BrisDoc Patient care by people who care

NHS

Research and Studies SOP

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Research SOP

Introduction

At BrisDoc, we recognise the value of research. Encouraging a research-positive culture in health and care organisations is important in:

- Contributing to the advancement of medical knowledge, patient care, and service delivery
- Enhancing clinical practice, improving health outcomes, and informing evidence-based decision-making
- Fostering innovation, quality improvement, and professional development.

This SOP outlines the process for considering and conducting research within BrisDoc, the checklist process should also be used for studies that don't reach the threshold of research but are being completed within the organisation. E.g. MSc projects. This is to assist with transparency and recording of positive initiatives which are having an impact on staff and patients.

Research Proposals

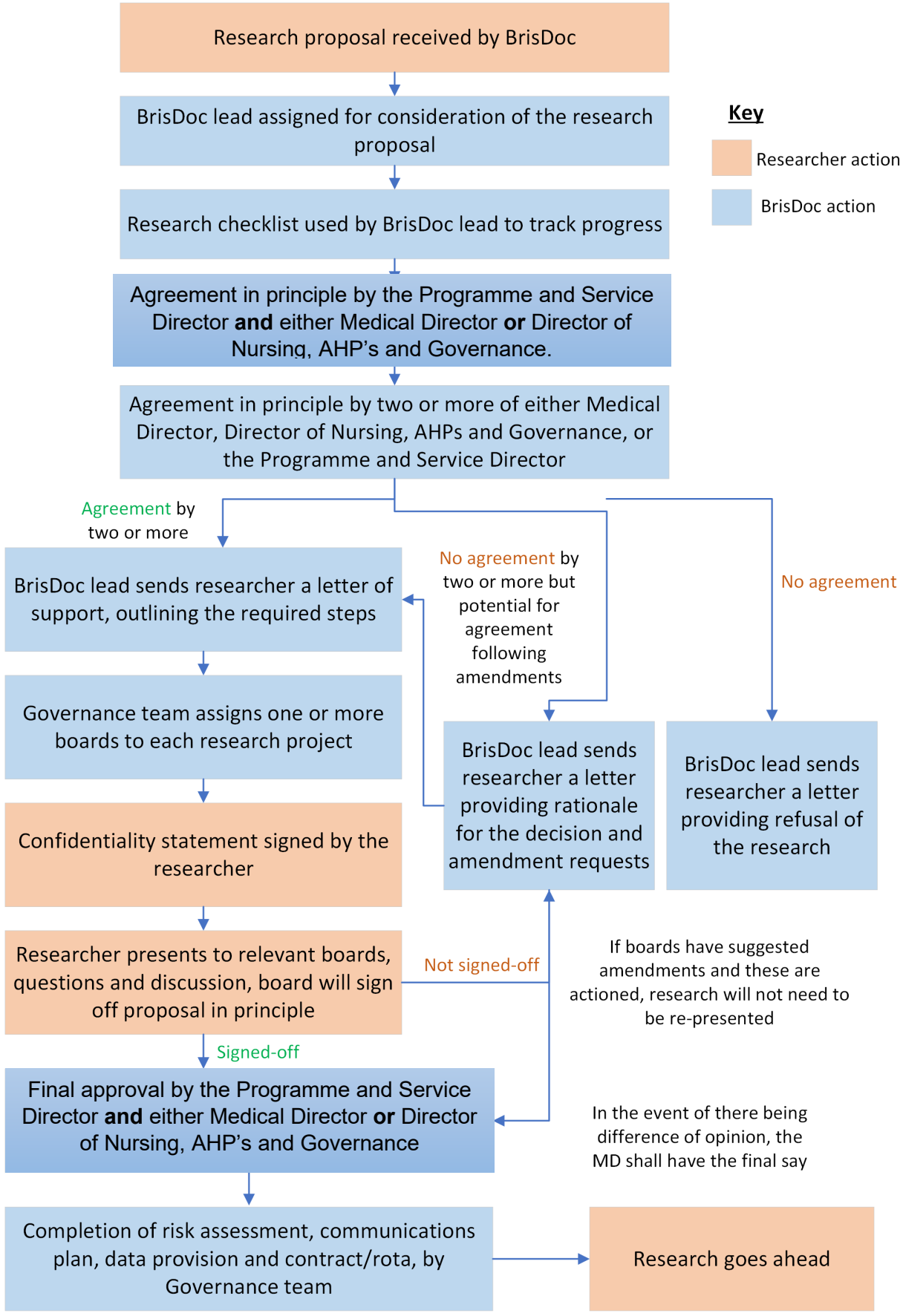
Proposals for research studies to be conducted through BrisDoc or using BrisDoc data may come from many different sources - commercial organisations, academic institutions, healthcare students, charities, Local Authorities, co-owners, and Integrated Care Systems among others.

On receipt of a proposal, colleagues must forward this to the governance team via brisdoc.governance@nhs.net. From here, researchers must be provided with this SOP to make them aware of the process and the checkpoints which must be met to enable the proposal to go ahead.

The Standard Operating Procedure

This section defines the required process to be completed for any research. Each step is explained in more detail in the following sections.

Research SOP



Assigning a BrisDoc Lead for the Proposal

The researcher will be assigned a Lead from the governance team. The BrisDoc Lead will:

- Liaise with the various boards and decision makers
- Be the main contact point for the researcher
- Record the research on the research log and create and upkeep a confidential folder to save all relevant correspondence and documents
- Ensure that this SOP is followed
- Ensure that all relevant boards have signed off on the research
- Ensure a Data Sharing Agreement (DSA) has been agreed and signed by BrisDoc's Information Governance (IG) lead
- Raise to a relevant director if any ethical or other concerns are flagged throughout the process.
- Ensure the data is available, appropriate and identify any pt concerns or consent issues.

Research Checklist

The research checklist (Appendix 1) must be used by the BrisDoc lead to track progress of any research proposals. This should be shared with relevant people who may be conducting the research or providing the resources to ensure the research can be conducted successfully. There are several points to be considered when assessing a research proposal for feasibility. The checklist offers a format to track progress and ensure all considerations are recorded.

Initial Review

An initial review will be conducted by the BrisDoc lead. The findings of this initial review with the researcher will be recorded on the checklist and should include considerations such as:

- Who is involved in conducting the research? Principal Investigator, GPs, Nurses, Ops staff. Are they up to date with research specific training – Good Clinical Practice certificate, research CV updated, informed consent training?
- How much time will the research take? What is the time commitment expected from participants?
- Is the project deliverable in the timescale requested?
- What are the financial implications?
- What additional resources are expected?
- Is there an overall benefit to BrisDoc participants being involved in the study?
- Will BrisDoc receive acknowledgment in subsequent publishing or have publishing rights?
- Does the study have approval from an Ethics Committee?
- If the study involves Investigational Medicines (a drug under investigation) or devices, is MHRA approval in place?
- Has informed consent been obtained from research participants? Are participants' autonomy, privacy and confidentiality being respected?
- Have conflicts of interest been disclosed and are being appropriately managed?

Agreement in Principle

When the above checklist has been considered, this must be approved in principle by two or more of the following:

- Medical Director
- Director of Nursing, AHPs and Governance
- Programme and Service Director

BrisDoc will then confirm its intent to support/not support the research study by sending a letter to the proposer outlining an understanding of the involvement and commitment to support the study.

This letter will also detail the required steps to enable the research to go ahead such as board approvals, data governance, fundings and external approvals (such as ethical approval).

Where approval in principle is *not* given, a rationale for this decision will be recorded and a letter sent articulating this position and the rationale. If there are amendments that could be made to gain approval, these will be clearly outlined in the letter to the participant.

The templates for these letters are available in appendix 2.

Governance and Approval Processes

For a research project to be signed off, the following steps must be completed:

- The governance team will assign one or more boards to each research project to receive the proposal, agree in principle, and to receive the results when available.
- The researcher will be invited to present their research proposal to the relevant board(s) and offer time for questions and discussions, then the board will be asked to sign off the proposal in principle.
- A confidentiality statement must be signed by the researcher.

Funding

While considering feasibility, it's important to consider the cost to BrisDoc, in the widest senses and the potential benefits. All teams' involvement should be considered e.g., operations, digital, clinical etc.

Where possible, funding should be provided to cover these costs. However, on some occasions this may be waived in the interest of benefits to the research and BrisDoc. This must be agreed prior to research being approved.

Data

Principles of good information governance must be observed throughout. Compliance with the following principles is important to ensure adequate data protection and compliance with relevant legislation.

- Researchers must adhere to applicable data protection laws, including but not limited to the General Data Protection Regulation (GDPR).
- Personal data should be collected, stored, and processed in compliance with relevant data protection regulations and guidelines.
- Anonymisation or pseudonymisation of personal data should be employed whenever possible to protect privacy and confidentiality.
- Data security measures must be implemented to safeguard research data from unauthorized access, loss, or disclosure.

In addition, a data sharing agreement (DSA) and data privacy impact assessment (DPIA) must be completed and approved if applicable. A template for these documents is available from the governance team.

Requests for data need to be clearly defined as part of the DSA and outlined in the checklist document. Special consideration needs to be given to ensure the request is adequate for the project, to avoid further requests for data to be pulled.

Data requests will be managed by the data analyst and shared via the Governance Team.

Any publication following research conducted within BrisDoc or using BrisDoc data must be subject to review by BrisDoc prior to its publication.

Final Approval

Once reviewed and approved at the relevant boards, and the necessary data security requirements and funding have been satisfied, a final approval will be sought from each of the three directors.

This will enable the research to go ahead and will remain with the governance team from this point forwards to ensure successful completion, along with escalation of any issues.

Final Steps Before Research

To ensure the research is conducted safely and in accordance with policy the following must also be completed:

- Risk Assessment
- Communications Plan
- Data Provision
- Contract/Rota

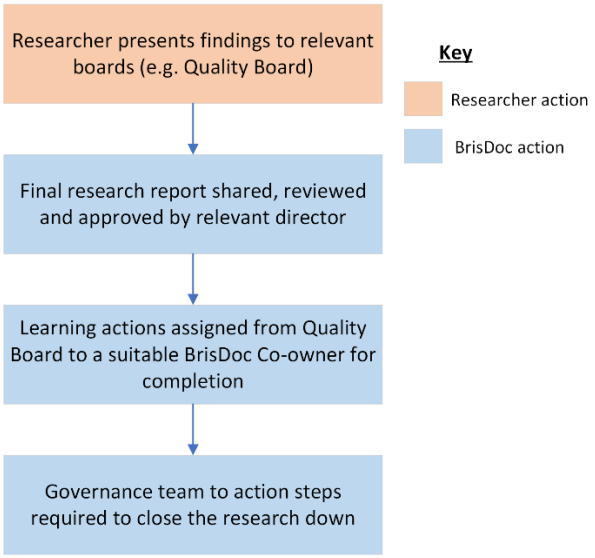
These should be completed in liaison between the governance team and the respective department within BrisDoc and completed prior to any research observations or interviews etc.

Post Research

BrisDoc is a learning organisation. Upon completing a research project, the researcher will be invited to relevant boards to present their findings. This will likely include Quality Board which is important to ensure that BrisDoc is aware of the key learning and output from any research.

The final research report should be shared, reviewed, and approved by the relevant director and learning actions assigned from Quality Board to a suitable BrisDoc Co-owner for completion. Further publications will also be shared with BrisDoc, as and when they arise.

Any steps required to close the research down will be coordinated and completed by the governance team. This includes formally noting the closure at the relevant boards, and signing off as closed on the checklist. All documents and records must be stored in the relevant governance folders.



Version Control

Date republished	Version	Reviewer	Amendments
05.10.2023	V1	Sarah Pearce	Document created
24/09/2024	V1.1	Traci Clutterbuck	Amended to include Improvement projects and Studies

Appendices

Appendix 1 – Research Checklist

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Appendix 2 – Acceptance / Rejection of research support template letters

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