UNIVERSITY OF BRISTOL PRE-REGISTRATION SUB-POLICY AND GUIDANCE

1. ABOUT THIS SUB-POLICY AND GUIDANCE

This sub-policy and guidance provides practical advice on how to enhance the transparency, rigour, and reproducibility of your research.

The term **must** is used to denote actions that are compulsory or necessary, **should** denotes best practice and aspiration to lead by example.

2. PRE-REGISTERING STUDY PLANS AND PROTOCOLS

Pre-register your study plan or protocol, ideally before the study begins, on a suitable repository so that it is free to read and reuse, either immediately or after an embargo period.

3. WHY SHOULD YOU PRE-REGISTER?

Pre-registration provides transparency in the research process, and allows for the study team's aims, objective, hypotheses, planned methods etc. to be capture at the point when they were finalised. Benefits include:

- A record of what was decided *a priori* before the study begins.
- Opportunities for others to comment and critique plans before the study begins.
- The ability for readers to verify that the final report aligns with the pre-registration.

It is important to note that a pre-registration document does not necessarily bind researchers to those plans; it simply provides a record of what they were at that point, so that deviations from that plan are transparent.

In clinical research, pre-registration of minimal information (e.g., primary outcomes) in a recognised repository such as ISRCTN or ClinicalTrials.gov may be a regulatory and/or journal requirement.

The latest version of the Declaration of Helsinki, which applies to medical research, states that "Every research study involving human subjects must be registered in a publicly accessible database before recruitment of the first subject." (article 35). Researchers conducting studies involving human subjects should therefore consider pre-registration of the study in the set-up phase.

4. WHY IS IT IMPORTANT?

- Transparency throughout the research process helps to foster trust, and provides opportunities for scrutiny, allowing decisions and assumptions to be challenged or critiqued.
- Pre-registration of design and analysis choices serves as a reminder to researchers, protecting against biases that can shape decision making once they reach the analysis stage.

- Study plans and protocols are valuable research objects in their own right, providing recognisable outputs for researchers and allowing research methods to be shared widely.

5. WHAT DOES IT MEAN IN PRACTICE?

5.1 RESPONSIBILITIES OF RESEARCHERS

Before beginning a study, researchers should consider:

- Pre-registering their study plans or protocol on an appropriate third-party platform (e.g., the Open Science Framework.
- Disseminating these plans via social media or other networks for feedback / peer review.
- Publishing via a Registered Report *.

* In this submission type, a journal reviews a study protocol as a Stage 1 submission and offers in principle acceptance irrespective of the eventual results.

The content of a study plan or protocol will vary from discipline to discipline, but could contain:

- The research question and motivation for / background to this (i.e., the prior literature).
- The methodology that will be used to answer the research question, including any choices / assumptions made, data collection methods, etc.
- The approach that will be taken to analyse data / interpret source materials, including sample size justification where appropriate.
- Information on ethics and governance arrangements, potential risks and how these have been mitigated, etc.
- Details of how data, code, and other research outputs will be shared.

5.2 RESPONSIBILITIES OF THE UNIVERSITY

The University will provide the infrastructure and resources to help researchers pre-register their reports appropriately, including:

- Providing advice and training on the use of pre-registration platforms.
- Monitoring best practice in this area and feeding this into guidance and training.

6. WHEN SHOULD STUDY PLANS OR PROTOCOLS *NOT* BE MADE PUBLIC?

In certain cases, researchers may be concerned about releasing methods or intellectual property before the study is complete (for example, so that potential participants remain blind to the study hypotheses, if appropriate).

In this case, many platforms that support the pre-registration of study plans and protocols allow for an embargo period to be set, so that the document is archived and date stamped, but not made public until a later date.

If the work may have commercial potential, consider protecting any intellectual property before publication. Note that this also applies to intermediate research objects such as data and code. For advice on protecting intellectual property researchers can contact the Commercialisation Team.

7. HOW WILL BEING OPEN HELP YOUR RESEARCH?

- Transparency allows for greater scrutiny of the research process, potentially improving research quality and trust in research.
- Pre-registration provides an opportunity to develop a clear study plan or protocol, and surface methodological choices and assumptions early.
- By preparing a detailed study plan or protocol issues such as preliminary authorship and contributions can be discussed and agreed early in the research process.

8. REFERENCES AND FURTHER INFORMATION

- Centre for Open Science Registered Reports
- Cancer Research UK Registered Reports Funding Partnership
- Creative Commons copyright licences
- ICMJE recommendations on trial registration (section L)
- UK Reproducibility Network Open Research Primers

9. GLOSSARY

https://www.bristol.ac.uk/media-library/sites/staff/documents/open_research_glossary.pdf