** to coordinate its review.

Upon the completion of the draft review by the responsible **RGT member**, they should pass the draft updated document to the **HoRG** for final approval. The **HoRG** and responsible **RGT member** should now follow the process under 'Authorising documents, with the following two alterations:

- Substituting 'draft document for 'document being reviewed' throughout.
- Substituting 'UNDER REVIEW' for 'DRAFT' in the watermark.
- Update the version number.
    - Where the update is substantial, and will lead to a change in practice, the first number *m* should be increased by one and the second number *n* changed to zero; in general, vm.n to vm+1.0 (e.g. v4.2 to v5.0).
    - Where the update is not substantial, the first number *m* should remain the same and the second number *n* increased by one; in general, vm.n to vm.n+1 (e.g. v2.1 to v2.2).

5.4 Dissemination and filing of a document and archiving of previous versions
The **RQO** should now export the authorised file to .pdf, ensuring that the name of the .pdf aligns with the name of the .docx file, but removing 'DRAFT' from the .pdf filename.

Both the .docx and the .pdf file should be uploaded to the **RGT documentation** folder in the Research Governance SharePoint group-page. Both should be filed in a folder corresponding to the document's title. Previous versions of the documentation should be renamed with 'SUPERSEDED' added at the beginning of the filename.

An email should be sent to the RGT with the document name in the subject line. The email should include:

- A link to the location of the current document .pdf on the SharePoint.
- An instruction to delete any previous local copies.
- The date of any training or walkthrough required for the documentation.
- The implementation date of the documentation, if applicable.
- An instruction to read and understand the documentation, if applicable.
- An instruction to sign off that one has read and understood the documentation, if applicable, within ten working days of receipt unless otherwise specified (e.g., for an urgent and important revision to the document).
- A link to the spreadsheet that records such signatures on the SharePoint, if applicable.

For documents relevant to staff outside of the RGT, e.g. the Safety Reporting SOP, the above process will be followed for all relevant teams.

The **RQO** should review the spreadsheet and follow-up on missing signatures after the deadline has passed.

For RGT documentation published on the University website, on the implementation date, or as close to it as practicable, the previous version of the document should be replaced with the updated version.

6. Related documents

Internal documents

N/A

External documents

N/A