Data Access Policy

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Contents

Summary of the ADVANCE study

The ArmeD SerVices TrAuma and RehabilitatioN OutComE (ADVANCE) study investigates both the physical and psycho-social outcomes of battlefield casualties. It is a collaboration between the Academic Department of Military Rehabilitation (ADMR, Stanford Hall), Imperial College London and King's College London.

This document is designed to detail the pathway to accessing ADVANCE study data, covering the processes and procedures involved for requesting data, modifying a request and querying data.

Data Access procedure overview

The ADVANCE study's policy on data access is based on the need to:

- Maximise the value of the study data for robust academic research.
- Ensure that data are handled within the scope of participant's signed consent.
    - Ensure work addresses topics that fall within the acknowledged remit of the study as understood by participants.
    - Ensure that participants are protected with good data security and participant confidentiality throughout.
- Ensure compliance with UK legal and regulatory requirements (e.g., the UK Data Protection Act, 2018 and the EU General Data Protection Regulation, 2018).
- Ensure work does not run the risk of upsetting or alienating participants or of reducing their willingness to remain as active members of the study.

1. Data availability

Before study data are made available for research, the Data Team are responsible for undertaking quality control, cleaning, processing, integration and imputation. Once data are made available quality control work will continue *ad hoc* based on feedback from Data Users working with the variables. If a quality issue is raised by a user, affected variables will be updated and all users with that variable will be provided with the updated version and rationale behind the change.

If data are generated as a result of a collaboration where a researcher or team has secured funding for the collection of new data, exclusive access may be granted for a limited period of time. This exclusive access is not based entirely on the fact that funding was obtained for data collection, and requests for short-term exclusivity will be considered on a case-by-case basis. If exclusive access is granted the variables will still appear on the DRF (appropriately flagged as restricted access) and applications for this data may still be submitted by other users. Any access applications received in this time will be presented to those with the exclusive rights to discuss if data release or collaboration would be appropriate. The Data Team will support and facilitate any necessary data sharing resulting from a collaboration.

2. Requesting access

2.1. Eligibility

Data collected and made available by the ADVANCE study is intended for use by the research community. We welcome requests for data from all '*bona fide'* researchers from all disciplines to maximise the use and impact of this resource.

'Bona fide researchers' are, in line with the MRC's definition, defined as researchers who work on high quality and ethically conducted research, employing rigorous scientific methods. Their research should be intended for publication, with the goal of benefiting the scientific community and the public, without unnecessary restrictions or delays. Bona fide researchers should also have a formal partnership with a legitimate research organisation, such as a recognised academic institution or research body, that has the expertise and capacity to lead or contribute to high-quality, ethical research. The process of applying for ADVANCE data remains the same, no matter the institution, field, or funding source.

It is acknowledged that international access to the ADVANCE study data is important and there should be no unnecessary barriers preventing such research. However, due to the sensitive nature of the ADVANCE study data, in some instances access may need to be barred to ensure our procedures for protecting participants' data from disclosure risk are robust. International access will be determined in accordance with the provisions of the UK Data Protection Act and the GDPR and with unanimous approval of the Project Board only.

2.2. Data Request Form (DRF)

Access requests must come via the ADVANCE online Data Request Form (DRF), a link to which can be provided by the Data Team or Project Board. The form captures the project proposal, including a title, hypothesis, lay-readable outline, all of which will be made available on the study website should the request be approved. The form also requires the requester to provide a date of anticipated project conclusion, specify each individual variable they would like to receive, and agree to the access requirements which include that they meet GDPR training/data security/publication and authorship standards.

The ADVANCE study Project Board will aim to review and respond to all data requests at their next meeting (meetings are held monthly) after submission. Any applications submitted less than 4 days before a meeting cannot be guaranteed to be reviewed and may be reviewed at the following meeting instead.

To avoid duplication of effort, potential Data Users and collaborators may wish to review the ADVANCE study website (ADVANCE Study | Military Trauma Rehabilitation Research) to get an overview of the available data (Longitudinal Data Plan - ADVANCE Study), and the research work (ongoing and past) that has used these datasets (Research Proposals - ADVANCE Study). It should be noted that whilst the study Project Board consider the issue of project overlap, applicants are encouraged to review the list of publications and approved applications on the study website themselves prior to submitting an access request.

2.3. Terms of access

In order for a proposal to be submitted for approval, a Data User must agree to the following Terms of Access embedded in the Data Request Form:

GDPR: They must undertake adequate GDPR training if they do not currently have, or have not recently refreshed, their GDRP training.

Data security: Submit a Data Security Plan outlining how they will keep study data safe through the duration of their work and confirm they have read and understood our Data Security policy document.

Identifying data: Data Users must not make any attempts to identify the participants in the study. Data will be provided with a pseudonymised set of identifiers unique to each Data User or research team, thus datasets cannot be combined between projects. If a Data User wishes to move data between projects they need to speak to a member of the Data Team and will either be provided with an identifiers' key or asked to submit a Minor Modification. Either way, a paper trail of the variables being combined will be captured in their DRF.

Data disclaimers: Some variables have features that users need to be aware of, or may wish to exclude from their dataset. These features arise from a variety of sources such as administrative errors, participant completion rates, the high intensity operational environment that some data were collected in, suitability of participants for certain tests etc. Data Users must acknowledge these, or ask for data to be excluded, to avoid unnecessary/unwanted data being shared.

Secure data transfer: All data transferred electronically must be encrypted using AES-256 encryption or equivalent (this encryption can be provided by tools such as 7-Zip compression). Passwords and datasets must never be shared via the same method as each other. Data will only ever be shared with the primary Data User listed on the DRF.

Authorship: For both internal and external reasons, all manuscripts relating to data from the ADVANCE study should be prepared using the scheme outlined in the study's Manuscript Development and Approval agreement.

Publicity and Dissemination: The project title, hypothesis, summary, key words, and author name and affiliation will be made available on the study website if the application is approved by the Project Board.

Derived variables: The ADVANCE Data Team recognizes that derived data are an important and useful resource for the Data Users associated with the study. We therefore request that, at the end of any project, Data Users flag any new variables that have been created which may be of use to future Data Users with the Data Team for discussion and possible integration in to the main data set.

If variables are easily reconstructed by another User, these variables (and some associated written work, e.g. published paper) will be signposted in future editions of the Data Request Form. The associated work should provide enough detail to replicate the derived variable. Alternatively, if variables are not easily reconstructed (for example, they are too complex or time-intensive to reconstruct) then the Data Team will hold these variables and release them to new Data Users as 'non-replicable' derived variables. This helps to encourage open science and improve the utility of the data for the wider research community over time.

Please note – it is required that any variables included in this form come from work that is published in a peer review journal, or at minimum have been reviewed by the ADVANCE study statistician. The Data Team staff may also carry out independent checks and/or validation of the data and results to ensure the continued data integrity and reliability of the study findings.

Data Destruction: One month prior to the anticipated project completion date Data Users will receive an automated email requesting confirmation that the project will be completed on time, or if an extension is required. If a project is completed, any copies of datasets provided as a result of a successful DRF, along with any related documents (electronic and paper), must be deleted or destroyed unless preservation is required as a result of publication. If ADVANCE data have been used in a publication and data preservation is required researchers are asked to return all data and files relevant to the analysis to the Data Team for long term storage (10 years by default) and then delete personal copies. Data Users can then request to access these stored datasets in the future if needed.

If requested by the study, data must also be deleted or destroyed immediately at any stage.

2.4. Amending an application after approval

Reasonable alterations to data requests can be made after a DRF's submission and approval via the same online form as the original request; this is considered a 'Minor Modification'. Minor Modifications must be completed in the following circumstances:

- If there is a request for an Additional User to be added to a project (anyone who will need access to the data provided must be recorded).
- If there is a change in the scope of the project. N.B. a *significant* change may be best captured with a new DRF.
- To request additional variables/data for a project.

The Data Team are responsible for providing access to the Minor Modification forms and approval is generally granted by a member of the management team or a single project board member. In the case of complex or extensive modification the resubmission will be reviewed by the Project Board as a whole at the next monthly meeting.

2.5. Additional users

At minimum, a DRF requires a Primary Data User and a responsible PI or Manager to be named and to sign off on project proposal prior to submission. However, additional researchers/collaborators may be included in the initial application or added to an existing project as an amendment. To request Additional Users at any time please contact the Data Team who can provide the relevant access/form.

It is worth noting that Additional Users are required to sign the same relevant Terms of Access documentation as a Primary User prior to accessing ADVANCE data. Equally, the Data Team will always refer to the Primary Data User of a DRF as the point of contact for any application and all data, updates, queries, or alerts will be sent to them with the expectation that they disseminate key information as needed.

2.6. Access to biological samples

Where possible, biological samples such as blood and urine have been collected at every participant visit. However, as a finite resource, the use of the biological samples will be carefully controlled. The study has a responsibility to optimise the value, and the amount of data, obtained from these samples.

It should be noted that if a project wishes to utilise these samples the full cost of processing them will fall to the applicants, though the ADVANCE Project Board reserves the right to specify where analysis will be run.

Therefore, it is strongly advised to discuss any plans with the Data Team and Programme Coordinator prior to submission of a request.

3. Confidentiality or security breaches

Data Users must maintain sufficient information security controls to protect the data from unauthorised use or access. If any breaches occur this must be reported to the Data Team and Programme Coordinator immediately. A data breach would be considered to be (but is not limited to):

- If data were sent to the wrong recipient, or if anyone unauthorised (not recorded on an active DRF) received information not intended for them.
- If equipment (e.g. laptops, hard drives) containing ADVANCE study data were lost or stolen.
- If data are not sufficiently encrypted during transfer.
- If devices with ADVANCE study data become vulnerable to a virus or malware.
- If there is reason to believe another individual has had access to information they should not have – either by entering a private office or accessing an unlocked device.

Furthermore, Data Users must not share, or provide access to, data with anyone outside of their approved user group (as defined in the DRF). As previously stated, to add an Additional Data User an amendment to the project proposal must be made through the online system.

4. Research outputs

Research outputs are any written or oral information that has been based on, or incorporated, ADVANCE study data and is to be distributed beyond the approved user group named in the successful DRF. This includes (but is not limited to) papers, conference presentations/posters, reports, seminars, theses, press releases, and funding applications.

4.1. Clinically relevant findings

An incidental clinically significant finding can be defined as a finding that has potential health importance, which is discovered unexpectedly while conducting research. In common with other studies, the ADVANCE study has robust procedures for reporting relevant values/findings, when necessary, at or close to the time of a participants visit. However, it should be highlighted that, at no time, should researchers attempt to contact participants about potentially clinically significant incidental findings. If concerning patterns emerge researchers are encouraged to speak to the Programme Coordinator and Project Board who will take the issue forward, reviewing consents and ethics processes as needed.

4.2. Peer reviewed papers

As previously outlined, it is expected that any work utilising ADVANCE study data should be prepared using the scheme outlined in the Manuscript Development and Approval agreement. This covers issues relating to access, authorship, acknowledgements, funding statements and more. We also ask for a lay synopsis of any published papers once they have been accepted by a journal.

4.3. Theses

Whilst it is not necessary to submit your thesis for review by the ADVANCE study Project Board before submission, the named PI on your DRF should be satisfied that the study data have been used, and acknowledged, appropriately prior to submission.

4.4. Policy briefings

Any policy briefings produced should be shared with the Project Board prior to release in order that the Communications Manager can offer timely support as needed, but equally so that the Project Board are made aware of any ongoing work.

4.5. Conference proceedings and other presentations

Conference submissions do not need to be reviewed prior to submission. However, all Data Users are asked to ensure that any ADVANCE study-based work presented incorporates appropriate acknowledgement of the study, the participants, and includes the study logo. Please contact the Communications Manager (Admin & Management - ADVANCE Study) for further information.

4.6. The media

The ADVANCE study's Communications Manager should be alerted to any formal press releases or media events relating to the study or work based on the study's data. All researchers publishing peer reviewed papers are also asked to provide a lay synopsis of any papers once they have been accepted by a journal. These synopses may then be published on the study website (Findings & Publications - ADVANCE Study), across the study's social media pages, or included in future core funding applications or reports to current funding bodies.

We encourage interaction with our social media accounts, and ask Data Users to alert the Communications Manager, whenever possible, to any upcoming presentations, talks, conferences, or other forward facing events they are attending so that this can be covered. We reserve the right to publish press releases on work done based on ADVANCE study data and expect cooperation from the Primary Data User.