**NEWCASTLE 85+ STUDY COLLABORATION AGREEMENT**



The Newcastle 85+ Study welcomes approaches from researchers who wish to collaborate in the analysis of de-identified Newcastle 85+ Study data.

Potential collaborators should initially complete this form. There are 9 sections in the form (A – I) and all sections must be completed.

Two copies of the form must be returned:

1. An electronic copy of this form should be returned to Dr Andrew Kingston, Newcastle 85+ Study Data Guardians Chair at : andrew.kington@ncl.ac.uk.
2. A paper copy with wet signatures should be sent by post to:

Dr Andrew Kingston

Biomedical Research Building,

Campus for Ageing and Vitality,

Newcastle University,

Newcastle upon Tyne

NE4 5PL

Once both copies are received, the application to collaborate will be reviewed by the Newcastle 85+ Study Data Guardians Group.

**SECTION A - FULL TITLE OF PROPOSED PROJECT**

**SECTION B - APPLICANTS**

LEAD APPLICANT DETAILS

Title……………………………………………………………..………………………………

Full name………………………………………………………………………………………

Position…………………………………………………………………………...……………

Institution…………………………………………………………………………..…………

Postal address…………………………………………………………………………………

Telephone number…………………………………………………………….………………

E mail address………………………………………………………………………………………

CO-APPLICANT DETAILS (copy as required)

Title……………………………………………………………………………………………

Full name………………………………………………………………………………………

Position…………………………………………………………………………………………

Institution………………………………………………………………………………………

Postal address…………………………………………………………………………………

Telephone number………………………………………………………………………………

E mail address…………………………………………………………………………………

NAMES OF ADDITIONAL COLLABORATOR(S) AND ORGANISATION(S)

………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………

**SECTION C – BACKGROUND, AIMS AND PROPOSED METHODS**

BACKGROUND: A short background to the project and why this analysis is needed

AIMS: state the aims and specific objectives

METHODOLOGY: The analysis strategy needs to be clearly outlined.

**SECTION D – VARIABLE REQUESTED**

Please state which data variables you require (you will also need to state which phase of the study you require the variables from). Please fill in table below and add additional rows as needed.

All interview schedules and GP record reviews are available on the website, as is a summary of the data collected across the 5 phases of the study:

<https://research.ncl.ac.uk/85plus/>

|  |  |
| --- | --- |
| **Requested variables from Newcastle 85+ study** | |
| Phase / interview | Section |
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| --- |
| **Requested mortality data from Newcastle 85+ study** |
| **Mortality data (derived variable from data of death) Yes / No** |
| **Cause of death Yes / No** |

If Mortality data is requested please supply the following details.

Organisations Data Sharing Framework Contract -Reference ; CON- XXXXXX – XXXXX (Version X.X)

Valid NHS Toolkit ODS Code;

Publication Date; \_ \_ / \_ \_ / \_ \_ \_ \_ Approved Date; \_ \_ / \_ \_ / \_ \_ \_ \_

All Newcastle studies should register the project with the University Toolkit please contact [igenquiries@ncl.ac.uk](mailto:igenquiries@ncl.ac.uk)

WHAT DURATION DO YOU REQUIRE THE DATA?

Please indicate in months ………………………………………….....................

**SECTION E - REQUEST FOR ADDITIONAL ASSAYS ON STORED BLOOD SAMPLES**

If you request additional assays on stored blood, the volume of material required and what phase you would like needs to be outlined. The use of these stored samples may require additional approvals with the ethics committee through a study amendment and it is suggested you speak with the PI beforehand. Please outline below:

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**SECTION F – DISSEMINATION OF FINDINGS**

Outline how and where you will publish your findings to academics, the NHS and the public.

**Academic journal(s)** – outline proposed submissions and timelines

**Conference(s)** – outline proposed presentations

**Public dissemination** – please outline

**SECTION G – PUBLICATION AND AUTHORSHIP POLICY**

No dissemination of results will occur without prior approval of the Newcastle 85+ Study principal investigator, who will consult with the Data Guardians Group and study management team as appropriate. This requirement includes original articles, conference abstracts and presentations.

**Original manuscripts**

Approval requires: (a) approval of an outline before drafting begins and (b) approval of a final draft prior to submission.

Initial outline

Before work begins on a manuscript, an outline proposal shall be circulated via the Newcastle 85+ Study principal investigator to the Data Guardians Group for approval. The outline shall include the following sections: (i) scope, (ii) key message, (iii) target readership, (iv) main areas of results, (v) anticipated impact, (vi) proposed authorship team (see authorship section below) and (vii) timescale for submission.

Outline proposals will be considered by the Data Guardians Group and the lead applicant informed of the outcome.

Full manuscript

*Title*

All manuscripts shall include the phrase “Newcastle 85+ Study” within the title

*Keywords*

In publications where keywords are used, a keyword should be “Newcastle 85+ Study”

*Acknowledgements*

The following standard form of acknowledgement shall be used as the default version for all publications, except where modified versions have been proposed by the writing team and agreed by the Data Guardians Group:

“The Newcastle 85+ Study has been funded by the Medical Research Council, Biotechnology and Biological Sciences Research Council, the Dunhill Medical Trust and the National Institute for Health Research School for Primary Care. Parts of the work have also been funded by the British Heart Foundation, Unilever Corporate Research, Newcastle University, NHS North of Tyne (Newcastle Primary Care Trust). Mortality data was obtained from NHS Digital. We acknowledge the operational support of the North of England Commissioning Support Unit, the National Institute for Health Research Clinical Research Network North East and North Cumbria, local general practitioners and their staff. We thank the research nurses, laboratory technicians, data management and clerical team for their work throughout, as well as many colleagues for their expert advice. Thanks are due especially to the study participants and, where appropriate, their families and carers.”

*Submission*

Final draft manuscripts shall be submitted for approval not less than two weeks before submission. Earlier drafts shall normally have been circulated prior to this.

*Publication*

To update the Newcastle 85+ Study Data Guardians Group (via the principal investigator) the outcome of any submission and if accepted to provide a pdf copy when it is published.

**Conference abstracts**

*Title*

All manuscripts shall include the phrase “Newcastle 85+ Study” within the title

*Conference presentations*

Study logo – please incorporate into the presentation

*Acknowledgements* – please acknowledge funders and the Newcastle 85+ Study team.

*Submission*

Abstracts to be published in journals or submitted to conferences shall be submitted to the Newcastle 85+ Study principal investigator, to be circulated to the Data Guardians Group for approval not less than two weeks before submission.

*Publication*

To update the Newcastle 85+ Study principal investigator if the abstract is accepted for a conference and notify when it is presented.

**Authorship**

All individuals listed as authors should qualify for authorship and should have participated sufficiently in the work to take public responsibility for appropriate portions of the content. The International Committee of Medical Journal Editors (ICMJE) recommends that authorship be based on the following 4 criteria:-

• Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND

• Drafting the work or revising it critically for important intellectual content; AND

• Final approval of the version to be published; AND

• Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Any other contributors to the work who do not qualify for authorship, but who have who have made substantial contributions (including writing and editing assistance) should be listed in the acknowledgement section.

*Publications and authorship*

Papers and abstracts originating with the Newcastle 85+ Study team

Authorship shall be discussed at an early stage by the writing team who will identify a provisional list and order of names. However, final authorship shall be decided at the point when a final or near-final draft is prepared.

The authorship shall include members of the Newcastle 85+ Study team meeting the above qualifications for authorship. Other co-authors may be included, when agreed to be appropriate by a majority decision of the Newcastle 85+ Study management team.

Any member of the core team who does not feel that they have made a sufficient contribution to the publication to warrant being named among the authors may withdraw their name. In journals where it is permitted to include a group as co-author, any withdrawing core team members will be represented by the inclusion of “The Newcastle 85+ Study Team” within the authorship. Where this is not possible, they will be included in the Acknowledgements.

The first author (or joint first authors) shall be the individual(s) who contributed most to the content of the publication.

The default position is that the last author and corresponding author shall be the Newcastle 85+ Study principal investigator (currently Dame Louise Robinson) although this may be varied by agreement in particular cases. The Newcastle 85+ Study principal investigator holds overarching ethical and organisational responsibility for the study and should therefore be involved and included in all publications.

Order of authorship between first and last position shall be agreed on a case-by-case basis and where no other factors are involved shall involve some degree of rotation.

For all members of the core team, the primary affiliation for publications arising from the Newcastle 85+ Study shall be “Newcastle 85+ Study, Population Health Sciences Institute, Newcastle University, Campus for Ageing and Vitality, Newcastle upon Tyne, NE4 5PL, UK”. If journals permit multiple affiliations to be declared, authors may where appropriate add a secondary affiliation.

The correspondence address for core publications shall be “Newcastle 85+ Study, Population Health Sciences Institute, Newcastle University, Campus for Ageing and Vitality, Newcastle upon Tyne NE4 5PL, UK”.

Final draft manuscripts shall be submitted for approval not less than two weeks before submission. Earlier drafts shall normally have been circulated prior to this.

Paper and abstracts originating with Academic collaborators based specifically on data from the Newcastle 85+ Study

As with core publications, authorship shall be discussed at an early stage by the writing team applying for the data who will identify a provisional list and order of names. However, final authorship shall be decided at the point when a final or near-final draft is prepared.

In publications from academic collaborators the authorship shall be the relevant academic collaborators and their colleagues (subject to approval by the 85+ management team) as well as the appropriate members of the core 85+ Data Guardians Group. Decisions about which core team members should be included will be made by the Data Guardians Group on a case-by-case basis but the Newcastle 85+ Study principal investigator (currently Dame Louise Robinson) holds the overarching ethical and organisational responsibility for the study and should therefore be involved and included in all publications.

For all members of the core team, the primary affiliation for publications arising from the Newcastle 85+ Study shall be “Newcastle 85+ Study, Population Health Sciences Institute, Newcastle University, Campus for Ageing and Vitality, Newcastle upon Tyne NE4 5PL, UK”. If journals permit multiple affiliations to be declared, authors may where appropriate add a secondary affiliation. For academic stakeholders, authors may declare their preferred affiliation.

For a publication that concerns findings focusing on a particular academic domain, the correspondence address may in appropriate circumstances be that of the academic who is designated as corresponding author.

Papers and abstracts originating through collaborations involving other studies

In some cases, results from the Newcastle 85+ Study will be included in publications from other studies, e.g. with the Leiden 85+ Study. All such cases shall follow as far as possible the procedures applying to publications from the Newcastle 85+ Study alone, although the particular circumstances will be likely to require that decisions be made on a case by case basis.

**USING MORTALITY IN ANY PUBLICATION, Abstract, Paper, Presentation**

Mortality data wherever possible must cite the copyright of NHS Digital in accordance with the Data Sharing Framework Contract 3.13 as follows;

*"Copyright © (year), the Health and Social Care Information Centre. Re-used with the permission of the Health and Social Care Information Centre. All rights reserved."*

**Data archiving**

Copies of any published work, conference presentation or report based wholly or in part on the Newcastle 85+ Study must be deposited with the principal investigator within 2 weeks so this can be reported in Research Fish.

**Failure to comply with the procedures for publication of results from Newcastle 85+ Study will be taken very seriously. If necessary, a letter may be sent to the journal or conference stating that the procedures have been violated.**

**SECTION H – DATA SHARING AGREEMENT**

PURPOSE

To use the data and supporting documentation supplied by from the Newcastle 85+ study only for the purposes of non-commercial research as specified in this application. Approval must be sought from the Data Guardians Group of the Newcastle 85+ Study for any other proposed use.

CONFIDENTIALITY

To act at all times so as to preserve the confidentiality of individuals and institutions recorded in the data. In particular, not to attempt to or to use the data to derive information relating to an identified individual or institution or to claim to have done so. The Collaborator must make not attempt to contact any individual if the data becomes identifiable within their possession.

DATA TRANSFER AND LOCATION

Internal collaborators at Newcastle University – data will be prepared and placed within a folder on a shared Newcastle 85+ results drive. You will be granted access to this drive. Data should not be copied or transferred elsewhere. Use of this drive will be monitored by the Data Guardians Group and audited in accordance with the terms of the University NHS Toolkit.

External collaborators - data are prepared and written to an encrypted container (Bit Locker). This is then sent to the external collaborator, on a DVD by recorded delivery. Once they receive this and acknowledge receipt, we will then send on the password to decrypt the data separately.

It is now policy at Newcastle University that prior to sharing any data with external collaborators, they are also required to sign an agreement with Legal services at Newcastle University. This is in addition to this collaboration agreement. If this collaboration agreement is agreed by the Data Guardians Group we will subsequently contact Legal Services.

COPYRIGHT

Mortality data where ever possible must cite the copyright of NHS Digital in accordance with the Data Sharing Framework Contract 3.13 as follows;

*"Copyright © (year), the Health and Social Care Information Centre. Re-used with the permission of the Health and Social Care Information Centre. All rights reserved."*

DATA ACCESS

All people who analyse or have access to the data must sign this collaboration agreement.

Any researcher who is undertaking analysis that includes mortality data must have completed an NHS toolkit at their own institution (including those working at Newcastle University) and provide evidence they have done so.

ACCESS TO OTHERS

Under no circumstances must any data be shared with anyone who is not listed in this application. If you wish to share the data with other people or the study team changes the Data Guardians Group must be informed in writing and this will be considered by the group.

DURATION OF ACCESS TO DATA

Collaborators will have access to the data for a determined period of time decided at time of application. During that time, regular short reports need to be completed 6 monthly and sent to the Data Guardians Group indicating how you are using the data. The time frame during which you will have access to the data will be determined for each application, dependent on the complexity of the proposed work. If the work is still in progress and the deadline is approaching, collaborators will need to justify why the work has not been completed. To have continued access to the data beyond the originally determined period, a new Data Sharing Agreement will need to be submitted to the Data Guardians Group, and if agreed a new period will be determined.

DERIVED DATASET DEPOSIT

At the conclusion of the research (or at any time at the request of the principal investigator on behalf of the Newcastle 85+ Study Management Team) to deposit in the Newcastle 85+ data archive, on a suitable medium and at the collaborating researchers own expense any new datasets/variables which have been derived from the data supplied or which have been created by the combination of the data supplied with other data. The deposit of the derived datasets will include sufficient explanatory documentation to enable the new data files to be accessible to others and programmes detailing how derived data were created.

ERRORS

To notify the Newcastle 85+ Management Team via the principal investigator of any errors discovered in the data.

DATA BREACH

Any data loss of mortality data needs to be reported immediately to [igenquiries@ncl.ac.uk](mailto:igenquiries@ncl.ac.uk) with full details of the loss.

CHARGES

If you are an external collaborator and require mortality data, you are required to be added to the agreement the Newcastle 85+ study has with NHS Digital. This incurs a cost and will be charged at the Data Access Request Service ‘Amendment’ rate. This can be found here ; <https://digital.nhs.uk/services/data-access-request-service-dars/data-access-request-service-dars-charges-2018-19>.

Other charges may apply for accessing the data and will be discussed at application

LIABILITY

In accordance with the Data Sharing Framework Contract of the Institution holding the data.

DESTRUCTION OF DATA

On completion of the specified project and after any derived data has been deposited and verified by the Newcastle 85+ data archive, to destroy or erase irrecoverably all complete, partial or derived copies of the data which have been made available for this application and to inform the Newcastle 85+ Data Guardians Group that this has been done. The only exception to this is where an application has been approved to use the data for a further project.

**SECTION I - SIGNATURES**

By signing this collaboration agreement I agree to abide by the regulations outlined in this document.

LEAD INVESTIGATOR

I will be directly undertaking statistical analysis of the raw data Y / N

(If yes, please note section H in this document)

Name (BLOCK CAPITALS)

Date

Signed ……………………………………………………………………………..

CO-APPLICANTS

I will be directly undertaking statistical analysis of the raw data Y / N

(If yes, please note section H in this document)

Name (BLOCK CAPITALS)

Date

Signed ……………………………………………………………………………..

CO-APPLICANTS

I will be directly undertaking statistical analysis of the raw data Y / N

(If yes, please note section H in this document)

Name (BLOCK CAPITALS)

Date

Signed ……………………………………………………………………………..

CO-APPLICANTS

I will be directly undertaking statistical analysis of the raw data Y / N

(If yes, please note section H in this document)

Name (BLOCK CAPITALS)

Date

Signed ……………………………………………………………………………..