WASHOUT

Project Title: Ward AdmiSsion of Haematuria: an Observational mUlticentre sTudy (WASHOUT)

Data governance policy

1. Policy Statement

Purpose

This policy outlines the principles that describe the rules to control the usage of data collected from REDCap for the WASHOUT study, between 1st January 2024 until the end of the study.

The policy also defines the roles and responsibilities of the BURST committee, National Co-ordinators and Collaborators in relation to data access, retrieval, storage, disposal and backup of WASHOUT data assets.

The purpose of the Data Governance Policy is to:

- Define the roles and responsibilities for different data creation and usage types, cases and/or situations, and to establish clear lines of accountability

- Develop best practices for effective data management and protection

- Protect the WASHOUT study data against internal and external threats (e.g. breach of privacy and confidentiality, or security breach)

- Ensure that a data trail is effectively documented within the processes associated with accessing, retrieving, reporting, managing and storing of data

Scope

This policy applies to all WASHOUT data

DATA GOVERNANCE POLICY 1
Version 1.0 02/10/2023

2. Background

The WASHOUT study is a UK-led, international service evaluation run by the BURST (British Urological Researchers in Surgical Training) Committee (see www.bursturology.com for details of committee members and their roles). The committee overlooks the entire study and claims ownership of the data

collected during the study period. A national coordinator from each country has been selected to help promote WASHOUT nationally and recruit new sites. They work closely with the Core Committee.

3. Data handling

Patient data

The WASHOUT study does not collect or store any patient identifiable data. Identifiable data will only be accessed by clinicians or healthcare workers normally involved in the care of that patient at that hospital. Storage and access to such data is the responsibility of the participating individuals where all local policies, approvals and data governance procedures should be followed.

Collaborator and hospital data

The personal data of collaborators and clinicians involved in the study will be collected and securely stored by BURST to enable administration of the study. The names of collaborators and their hospitals will be shared with other collaborators in private study communications detailing recruitment "league tables".

Data creation

Data can be created and uploaded on to REDCap by any collaborator of the study who has an individual username and password for the WASHOUT study given during registration. The user should try to ensure good quality data is uploaded. Data should be original. Any falsification of data is serious research malpractice and may be reported to the appropriate governing bodies.

Data access

Ordinary users will have access to their institutional data that they have uploaded during the study period. Ordinary users will not have access to any data from outside of their own institution, neither to view nor to download. BURST Core Committee members will have access to the full data set online in the secure REDCap environment to view during the study for the purposes of data management and quality control.

The data held by and accessible by the BURST Core Committee is anonymous. The smallest population group that a patient can be placed within, based on the data held by BURST is the hospital catchment area, male or female and age within 5 years. The hospital catchment area details are not contained within the same database as the patient level data.

Any access to data outside of a user's immediate institution should be requested from the Committee by emailing admin@bursturology.com. **Requests should include the specific data required, the reason for the request, and the intention for use of this data - including the proposed audience that it will be used for. The Committee has the right to deny requests or to withdraw the right to access if it deems necessary.**

Data may be requested during the study collection period or after completion, for a period of no longer than one year after the study is closed.

If the request is approved, raw data will be exported from REDCap in a .csv file format and provided for download from a secure link.

Data usage

The Committee has the right to full usage of the dataset, primarily for the purposes of the objectives and outcomes outlined in the WASHOUT protocol, as well as any future uses following the completion of the study.

Senior members of the study steering group are the only people permitted to make dataset downloads (larger than the set from one individual institution) from REDCap at any time, unless a formal request is made and approved (e.g. by the official study statistician).

Access to national WASHOUT data by National Site Coordinators

National site coordinators that have participated in the study may request their national data, for the purposes of presenting this data locally, regionally or nationally. Assuming the greatest contribution from a collaborator from a country is the national site coordinator, it is expected that national site coordinators be given priority over other collaborators from the same country to use the data. Exceptions would be if another collaborator from the same country who was not a national site coordinator contributed more to the success of the study. In cases of dispute BURST will make final decisions on who has contributed the most. Permission to use the data will be granted on grounds of fair use and BURST reserves the right to withdraw permission to use the data or intervene in sharing of the data should the policy of fair use be violated.

Access to national WASHOUT data by other national collaborators

National site coordinators may coordinate and grant permission to other collaborators from the same country to view and use the data for similar usage. The same conditions for use of data from the WASHOUT study stated in this document apply to them too and it is the responsibility of the national site coordinator to ensure this is adhered to. In cases of dispute BURST reserves the right to grant access to national data to other collaborators from the same country.

National or International conference, paper or thesis submission

All submissions to a conference or manuscripts for publication based on WASHOUT data must be approved (in abstract or full paper form) by the BURST committee prior to submission. Collaborators intending to submit to a conference, write a paper or include the work as part of their thesis or equivalent should discuss their plans with the BURST committee prior to drafting any document. For conference submissions the full abstract should be sent to BURST for approval at least 14 days prior to the intended submission date. For papers or use as part of a thesis, the full paper or relevant thesis chapter(s) should be sent to BURST for approval at least 28 days prior to intended submission. Notification of acceptance of submitted work is mandatory as this allows BURST to keep track of impact of the work.

What to include on conference, paper or thesis submissions

On submissions, if the data set being presented is preliminary (i.e. before closure of the study), this must be stated in any presentations or publications. BURST does not hold any accountability for the

interpretation or analysis of data given to individuals.

Presentation and publications from the WASHOUT dataset must include the relevant authors, and must be approved by the Committee before submission.

For the purposes of presentations, the presenting author / collaborator can be named as first author. Other national collaborators may be included on the mainline authorship line at the discretion of the presenting author. The BURST WASHOUT study steering committee must also be included on the mainline authorship of any outputs from the study data. That authorship list will be confirmed at the time of any submissions. The authorship line must end with "On behalf of the BURST Research Collaborative" or "BURST Research Collaborative" and affiliations of all authors must include the BURST Research Collaborative in addition to any local institutional affiliations the presenting author chooses to add.

Any presentations, publications or reports **must acknowledge all national collaborators in the dataset being used, including their full names and institutions**. These names should be listed as a minimum in the Appendix of a paper, in a box on a poster or on a slide in a presentation. For publications, the journal should be asked by the submitting author to name these collaborators as PubMed Indexed collaborators. Advice can be obtained from BURST on how to approach this with journals if required. If in doubt as to the names of national collaborators, please contact BURST who can assist with these details.

After presentations are complete or publications are accepted the corresponding author must inform BURST about the success with details.
Please include details of any prizes won.

Local data use by collaborators from a site

Individual collaborators may use their institutional dataset, without prior request, by exporting the data from REDCap, and may present this locally e.g. for audit and service evaluation purposes. This is encouraged by BURST for local clinical governance. After a local presentation, collaborators are asked to email admin@bursturology.com to inform them the date and location of their presentation, specifying that it used local data. This will be used by BURST to demonstrate impact.

Data storage

Any data received from the WASHOUT study must be stored within the requesting institution in a secure location with password protection. It should not be stored on personal devices. Data should only be available to collaborators partaking in the WASHOUTstudy and should not be shared with external members unless approved by the BURST Committee.

Any further queries regarding data governance should be liaised with the Committee via email: admin@bursturology.com