NEWCASTLE 85+ STUDY COLLABORATION AGREEMENT

WORKED EXAMPLE ONLY - FICTIONAL APPLICANTS AND PROJECT - DO NOT SUBMIT

All red text illustrates what an applicant might enter. Black text is retained from the February 2020 form and may include historic instructions. Confirm the current form, submission route, governance requirements and charges with the Newcastle 85+ Study team.

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

EXAMPLE - Time-updated prescribed medication burden and difficulty managing medicines between ages 85 and 90: a longitudinal Newcastle 85+ Study analysis

Illustrative teaching example; this is not an approved project and does not claim novelty.

SECTION B - APPLICANTS

LEAD APPLICANT DETAILS

Title……
EXAMPLE - Dr

Full name……
EXAMPLE - Maya Patel (fictional)

Position……
EXAMPLE - Research Fellow in Ageing and Medicines

Institution……
EXAMPLE - North East Example University (fictional)

Postal address……
EXAMPLE - Example Department, 1 Research Way, Exampletown, EX1 1AA

Telephone number……
EXAMPLE - +44 (0)191 000 0000 (fictional)

E mail address……
EXAMPLE - maya.patel@example.org

CO-APPLICANT DETAILS (copy as required)

Title……
EXAMPLE - Dr

Full name……
EXAMPLE - Sam Green (fictional)

Position……
EXAMPLE - Senior Lecturer in Medical Statistics

Institution……
EXAMPLE - North East Example University (fictional)

Postal address……
EXAMPLE - Example Department, 1 Research Way, Exampletown, EX1 1AA

Telephone number……
EXAMPLE - +44 (0)191 000 0001 (fictional)

E mail address……
EXAMPLE - sam.green@example.org

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

EXAMPLE - No additional raw-data users. A Newcastle 85+ Study collaborator and any additional analyst will be named and approved before access; neither will be assumed at initial submission.

SECTION C – BACKGROUND, AIMS AND PROPOSED METHODS

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

EXAMPLE - Background: Medication burden is common in very old age, but the practical ability to take medicines may change as cognition, living arrangements and functional capacity change. A longitudinal analysis can distinguish whether higher prescribed-medication burden precedes later difficulty or need for help, rather than merely being associated at one interview.

EXAMPLE - Existing Newcastle 85+ work checked: The literature review includes Characterising polypharmacy in the very old (10.1371/journal.pone.0245648), polypharmacy and dependency transitions (10.1093/ageing/afac227), and difficulty taking medicines (10.1111/bcp.15858). The proposed question may overlap these outputs and must be discussed with the study team before it is treated as novel.

EXAMPLE - Evidence gap: The illustrative gap is the lagged association between medication burden at one GP record-review wave and the medication-management response at the next health-assessment wave, with explicit handling of proxy response, attrition and death.

EXAMPLE - Public benefit: Results could help clinicians and services identify when a rising medication burden should prompt a review of practical medicine-management support. No individual-level clinical decision will be made from the research data.

AIMS: state the aims and specific objectives

EXAMPLE - Primary research question: Among Newcastle 85+ participants with linked health-assessment and GP record-review data, does a higher count of active regular prescribed medicines at the preceding wave predict greater difficulty taking medicines or needing another person's help at the next wave between baseline, Phase 3 and Phase 4?

EXAMPLE - Primary aim: Estimate the lagged association of time-updated regular prescribed-medication count with the four-category questionnaire response on ability to take medication.

EXAMPLE - Specific objectives: 1) describe regular and acute medication counts at Phases 1, 3 and 4; 2) estimate Phase 1 medication burden -> Phase 3 medication-management outcome and Phase 3 burden -> Phase 4 outcome; 3) examine whether living alone or baseline cognition modifies the association; 4) assess sensitivity to proxy response, missingness, attrition and death.

EXAMPLE - Scope/overlap decision: Proceed only if the Data Guardians confirm a distinct question or an agreed collaboration with the authors of overlapping Newcastle 85+ work.

METHODOLOGY: The analysis strategy needs to be clearly outlined.

EXAMPLE - Design: Longitudinal observational analysis using pseudonymised row-level data.

EXAMPLE - Population: Participants with Phase 1 GP medication data and the Phase 1 medication-management item, plus at least one eligible Phase 3 or Phase 4 outcome. Include community and care-home residents and retain

valid informant-assisted responses permitted by the schedule. Final inclusion counts will be confirmed in a feasibility table.

EXAMPLE - Phase map: Baseline/Phase 1 (age about 85), Phase 3 (36 months; age about 88) and Phase 4 (60 months; age about 90). Link waves by the study pseudonymous identifier.

EXAMPLE - Exposure: At each GP record-review wave, use the completed medication rows, prescription source/status code and Drug Code. Derive the count of active regular medicines; retain acute items separately. Illustrative categories: 0-4, 5-9 and 10+ medicines. Do not request dose, strength or adherence because these are not fields in the cited schedules.

EXAMPLE - Primary outcome: Phase 1 Interview 1 H61 and Phase 3/Phase 4 H46, 'Are you able to take your medication?', retaining the four ordered responses: no difficulty; some difficulty; only with an aid/appliance; unable without another person's help.

EXAMPLE - Secondary outcomes: Pill-organising box use (Phase 1 H63; Phases 3/4 H47), help with medication (Phase 1 H64; Phases 3/4 H48), helper type, help frequency, additional helpers and adequacy of help (Phase 1 H65-H68; Phases 3/4 H49-H52).

EXAMPLE - Covariates: Sex and interview date/age; Phase 1 B1-B4 general health and longstanding-illness count; E4/E7 living alone and household size; Section F study-derived SMMSE total and validity/omission indicators; M2-M4 education; phase, time since baseline and participant/informant completion indicators.

EXAMPLE - Feasibility: Before release, request counts at each wave for linked GP-review plus H61/H46 data, counts in each outcome category, deaths before the next wave and missingness by variable. Do not assume a sample size from the public questionnaire.

EXAMPLE - Primary model: Fit a pooled lagged ordinal regression for the four-category outcome with participant-clustered standard errors (Phase 1 exposure -> Phase 3 outcome; Phase 3 exposure -> Phase 4 outcome). Report adjusted odds ratios per additional medicine and by the pre-specified count categories.

EXAMPLE - Secondary analyses: Binary outcomes of any difficulty (responses 2-4) and needing another person's help (response 4); test interaction with living alone and SMMSE only if cell counts support it; compare regular and total active medication counts.

EXAMPLE - Missing data: Keep 'don't know', 'not applicable', 'refused' and 'not asked' distinct in data checking. Do not impute the primary outcome. Consider multiple imputation for covariates only if assumptions and event counts are adequate; otherwise use complete-case analysis with a missingness table.

EXAMPLE - Attrition and death: Describe loss to follow-up and use date of death/vital status to distinguish death from other non-response. Primary analysis concerns observed next-wave outcomes; sensitivity analyses will use inverse-probability weighting if feasible. Cause of death is not needed.

EXAMPLE - Security and disclosure: Only the two named analysts will access row-level data in the institutionally approved environment specified by the final agreement. No re-identification, local copies, unapproved cloud/AI services or row-level outputs. Apply small-cell and rare-combination checks before release.

EXAMPLE - Reproducibility and closeout: Version-control analysis code; return code, a variable derivation log, missing-data decisions and derived-variable metadata to the study; report errors; destroy or close access as required by the final agreement.

EXAMPLE - Timetable: Months 1-2 governance and feasibility; 3-5 data checks/derivations; 6-10 analysis; 11-13 study review and manuscript; 14-16 revisions and public summary; 17-18 deposit of code/metadata and closeout.

EXAMPLE - No linkage to external datasets, no biological samples and no individual-level clinical feedback are proposed.

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
EXAMPLE - Phase 1 - Interview 1	**EXAMPLE** - Front sheet and Section A1: SEX; date of first visit; A1 age at last birthday. Do not supply name, address, postcode or full date of birth.
EXAMPLE - Phase 1 - Interview 1	**EXAMPLE** - B1-B4 General Health: B1 self-rated health; B2 longstanding illness/disability; B4 count of longstanding illnesses. Include item-level missing codes.
EXAMPLE - Phase 1 - Interview 1	**EXAMPLE** - E4/E7 Living Arrangements: lives alone and number of people in household; M2-M4 Education: age left school, full-time higher education and years of higher education.
EXAMPLE - Phase 1 - Interview 1	**EXAMPLE** - Section F SMMSE: study-derived total score plus F1 omission and F30/F31 performance-limitation indicators. Confirm the maintained score definition; do not request free text.
EXAMPLE - Phase 1 - GP Record Review	**EXAMPLE** - Section A MEDICATION: dates A-C; every completed row's Drug, Repeat/Acute/Prescribed by other/Unclear/Omitted status and Drug Code. These are the schedule's available medication fields; dose and strength are not requested.
EXAMPLE - Phase 1 - Interview 1	**EXAMPLE** - Section H medication management: H61 ability to take medication; H63 pill organiser; H64 help; H65 helper; H66 frequency; H67 additional helper(s); H68 adequacy of help.
EXAMPLE - Phase 3 - GP Record Review	**EXAMPLE** - Section B MEDICATION: reference-date fields A-C; each completed row's Drug, prescription source/status code and Drug Code. Retain acute/regular distinction.
EXAMPLE - Phase 3 - Interview 1	**EXAMPLE** - Section H46: H46 ability to take medication; H47 pill organiser; H48 help; H49 helper; H50 frequency; H51 additional helper(s); H52 adequacy. Also B1-B4 and relevant participant/informant and omission indicators.
EXAMPLE - Phase 4 - GP Record Review	**EXAMPLE** - Section B MEDICATION: reference-date fields A-C; each completed row's Drug, prescription source/status code and Drug Code. Retain acute/regular distinction.
EXAMPLE - Phase 4 - Questionnaire	**EXAMPLE** - Section H46: H46 ability to take medication; H47 pill organiser; H48 help; H49 helper; H50 frequency; H51 additional helper(s); H52 adequacy. Also B1-B4 and relevant participant/informant and omission indicators.
EXAMPLE - Phases 1, 3 and 4	**EXAMPLE** - Pseudonymous study identifier, phase/reference date, relevant interview/GP-section completion status and supplied missing-value codes. No direct identifiers.
EXAMPLE - Derived variables, if maintained	**EXAMPLE** - Regular active medication count, acute medication count, 0-4/5-9/10+ categories, time since baseline and maintained SMMSE total. Supply definitions/version; otherwise supply only the specified raw items and the analysts will return derivation code.
EXAMPLE - Mortality/censoring	**EXAMPLE** - Vital status, date of death where permitted, and administrative censor date for distinguishing death from other attrition. Cause of death is not requested.

Requested mortality data from Newcastle 85+ study
Mortality data (derived variable from data of death) Yes / No **EXAMPLE - YES: date of death/vital status only, for attrition and sensitivity analyses.**
Cause of death Yes / No **EXAMPLE - NO: cause of death is not required.**

If Mortality data is requested please supply the following details.

Organisations Data Sharing Framework Contract -Reference ; CON- XXXXXX – XXXXX (Version X.X)
EXAMPLE - Host organisation's current reference to be supplied by its IG/DPO and confirmed with Newcastle University. Do not invent or copy a reference from this example.

Valid NHS Toolkit ODS Code;
EXAMPLE - Current DSPT/ODS evidence, if required by the data-supplier terms, to be supplied by the host IG/DPO. Do not invent a code.

Publication Date; _ _ / _ _ / _ _ _ _ Approved Date; _ _ / _ _ / _ _ _ _
EXAMPLE - Publication/approval dates to be taken from the current institutional assurance record after governance review.

All Newcastle studies should register the project with the University Toolkit please contact igenquiries@ncl.ac.uk

WHAT DURATION DO YOU REQUIRE THE DATA?

Please indicate in months …….....
EXAMPLE - 18 months. This covers approvals, feasibility, data preparation, analysis, study review, manuscript drafting, return of code/metadata and formal closeout.

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:

EXAMPLE - None. No stored blood, biological samples, new assays or laboratory work are requested.

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

EXAMPLE - Academic journal: One paper provisionally titled 'Medication burden and difficulty managing medicines in the Newcastle 85+ Study'. Target journal to be agreed after analysis. Submit an outline to the study by month 10 and a full draft for study review by month 13.

EXAMPLE - Authorship/contribution: Discuss authorship at project start and review contributions against ICMJE criteria. Data access, seniority or governance membership alone will not determine authorship.

Conference(s) – outline proposed presentations

EXAMPLE - Conference: One ageing, medicines or geriatric-medicine conference abstract after the primary analysis. Submit the abstract to the study for approval at least two weeks before the conference deadline and use the approved study acknowledgement/logo.

EXAMPLE - NHS/professional audience: A one-page briefing for medicines-optimisation and older-people's services, subject to study review and disclosure control.

Public dissemination – please outline

EXAMPLE - Public dissemination: A plain-language web summary explaining the question, what was found, limitations and why the findings must not be used to make decisions about individual participants.

EXAMPLE - Study review: No manuscript, abstract, presentation, briefing or public summary will be released before the required Newcastle 85+ Study review and approval.

EXAMPLE - Return to study: Deposit final code, medication-count rules, outcome definitions, missing-data decisions and derived-variable metadata; report discovered data-quality issues promptly.

EXAMPLE - Progress: Provide six-monthly status updates and notify the study before adding users, changing the question, requesting extra variables or extending access.

EXAMPLE - The applicants have read Sections G and H and understand that this worked example does not replace the final approved agreement or current institutional requirements.

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 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
EXAMPLE - Y - Dr Maya Patel would analyse row-level data.

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

Name (BLOCK CAPITALS)
EXAMPLE - DR MAYA PATEL (FICTIONAL)

Date
EXAMPLE - 23 July 2026 (illustrative)

Signed ……..
EXAMPLE - NOT SIGNED - WORKED EXAMPLE ONLY

CO-APPLICANTS

I will be directly undertaking statistical analysis of the raw data Y / N
EXAMPLE - Y - Dr Sam Green would analyse row-level data.

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

Name (BLOCK CAPITALS)
EXAMPLE - DR SAM GREEN (FICTIONAL)

Date
EXAMPLE - 23 July 2026 (illustrative)

Signed ……..
EXAMPLE - NOT SIGNED - WORKED EXAMPLE ONLY

CO-APPLICANTS

I will be directly undertaking statistical analysis of the raw data Y / N
EXAMPLE - Not applicable - no additional raw-data user.

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

Name (BLOCK CAPITALS)
EXAMPLE - Not applicable - no additional raw-data user.

Date
EXAMPLE - Not applicable - no additional raw-data user.

Signed ……..
EXAMPLE - Not applicable - no additional raw-data user.

CO-APPLICANTS

I will be directly undertaking statistical analysis of the raw data Y / N
EXAMPLE - Not applicable - no additional raw-data user.

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

Name (BLOCK CAPITALS)
EXAMPLE - Not applicable - no additional raw-data user.

Date
EXAMPLE - Not applicable - no additional raw-data user.

Signed ……..
EXAMPLE - Not applicable - no additional raw-data user.