Operationalising Responsible Data Sharing and Reuse in a Clinical Trials Unit

Introduction
Funders, publishers and institutions increasingly expect trial data to be shared transparently and reused responsibly. However, within many Clinical Trials Units (CTUs), data access and sharing processes have evolved through layered documentation, disparate storage locations and manual workflows, creating burden for both requesters and reviewers. This work describes an ongoing structured review and redevelopment of a joint School of Medicine and CTU data request and data sharing process, with the aim of supporting proportionate, auditable and sustainable open data sharing principles with operational feasibility.

Methods / Approach
A structured, iterative process review is being undertaken, covering governance, people, technology, and supporting documentation. Activities include: mapping existing workflows and repositories; reviewing membership, remit and operating model of the Data Custodian and Academic Proposal (DCAP) Committee; and examining request intake mechanisms, review criteria and audit trails. Proposed changes such as introducing validated online request forms, relocating process management documents to a permissions-controlled workspace environment, and defining standardised study-level 'data packs', are being co-developed, with clear role delineation for statisticians, data managers, and the Research Support Library team. SOPs are being reviewed to improve clarity, reduce unnecessary barriers and align with established external frameworks, including FAIR and CARE data principles.

Results Structure and Timeline
As this work is ongoing, outputs are being developed and implemented in phases. Emerging elements include: a single online intake route for internal, external, and collaborator data requests; clearer triage between fully anonymised data and requests requiring controlled access; revised workflows with standardised review criteria and documentation; a central collaborative workspace providing visibility of request status while maintaining audit trails; and a proportionate, study level 'data pack' created for funded studies at close out and deposited in the institutional data repository to assign persistent identifiers (DOIs), and support controlled or open access to facilitate onward data sharing in line with consent and governance decisions. Development and pilot implementation are expected to continue through 2026, with iterative refinement informed by user feedback.

Potential Relevance and Impact
This work highlights the operational challenges of embedding responsible data sharing within CTUs and the importance of co-design, proportionality and clear governance boundaries. The approach offers a transferrable framework for CTUs seeking to modernise data sharing processes while supporting the principle of 'as open as possible, as closed as necessary'. Process level evaluation using prospective metrics (turnaround times, completeness, approval rates, and repository deposits) is planned to inform ongoing refinement.

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