Data Access Policy v2

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NICOLA Data Access Committee
Centre for Public Health
Queen's University Belfast
Institute of Clinical Science B
Grosvenor Road Belfast BT12
6BJ

Email: nicola-research@qub.ac.uk

Tel: +44 (0) 2890 978923/ +44 (0) 2890 978926

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Summary

The **N**orthern **I**reland **CO**hort for the **L**ongitudinal study Of **A**geing (NICOLA) is an omnibus panel study with longitudinal follow-up of a stratified random sample of 8,478 men and women aged 50 years and over in Northern Ireland. The study was designed to be complementary to The Irish Longitudinal Study on Ageing (TILDA) that has been in progress in the Republic of Ireland since 2009.

Together, NICOLA and TILDA provide an 'all-Ireland' perspective of the social, behavioural, economic, and environmental aspects of ageing for those living on the island of Ireland. NICOLA has also been designed to complement the English Longitudinal Study of Ageing (ELSA) in order to provide potential for comparisons between the health of older adults in Northern Ireland and England. This places Northern Ireland in the network of existing longitudinal ageing studies across the world. A unique aspect of NICOLA is its specific focus on transition points in ageing and the effects of diet on the ageing process. The study also focuses in on other research areas that are of unique relevance to Northern Ireland, such as experiences of the Troubles. Ethical approval for Wave 1 and Wave 2 of NICOLA was granted from the School of Medicine, Dentistry and Biomedical Sciences Research Ethics Committee, Queen's University Belfast, and Wave 3 from the Health and Social Care Research Ethics Committee A (HSC REC A 24/NI/0078**)** (QUB, Ethics Reference date of approval: Wave 1, 19/09/13; Wave 2, 19/06/17; Wave 3, 23/07/2024).

Baseline data collection (Wave 1) for NICOLA commenced in December 2013, with data collected from 8478 participants via a computer assisted personal interview (CAPI). Data was also collected from a physical health assessment, a self-completion questionnaire and food frequency questionnaire. Wave 2 took place between 2014 and 2022. Wave 3 is underway with data collection due to complete in- 2027.

Interview and self-completion questionnaires data (Wave 1 and Wave 2) includes: socio-economic and sociodemographic factors (e.g. finances, employment, retirement), self-reported measures on mental, physical, and cognitive health, help and helpers, health and social care utilisation, health behaviours, medication use, social connectedness, social participation, personality measures and dietary intake.

Health assessment data (Wave 1) includes: biological samples (blood), multi-omic biomarkers, cardiovascular function, cognitive function, respiratory function, physical activity, visual and retinal function, and anthropometry.

The purpose of this document is to describe in detail the general processes and procedures involved in accessing the NICOLA data resource *(defined as data already collected and the participants themselves for the purposes of new data collection)*. We aim to encourage and facilitate data access with all '*bona fide'* researchers and research organisations as defined by UK Research and Innovation (UKRI) (https://www.ukri.org/) and welcome proposals from researchers, either for collaborative projects or for other forms of data access in order to help advance research knowledge.

By 'bona fide' researcher we mean:
A person with the professional expertise and experience to conduct 'bona fide' research; and a formal relationship with a bona fide research organisation that requires compliance with appropriate research governance and management systems.

By 'bona fide' research organisation we mean:
One that has the capability to lead or participate in high quality, ethical research. It will have a public commitment to adhere to recognised research and information governance good practice. (It is not a requirement that such research is the primary business of that organisation, or that all of the research undertaken by that organisation is published. Nor is it a requirement that the organisation be publicly funded.)

This policy document ultimately aims to help researchers conduct their studies in a transparent and streamlined manner. If your query specifically relates to biological samples, please refer to our separate Sample Access and Preservation Policy Document which provides guidelines regarding the use and preservation of biological samples from NICOLA.

1. Data access procedure: Overview

1.1 The NICOLA data resource

NICOLA is run as a resource to be used by the research community. We encourage and facilitate data sharing by all researchers from all disciplines in order to maximise use of the resource. The process for accessing data is the same for all individuals, regardless of research area, institution, location or funding source, provided the proposed research is in the public interest and is **not** being carried out for direct personal or commercial gain.

1.1.1 Principles of NICOLA data sharing

The NICOLA resource encompasses a wide range of data on multiple exposures which will span a period of many years. As a result of the breadth of data being collected, a wide range of investigators are involved in determining which questions are most relevant and how best to address them. The NICOLA Data Access Committee (DAC) therefore welcomes proposals for collaboration with other investigators, particularly if the proposed research will help to strengthen research capacity. In some cases this may lead to external investigators participating in projects that are already in progress or planned by the NICOLA research group or it may lead to new collaborative projects being undertaken.

As the data owner and custodian of the NICOLA data, the DAC must maintain the integrity of the database for future use and regulate data access to comply with prior conditions agreed with the study funders and local ethics and governance structures. Data security is an integral part of the NICOLA study protocols. The NICOLA Steering Committee (NSC) has decided that data will only be accessed through a 'safe setting' system with appropriate security safeguards in place to secure the confidentiality and integrity of the data. In general, individual level data cannot be released outside the realms of the NICOLA in-house research group with the exception of data that is archived with the UK Data Service, The Gateway of Global Aging, Dementia Platform (DPUK) and UK Longitudinal Linkage Collaboration (UK LLC). Individual level molecular data is also deposited with the European Genome-phenome Archive (EGA) however not linked to phenotype information. These procedures for data access reflect the general principles of:

- Ensuring high quality research is fostered that will advance knowledge and help strengthen research capacity in Northern Ireland
- Protecting participants and acting within the scope of their signed consent
- Ensuring compliance with UK legal and regulatory requirements e.g. the UK Data Protection Act, 1998 (superseded by General Data Protection Regulation [GDPR] from 25th May 2018; the UK Human Tissue Act, 2004.

The vast majority of data are accessible upon request and we do not consider the issue of potential overlap between research projects i.e. no exclusivity, although we favour collaboration to maximise outputs from related projects where possible. The researcher section of the NICOLA website

https://www.qub.ac.uk/sites/NICOLA/Informationforresearchers/ provides an up to date list of publications that have used the resource and also provides the title and a brief summary of all approved applications to use the resource since August 2016. The website also describes the resource and summarises the types of data available and is therefore a useful place to start to give you an idea as to whether NICOLA would be potentially valuable in addressing your research question(s). The data dictionary/codebook, which can also be accessed via the NICOLA website, provides details on variable names and labels for the NICOLA data currently available. It provides information on frequencies and coding details for data relating to the CAPI, self-completion questionnaire, health assessment, dietary questionnaire (food frequency questionnaire) and biological samples. These will be valuable tools when preparing a proposal to access data and/or samples.

Access to the NICOLA data resource must be requested using the formal procedures described in this document and is subject to eligibility, the NICOLA funders' terms and conditions and QUB policies and procedures.

1.1.2 Terms of data access

The following terms must be adhered to in order to access the NICOLA data:

- A Data Access Agreement will be required that includes undertakings to safeguard participants' privacy (although all data provided will be anonymised), confirms NICOLA ownership of the accessed data, requires that any derived variables, new variables and/or results will be incorporated into the NICOLA data repository (at an individual result level), and undertakes to submit noteworthy findings for peer-reviewed publication.
- Access to data will only be permitted for purposes consistent with the aims and ethics of the original study (including the original signed participant consent form).
- Applicants/recipients of the data should be acting as members of a recognised academic institution, research organisation or health organisation or be '*bona fide'* researchers as defined by the UKRI. Requests for data should come from a recognised email domain (e.g. qub.ac.uk) or an appropriate letterhead.
- There is negligible risk that the proposed research will produce information that may allow individual NICOLA participants to be identified.
- The research proposal does not violate (or potentially violate) any of the consent given by the participants.
- The research proposal does not violate (or potentially violate) any of the ethical permission granted to NICOLA from which data or samples are requested.
- The research proposal addresses topics that fall within the acknowledged remit of the NICOLA study, as understood by participants.
- There is no substantive risk that the research proposal might upset or alienate NICOLA participants or reduce their willingness to continue as participants.
- There is no substantive risk that the application might harm individuals in the NICOLA study, or the NICOLA study as a whole.

1.2 Requesting access to data

Details regarding the process of applying for access to NICOLA data are provided in Appendix 2.

Researchers are required to take the following steps in order to access the NICOLA data:

Stage 1) Submission of proposal: An outline of the proposed study should be submitted using the NICOLA research proposal form available within the researcher section of the NICOLA website (https://www.qub.ac.uk/sites/NICOLA/Informationforresearchers/). This proposal should clearly state the purpose of requesting the NICOLA resource. The proposal should include the following: contact details of the Principal Investigator (or supervisor for PhD students), project title, aim / hypothesis, start and the proposed end date of the research, the names of those in the research team, study design (including methods, statistical tests and proposed outcomes), confirmation of ethical approval (if required), data requested, justification of the data requested, proposed method of data analysis, name, affiliation and role of all persons who will be accessing the data. It is the responsibility of the applicant/researcher to ensure that the study for which the NICOLA data is being used has the appropriate research ethics approval, research governance and funding approval (if relevant). It is also the responsibility of the applicant to ensure that details of proposed users of the NICOLA data are detailed within the research proposal form. We ask for a list of variables that are being requested to be listed in an excel form and attached with the proposal application. The variable lists can be accessed through the data dictionaries on the researcher section of the NICOLA website (https://www.qub.ac.uk/sites/NICOLA/Informationforresearchers/). An application checklist is also required and available on the website. For multiple projects individual forms must be submitted; one per project. Any queries regarding eligibility for requesting access to data should be directed to the NICOLA Research Support Team (RST) @ nicola-research@qub.ac.uk prior to submitting the research proposal form.

***Stage 2) Review of proposal*:** Proposals will be reviewed by the NICOLA Data Access Committee (DAC), which meet approximately every other month. The meeting dates are listed on the NICOLA website. Each proposal will be reviewed on an individual basis. Decisions on research proposals will fall into one of the following categories:

(i) approved in principle pending ethics/funding
(ii) approved with no alterations/conditions
(iii) approved with conditions/minor changes required
(iv) approval not granted – requires major changes and/or resubmission required
(v) approval not granted – not supplying data for this study

The researcher will receive an email informing them of the decision. Researchers may also be directed towards local NICOLA subject leads to discuss your proposed research. The Committee will aim to respond in writing within 30 working days of review to inform you of the outcome. The NICOLA DAC reserves the right to impose additional restrictions as appropriate. Any queries relating to proposal submissions should be directed to nicola-research@qub.ac.uk.

***Stage 3) Data Induction**:* The NICOLA RST will act as liaison and assist you, the researcher in accessing the required data. You will be requested to read and sign the appropriate Data Access Agreement and Confidentiality Forms in order to ensure the confidential use of the data. For external researchers: you will be sent a Data Access Agreement to enable remote access (or data transfer, only in exceptional cases agreed by the NICOLA Data Access Committee). This agreement lays down the general terms and conditions of accessing the NICOLA data. The Agreement has to be signed for and on behalf of the recipient institution by a duly authorised person and by the Recipient Investigator. The Agreement is then signed off by The Queen's University Belfast Research Contracts department. For internal QUB researchers: you will be sent a Data Access Terms and Conditions document, which provides details for accessing the data remotely, which you will be asked to read and sign.

Stage 4) Data Access: Following the induction process, the researcher will be given instructions as to how they connect remotely to the secure server to access their bespoke dataset. Remote access or data transfer is only permitted when the study proposal has been approved and the Data Access Agreement (or Data Terms and Conditions document for internal researchers) has been signed.

Only in exceptional circumstances, where data cannot be accessed remotely, an alternative method of securely accessing data may be offered which will involve either i) attending the physical 'safe setting' within the Centre for Public Health, QUB and accessing the required data using a unique username and password or ii) by secure transfer of data to the High Performance Computer based in QUB, where the researcher will access the required data using a unique username and password.

The DAC reserves the right to check that all objectives in the original proposal are completed by cross reference to publications and to make available any additional analyses that were in the initial proposal but that have not been published, via letters to journals and/or on our website, in order to avoid publication bias.

If a researcher is seeking funds for their research from a funding body, the DAC must receive the completed NICOLA research proposal form at least **one month prior** to the submission deadline. It may not be possible to approve those received less than one month before the submission deadline in time for the deadline. It is the responsibility of the researcher to ensure compliance with their funder's terms and conditions with respect to their use of NICOLA data and samples.

1.2.1 Students accessing data

Supervisors are ultimately responsible for their MD/PhD, MPhil and undergraduate students in the same way that PIs are responsible for their researchers. We request that any **proposals for student projects are therefore submitted by the supervisor** rather than the student themselves.

1.2.2 Proposal amendments

Amendments to a proposal (after it has been approved) should be addressed using the NICOLA research proposal amendment form. The proposal amendment form should be submitted to the following email address: nicola-research@qub.ac.uk . A typical amendment could include any of the following:

- Change to the researchers accessing the data, additional researchers being added to the proposal
- Change in institution/affiliation of researchers
- Any additional data required
- Change in funding source
- Change in start / end date
- Extension of research scope (please note: the DAC may request for this to be submitted as a new proposal)

If a researcher wishes to re-use a dataset that has already been provided for a previous project (for example: to study a new aim or for a different student to use the data) then a new proposal will be required. The new proposal should include reference to the original proposal number (reference number provided when a proposal has been approved) and title. All applicants will also be required to complete a new Data Access Agreement (external applicants) or sign terms and conditions of access (internal applicants).

1.2.3 Duration of data access

If a project has been dormant (i.e. if the researcher has not communicated with NICOLA for more than 2 years), then it will be considered as 'closed'. A project can be extended by submitting an amendment to the Data Access Committee. The policy on this does change and older projects in particular should be aware of changing guidelines. This may include having to i) submit a new proposal; ii) ensuring that all co-applicants are known to NICOLA or ensuring that changes in researchers working on the proposal (or no longer working on the project) are clearly communicated to the NICOLA DAC, and iii) generating an updated dataset as mentioned above. If the dataset is more than 2 years old, it will require a 'data refresh' to account for withdrawals of consent, deaths and any other updates to the data in the main data resource.

1.3. Charges for access to existing data and new data collection

There is currently no charge for accessing existing NICOLA data or for new data collection. This is subject to change and will be reviewed on an annual basis.

A charge may apply for more complex proposals. This will be determined at the initial stage of application and the applicant will be informed of any charges arising. Any charges will be applied on a cost recovery basis and will be non-negotiable. The cost will be determined on a project by project basis, depending on the complexity of the request, and will reflect only the true costs to NICOLA of providing the resources requested. Data will not be provided until an invoice has been settled or a purchase order number is received by our finance department.

1.3.1 Submitting student projects

The supervisor of the student is ultimately responsible for the work being undertaken by their student, in the same way that PIs are responsible for their researchers. We request that any proposals for projects that are to be completed by students are therefore submitted by the supervisor rather than the student themselves. Each student project (by this we mean research that will in part or in whole contribute to a student's submitted work regardless of whether it is postgraduate or undergraduate) must be submitted separately, regardless of how similar multiple projects might be and whether or not they fall under the remit of a researcher's existing approved project.

1.4 Management of NICOLA data

The organisational structure of NICOLA is detailed in Appendix 1. The NICOLA data resource is governed specifically by the NICOLA Steering Committee (NSC), Data Access Committee (DAC) and Research Support Team (RST) whose function is detailed below.

1.4.1 NICOLA Steering Committee (NSC)

The NSC provides oversight on all research carried out on study participants and on NICOLA data, and advises on the best ways of optimising scientific potential. The NSC meets approximately five times per year and is chaired by Professor Bernadette McGuinness (NICOLA Principal Investigator). Members of the NSC are made up of the various NICOLA work programme leads. Membership of the NSC is subject to change. Current work programme leads are as follows:

- *Multi-omics: Prof Amy Jayne McKnight (QUB)*
- *Cognition: Prof Bernadette McGuinness (QUB)*
- *Nutrition: Dr Claire McEvoy (QUB)*
- *Environment: Prof Ruth Hunter (QUB)*
- *Vision health: Dr Ruth Hogg (QUB)*
- *NICOLA Clinical Lead: Dr Emma Cunningham (QUB)*
- *NICOLA Operations Lead: Dr Gareth McKay (QUB)*

1.4.2 NICOLA Data Access Committee (DAC)

The DAC are responsible for reviewing and approving proposals for NICOLA data access and for agreeing the Terms of Access. The DAC currently comprises Prof Bernadette McGuiness, Dr Gareth McKay, Dr Amy Jayne McKnight, Mrs Angela Scott, Dr Leeanne O'Hara, Dr Ruth Hogg and Dr Ruth Hunter. The committee provides oversight and guidance with any applications for data access which raise specific issues. Members of this committee are appointed for a fixed term as defined by the Operations Management Group (OMG). Membership of the committee is reviewed periodically.

1.4.3 NICOLA Research Support Team (RST)

The NICOLA Research Support Team (RST) consists of the NICOLA Scientific Officer, the NICOLA Data Manager, and the Centre's Senior IT Technician. Together, they are responsible for overseeing all data governance processes.

Data Manager

The Data Manager ensures compliance with the Data Access Policy and manages data in accordance with the Data Protection Act 1993 (superseded by the General Data Protection Regulation [GDPR] from 25 May 2018). They are responsible for maintaining the quality, integrity, security, and accessibility of the data, and for protecting it against unauthorised access. Key responsibilities include:

- Preventing improper disclosure of data during storage, transmission, receipt, and archiving
- Managing and curating research data generated by NICOLA
- Cleaning incoming data, validating linkages, and performing internal quality and validity checks
- Preparing dataset documentation and handling metadata
- Securely providing access to the NICOLA data resource
- Archiving data and screening output data and syntax files submitted by researchers
- Incorporating newly derived variables into the original dataset
- Uploading approved DAC data files to the researchers' remote 'safe setting'

Scientific Officer

The Scientific Officer acts as a liaison between the Data Access Committee (DAC) and data access applicants. They are also responsible for obtaining data access agreements and data transfer agreements for approved proposals.

Senior IT Technician

The Centre's Senior IT Technician is responsible for setting up remote access 'safe setting' accounts and providing users with instructions for secure use.

2. Types of data and rules governing access

In general, NICOLA does not support applications for new sub-studies involving separate contact with participants. Any specific request for a sub-study to be carried out will be under the remit of the NSC. In addition, the content for Wave 3 of NICOLA has been agreed and therefore the NSC will not be accepting requests for new forms of data collection for Wave 3.

A wide range of data is available through the resource. NICOLA collects data directly through questionnaires and health assessment clinics. Data is also derived from the analysis of biological samples and photographic

or digital images collected during the health assessment. NICOLA will also seek permission to access records on existing statutory databases to provide as comprehensive and robust data linkage as possible.

The data dictionary includes detailed documentation on the data collected via questionnaires and clinics and some other subsets of data and is available for download from the NICOLA website. Any queries relating to NICOLA data can be emailed to the NICOLA RST (nicola-research@qub.ac.uk.). NICOLA Wave 3 data dictionary is in development.

Proposals for access may be refused. Reasons for refusal include the following:

- Lack of availability of data/samples;
- Applicant not being a 'bona fide' researcher as defined by the UKRI;
- The proposed work, in the view of the DAC, risks bringing the study into disrepute;
- The proposed work risks disclosure of identifiable information relating to any individual participant;
- In the view of the DAC, there is a conflict of interest in relation to the proposed project;
- The proposed outputs of the project are outside the scope of the NICOLA ethical approval, funders' terms and conditions or QUB policies and procedures;
- Access to data obtained via linkage to health and administrative records is subject to complying with the terms imposed on NICOLA by the original data owners.

2.1 Questionnaire, clinic and bio-samples

We aim to ensure that data collected from NICOLA participants is made available as soon as possible after data collection and data cleaning is complete. Non-genetic results obtained from bio samples are made available to bona-fide researchers as soon as each batch of assays has been completed. All potential identifiers are removed and disclosure risks are considered such that data may be grouped where appropriate.

2.2 Molecular data

Full details of the type of molecular data from NICOLA will soon be made available on our website. This includes genome wide microarray data (GWAS data), epigenome-wide microarray data (EWAS data), gene expression data (RNA-Seq by next generation sequencing) direct APOE genotyping, and telomere length on a subset of NICOLA participants.

If you require any bespoke genomic data not described above, please contact the NICOLA Scientific Officer *prior* to submitting a proposal to discuss your needs.

2.3 Potentially Identifiable data

Some of the data that NICOLA have collected could be used to readily identify study participants. These include but are not limited to: personal details such as names, addresses (including postcodes), dates of birth; 'free

text' information that could contain identifiers; or other clinical data in a format that could readily identify a participant.

The study team will not link any of these data directly to the data held by freely accessible data repositories such as DPUK, UKDS, or Gateway to Global Ageing; this would breach the agreements we have in place with participants to maintain their confidentiality and may enable a study participant engaged in research to identify themselves.

The following safeguards have been implemented in NICOLA to protect the confidentiality of the data resource, the integrity of the data and the availability of the data:

1. Data will be secured against unauthorised access (confidentiality)
    i. the data can only be accessed via the NICOLA "safe setting" accessed remotely via a secure server (other than in exceptional circumstances and after consultation with NICOLA DAC).
    ii. the NICOLA RST will take all measures possible to ensure that any NICOLA data, located within either the UK Data Service, Dementia Platform UK (DPUK), UK Longitudinal Linkage Collaboration (UK LLC), Gateway to Global Ageing or within the NICOLA database will not be disclosive.
    iii. there will be no access to data which could indirectly disclose identifying material e.g. postcode, employment codes.
    iv. potentially identifiable data such as retinal images, facial images and molecular data will be kept separate from other data and will not be linked directly to the accessible data resource.
2. It is not possible to use devices such as pen drives, USB drives, external hard drives, modem and other electronic modes of data transfer. Data will be safeguarded against unauthorised modification (integrity)
    i. the NICOLA RST reserve the right to check syntax files used by researchers.
    ii. outputs generated from the data will be checked and screened for disclosure control by the Data Manager prior to release to the researcher.
3. Data will only be accessible to authorised researchers (availability)
    i. all researchers requiring access to the data will be required to sign a confidentiality agreement and data access agreement prior to accessing the data.
    ii. data which are deemed by the NICOLA RST to be potentially identifiable (for example retinal images) or identifiable (for example facial images) because of their nature or because the level of aggregation is insufficient to guarantee respondent confidentiality, will not appear in the archived dataset.

2.3.1 Address data

As a rule, the NICOLA team will **not** provide geographical data such as exact address or complete postcode data to researchers due to issues of identifiability. Unidentifiable datasets for specific geographical related

research will only be generated by the RST. Potential identifiers will not leave the “safe setting”. Research studies which specifically require geographically-related data will be reviewed on a project-by-project basis by the RST. Each project proposal will be judged uniquely on its own merits and disclosure risk. Requests for specific geographies may be denied in cases where it is believed participants’ disclosure may be at risk.

2.3.2 Date of birth

Complete dates of birth and other dates (e.g. date of health assessment or questionnaire completion date) are not usually made available; only month and year of birth is released as standard. The age of any data collection sweep is always computed and made available.

2.3.3 Other potentially sensitive data

NICOLA collects a variety of 'clinically interpretable demographic / phenotypic data', including a range of images (such as retinal images and facial images) and information on ethnicity, religion, experiences in the troubles etc. In many cases, these interpretable data may be actually identifying in their raw format. As described in section 2.3, access to such data requires special procedures, analogous to those governing access to molecular data.

2.4 Linked data

NICOLA is in the process of facilitating linkage of data to routinely collected health related records including primary care data, hospital in-patient and out-patient systems, prescribed medications, eye screening records and other screening programme records. These data are held within external organisations including the Honest Broker Service (HBS) which is part of the Health and Social Care (HSC) Business Service Organisation and also the Northern Ireland Cancer Registry (NICR). To facilitate this process, NICOLA obtained separate ethical approval for data linkage. The data linkage process also requires complying with data usage and access agreements with the relevant data owners. The data access conditions differ for each data set we link to, and they are also updated over time. The following is considered when we consider requests to access linkage data:

- **The scope of the research investigation**: linked data are provided solely for the investigation of a single research hypothesis. Requested data should be relevant to the research investigation.
- **Consent status**: access to linked data is frequently subject to participant consent status. Participant are free, at any time, to withdraw from the study, or withdraw their consent from linking to third party data. Once released, it is acceptable that researchers can access the data for the duration of the research being undertaken, regardless of consent change. However, if additional data are requested these will be filtered according to current consent status which may result in a different sample size.
- **Changing access conditions:** data access conditions can (and do) change over time, sometimes with little warning. NICOLA, and third party data users, are required to comply with any new data sharing conditions. This may impact research investigation in unforeseeable ways.

- **Trusted Research Environment (TRE):** Projects requesting access to linked data held by the HSC HBS, will have in the first instance to submit a research proposal to the NICOLA DAC. Upon approval by the NICOLA DAC, the researcher can then apply to the HBS to access the linked, de-identified health related dataset. Please note that the linked data set within the HBS can only be accessed via a safe setting which is accessible via attendance at the Safe Haven in BSO headquarters in Belfast or remotely via the Health Data Research Northern Ireland UK Secure e-Research Platform (HDRNI UK SeRP). This service provides secure project areas (or virtual platforms) where researchers can analyse the data. If researchers also require access to other NICOLA data as part of their approved research than a separate bespoke dataset can be prepared by the NICOLA data management team and transferred to the HBS. The bespoke dataset will then be combined with the relevant HSC data within the safe haven of the HBS. All analysis will take place in the TRE of the HBS and it is not possible for researchers to export anything from the server. Instead, all outputs will come via the NICOLA data management team who will screen them for statistical disclosure risk.
- **Quality of linked data:** NICOLA provide linked data on the understanding that these are routine records being used for a secondary (i.e. research) purpose. NICOLA cannot guarantee the accuracy of the data and have no direct means of verifying the data with the exception of comparing it against self-reported data if relevant. Where possible we will document the data using information provided by the data owner and provide quality information about the linkage process where available.
- **International researchers:** some data access agreement specify that data cannot be sent outside of the UK or the European Economic Area (EEA) – there requirements are beyond our control.
  It should be noted that we are required (as requested by the Information Commissioner's Office) to post a lay summary of all projects using linked health data on the NICOLA website. It must typically remain there for 4 weeks before the project team can be provided with data, in order to give participant the opportunity to inform us if they want to opt out of any specific project.

  We encourage potential users to contact the NICOLA data management team in advance of submitting their project proposal. Further information on the extent and availability of linked data will be detailed on the website in due course, upon ethical approval.

2.5 Secure research servers

The NICOLA technical support team have established a secure server for researchers to access the data remotely. For all NICOLA servers, the protection of our participant's confidentiality and the security of sensitive data is paramount. Users are not permitted and are not able to directly extract any data (either physically or by copying information from the screen). All outputs from analyses must go through the NICOLA data management team or HBS data management team who will conduct disclosure control checks. The extraction of individual level data is unlikely to be permitted (if you have a need for this, please discuss it with the NICOLA Data Manager). It is the responsibility of the user in the first instance to ensure the data are non-disclosive (it is mandatory that all users understand this before access is provided).

3. Data Provision

3.1 Access and use of the 'Safe Setting'

You will be assisted at key stages of your project by a member of the RST who will advise you on the procedure for accessing the data, inducting you into the 'safe setting' system, administering the necessary paperwork (such as confidentiality forms) and ultimately providing you with your working dataset. The NICOLA data will have been cleaned previously by the Data Manager and will therefore be ready for use. The NICOLA data is managed in-house and can only be accessed via a restricted means i.e. a 'safe setting'. All NICOLA data will remain within the 'safe setting' location. Data users will be granted access to the NoMachine Platform accessed by a two factor authentication process. The following computer programs will be available to use: SPSS, Stata, R/R Studio, Microsoft Excel. Please contact the RST if you need to use other specific software to analyse the data. All outputs generated from your data will be screened for statistical disclosure by the Data Manager prior to release from the 'safe setting'. Further details regarding the process for statistical disclosure control screening of data outputs are provided in Appendix 3. If you have electronic materials/files that you wish to bring to the safe setting please discuss with the Data Manager who will assist in transferring these to your NoMachine account.

3.2 Confidentiality form

Protecting the confidentiality of the study participants is a primary concern of NICOLA DAC. This is a particular issue as NICOLA is a regionally-based study. The principal investigator and any member of their team who will directly access the data will be requested to adhere to a number of clauses regarding confidentiality which will be explained during the induction process.

4. Summary of researcher responsibilities

This section summarises the main responsibilities of any researcher wishing to work with the NICOLA resource. The same rules apply to *all* researchers regardless of whether they are a member of NICOLA staff, a new collaborator or a long-term collaborator.

4.1 Project proposals

If the NICOLA DAC notices project overlap when approving projects they may suggest possible collaborations, but the researcher is under no obligation to act on this: this is a suggestion rather than a prerequisite of project approval. Once the project is agreed, the NICOLA study group can publish the title, name(s) and affiliation(s) of the chief investigator(s), the lay summary and the scientific abstract of any research for which access to NICOLA data has been granted, and can add information regarding the status of the project.

4.2 Funding

All projects must be appropriately funded. If seeking external grant funding, please submit your research proposal to the NICOLA DAC at least one month prior to any funder's deadline data. We request that any negotiations with funders MUST be communicated to the NICOLA DAC all times. Funders are reviewed as part of our 'due diligence' checks when reviewing new proposals.

A researcher must send NICOLA DAC a copy of the final submitted grant the award letter and any other relevant documentation when it is received. It is the researcher's responsibility to ensure there is no conflict between their funder's terms and conditions and NICOLA's formal paperwork (Data Access Agreement, User Responsibilities, where applicable).

4.3 Data access

Researchers must adhere to the NICOLA data access policy at all times and must comply with the terms and conditions of data access. Current and future access to the NICOLA resource is at risk if any researcher is found to be breaking these rules. In particular, data must NOT be shared with any other researchers. Serious breaches of data access rules will be prosecuted to the full extent of the civil or criminal law.

4.4 Information Security

Data users must maintain sufficient information security controls to protect the data for unauthorised use or access. In particular, we are looking for a strong institutional commitment to Information Security and a commitment to store and analyse the data in a secure system and staff requirements to maintain confidentiality. These terms (and others) are agreed to be met by signing the DAA. Where we have any concerns around security, we reserve the right to complete a Data Privacy Impact Assessment (DPIA) which may increase the time required to approve a project.

Data users must not share, or provide access to, data with anyone outside of their approved user group (as defined in the project approval). If you need to add additional data users, please complete the project amendment form which is found on the researcher section of the NICOLA website.

4.5 Confidentiality/security breaches

Any breaches of data security must be reported immediately to the Data Manager who will pass the issue on to the NICOLA Operations Management Group (via the Project Manager) for investigation. Examples of data security breaches include (but are not limited to):-

- Any unauthorised person (i.e. who has not signed a data access agreement for the relevant data set) gaining access to the NICOLA 'safe setting';
- Sharing NICOLA data with unauthorised persons;
- Failing to ensure data are sufficiently encrypted during transport;

- Disclosure of 'safe setting' login details to unauthorised persons;
- Failure to comply with any of the statements as detailed in the Data Access Agreement

4.6 New variables and derived variables

At the end of your research, you will be expected to confirm that you no longer require access to the data. If the data was supplied as part of a Data Transfer Agreement then you will be expected to confirm deletion of your supplied dataset. Failure to confirm deletion of the dataset within 4 weeks of the end of your project may risk your future access to the resource.

Any new variables or derived variables (such as newly derived variables coming from secondary analyses) created as part of any research project involving analysis of data must be lodged with the NICOLA RST after an agreed period of time for archiving and/or merging with the main data resource, along with appropriate documentation detailing methods, and how the respective variables were created and associated syntax/code. The derived variables will be made available to all researchers after those who were responsible for creating the derived variables have published their own work or no later than 24 months after completion of the research analysis (whichever falls sooner); authors must acknowledge the researcher responsible for creating the derived variables in all research outputs. If you fail to complete this request and we receive a specific request from another researcher to access that data, we will contact you. We would then expect you to fulfil the request within 4 weeks. Failure to return data as required to the study or failure to provide the necessary details regarding the creation of the new or derived variables at this point may risk your future access to the resource and may result in any further applications to access NICOLA data and/or samples being suspended until the issue is resolved. If considered appropriate, the NICOLA RST may carry out independent checks and/or validation of the data and results to ensure the continued data integrity and reliability of the study findings.

4.7 Intellectual Property

QUB has ownership over the NICOLA resource in its entirety, including any data generated and bio samples collected. As such, any requests to access the data must be made through the NICOLA DAC. Any data generated through an approved project must remain within the resource to encourage ongoing use by the research community.

The Recipient must not share any data or bio samples related to, or derived from, the NICOLA study with any third party, including (but not limited to) collaborator institutions or commercial organisations.

For the avoidance of doubt the resources provided under this Agreement are not provided for commercial use. However it is acknowledged that its use for research purposes may generate new foreground Intellectual Property. Should the Recipient develop any invention or technology (including any related Intellectual Property) from its use of the resources provided under this Agreement ("Study Inventions") then it hereby agrees to:

i) Make QUB aware of such Study Inventions promptly upon their disclosure internally to the technology transfer office or similar unit in the Recipient organisation;

ii) Provide QUB with a summary of the intended exploitation strategy for such Study Inventions;

iii) Grant to QUB an irrevocable, perpetual, world-wide, royalty-free licence to use the Study Inventions for the purposes of academic teaching and academic research, including non-commercial research projects funded by a third party; and

iv) In consideration of QUB's valuable contribution to the Study Inventions by its provision of the resources supplied under this Agreement, that should the Study Inventions generate any revenue from its use, exploitation, or commercialisation, then the Recipient hereby agrees that QUB shall be entitled to participate and share in the revenues arising from the Study Inventions. The Recipient agrees that, prior to the exploitation or licensing of any Study Inventions, the Parties shall meet to negotiate and agree an appropriate revenue share and payment terms for and to QUB.

In the event that the Recipient cannot provide an exploitation strategy for Study Inventions (under Clause 4.5 (ii) above), or does not wish to exploit commercially such Study Inventions, then it hereby grants to QUB the option to take assignment of the Study Inventions which QUB may itself, directly or indirectly and without limitation, seek to exploit commercially. Such assignment agreement shall include an appropriate revenue share back to the Recipient, under such terms as the Parties may agree between them at the time of the assignment.

4.8 Publications and dissemination of research data and results

4.8.1 Peer reviewed papers and other research output

Researchers should submit all noteworthy findings from NICOLA for peer reviewed publication. A copy of all outputs (e.g. full papers, reports, policy documents, PhD theses (NICOLA related chapters), media contributions) must be sent to the NICOLA RST for approval (link to NICOLA Research Support Team) along with a completed papers checklist (available on the NICOLA website) at least 28 days *prior* to journal submission. This includes any research output being placed in the public domain (for example working papers, non-peer reviewed papers). Conference abstracts do not have to be submitted prior to the conference but must be sent to the RST prior to being published in conference proceedings or journals. All papers will be read to check participant confidentiality is protected and to ensure that the paper will not bring the study into disrepute. The NICOLA RST will also be checking for compliance with the NICOLA publication guidelines (as detailed within the NICOLA papers checklist) including correct insertion and accurate description of NICOLA affiliations, ethical approval and acknowledgments. Researchers will be notified in writing regarding the suitability of each paper for publication (in respect of the above criteria) and if any changes are required to the paper. Further details regarding the process used for screening NICOLA publications are provided in Appendix 4. The NICOLA RST reserves the right to require that any paper which could potentially breach the confidentiality of any NICOLA participant(s) be withheld from submission for publication. The NICOLA RST will work with the

authors to overcome such breaches. If a breach of these rules is identified this will result in any further access to the NICOLA resource being denied for all authors/co-authors of the publication.

The NICOLA RST may also provide advice, suggestions and feedback to authors where they feel this may be helpful but their role is not to provide formal peer review. Uptake of any feedback from the NICOLA RST is solely at the discretion of the authors. Under all circumstances the NSC reserves the right to submit letters or papers for publications in response to any paper to explain study procedures or to express a coherent scientific argument. Any appeals against a decision by the NICOLA RST regarding publication will be directed to the NSC.

In some cases, it may be appropriate for members of the NICOLA research team to be invited to be co-authors (and invitees may or may not wish to accept co-authorship). Further details regarding requirements for NICOLA papers along with some accompanying notes are available with the papers checklist. Researchers must inform the NICOLA RST when a paper has been accepted for publication and also send the RST a paper and electronic copy of the final published version to the following email address: nicola-research@qub.ac.uk. A list of publications arising from NICOLA will become available on the study website in due course.

4.8.1.1 Rules on Open Access

4.8.1.1.a Papers

NICOLA fully supports the Wellcome Trust and the RCUK policies on open access. In summary, this means that if a) the specific research presented in a paper is wholly or partly funded by the Wellcome Trust or b) any contributing author is wholly or partly funded by the Wellcome Trust (via salary or fellowship/studentship) any publication must be made open access. It is the senior author's responsibility to ensure that any papers published comply with this policy. It is the responsibility of the grant-holder under part a) above or the individual author(s) under part b) above to cover the costs of making a publication open access. Please see the Wellcome Trust website for more information. If your research is wholly or partly funded by the one of the research councils in the RCUK you are required to make your research paper Open Access and by publishing in a compliant journal. Please see the UKRI website for more information. For papers which include authors/co-authors from QUB, a copy of the accepted paper must also be uploaded (by the QUB author) onto PURE, QUB open access institutional repository within 3 months of journal acceptance.

Please note that secondary analyses of NICOLA data that is not funded by the Wellcome Trust nor has any contributing author supported by the Wellcome Trust does not need to comply with the Wellcome Trust policy; however, NICOLA would encourage this wherever possible.

4.8.1.1.b Journals

A number of journals request that datasets used in a publication are deposited in publicly available resources.

Our data management policy does not permit this beyond the data that will be deposited in the UK Data Service and Dementias Platform UK (DPUK), UK Longitudinal Linkage Collaboration (UK LLC) and the Gateway to Global Ageing.

4.8.1.1.c Grant applications

It has also come to our attention that some funders are also requesting that data be made publicly available. Our data management policy does not permit this beyond the data that will be deposited in the UK Data Service, Dementias Platform UK (DPUK), UK Longitudinal Linkage Collaboration (UK LLC) and the Gateway to Global Ageing.

4.8.2 Theses

We request that an electronic copy of any thesis that use NICOLA data is provided to us as soon as possible after a degree is awarded. Please note that any images within an electronic thesis require copyright approval.

4.8.3 Policy briefings

We encourage researchers to produce policy briefings wherever possible. We ask that these or similar documents are shared with us prior to release. This ensures we are aware of ongoing work and means our communications team can work with you to ensure details are correct and provide advice and support where necessary. Please submit any documents to nicola-research@qub.ac.uk.

4.8.4 Reports and other publications

We request that an electronic copy of any reports and other publications that use NICOLA data is provided to us as soon as possible.

4.8.5 Conference Proceedings

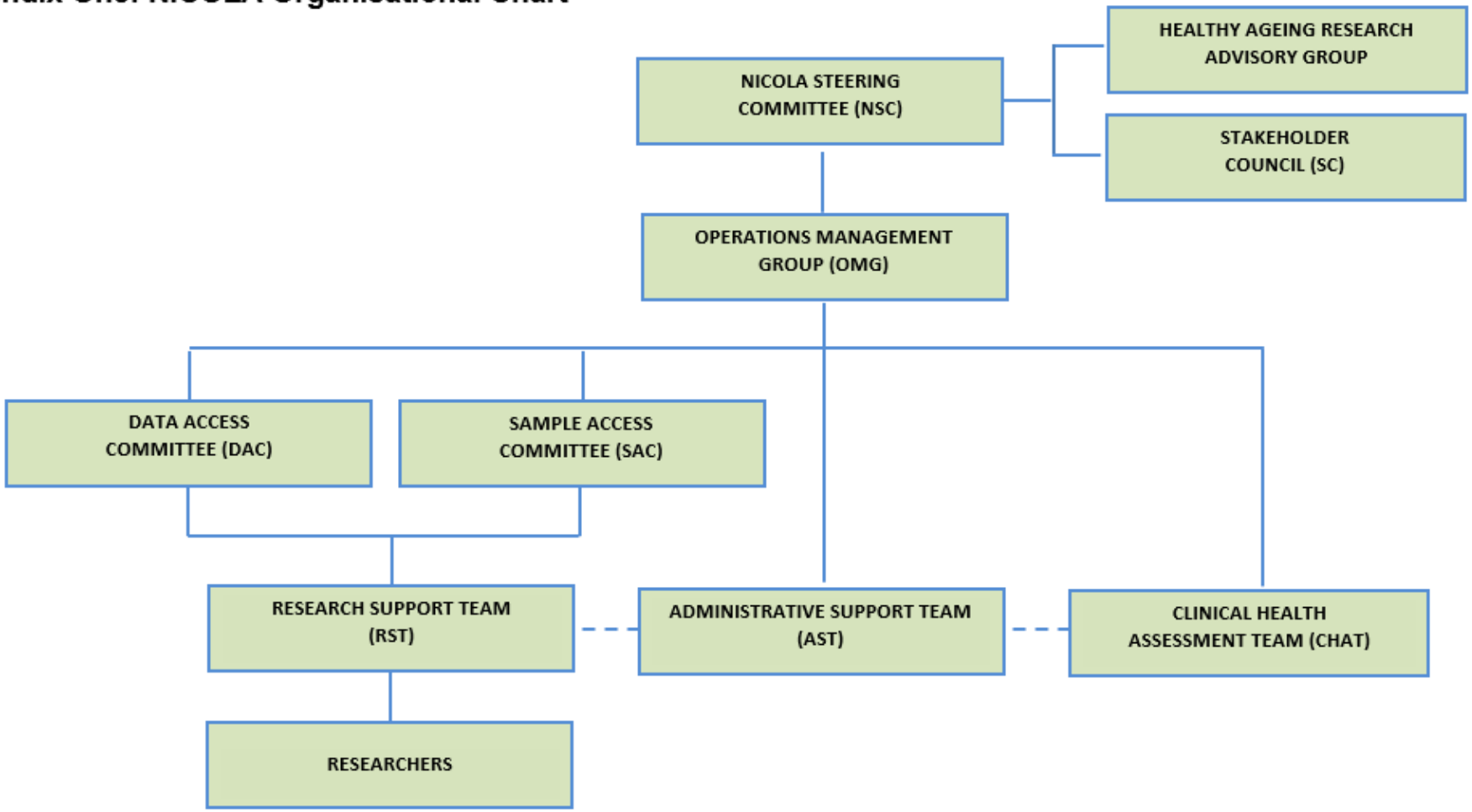
Conference abstracts do not have to be submitted to the NICOLA RST prior to the conference but must be sent to the RST prior to being published in conference proceedings or journals. We also request that any posters or presentations at conferences or other meetings that use data from NICOLA must include an acknowledgment to the study and the participants along with the study logo. Please refer to the researcher section of the website for an example acknowledgment slide that can be used in oral or poster presentations.

4.9 The Media

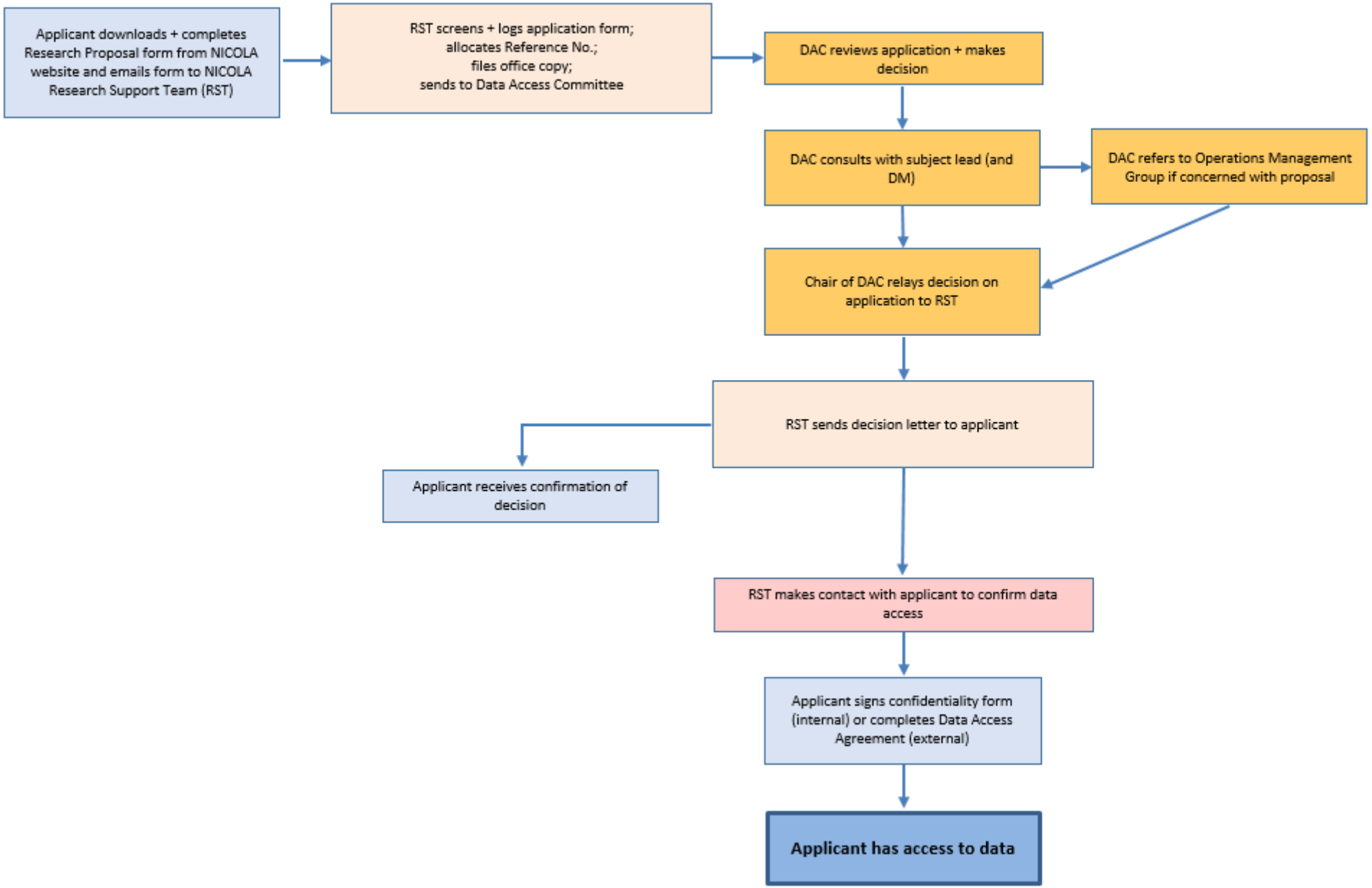
All press releases on research arising from the study must be written in conjunction with NICOLA Operations Management Group (OMG) and under the guidance of QUB communications team. We reserve the right to publish press releases on certain articles and expect the lead author of the article to agree the press release with the public relations team and to be available to deal with media enquiries and interviews. We may also ask authors to prepare a précis of important papers and/or lay summaries to include in reports to funders and future applications for future core funding.

APPENDICIES

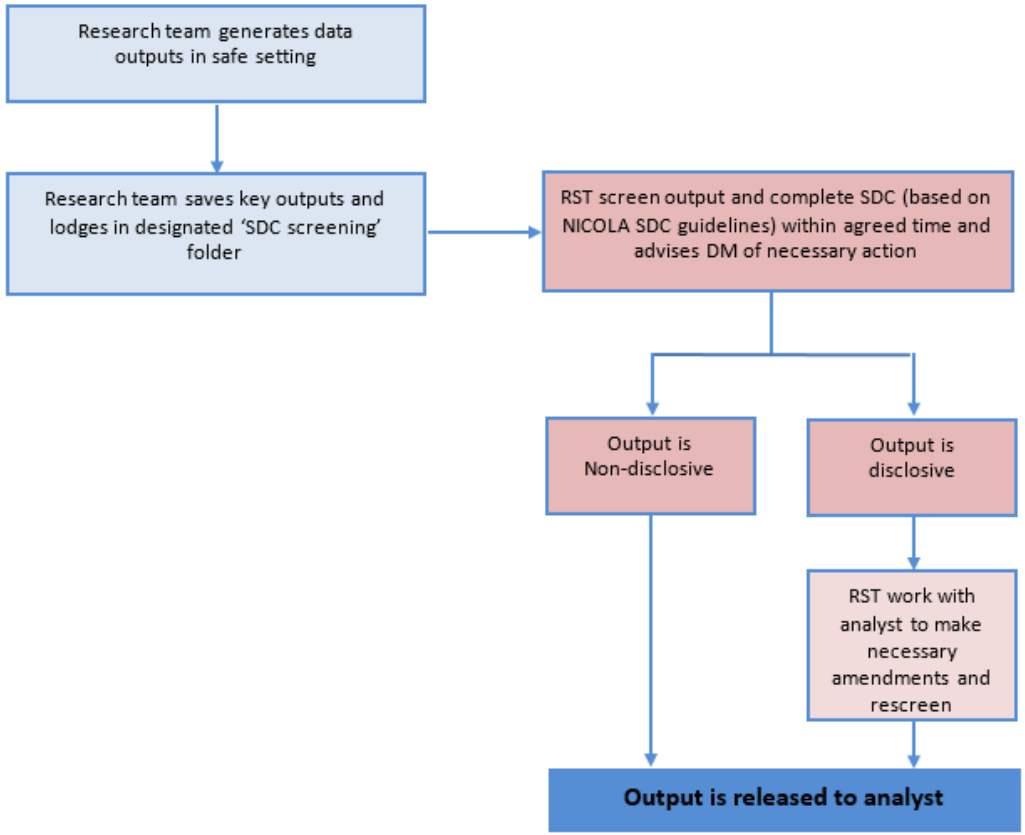
Appendix One: NICOLA Organisational Chart



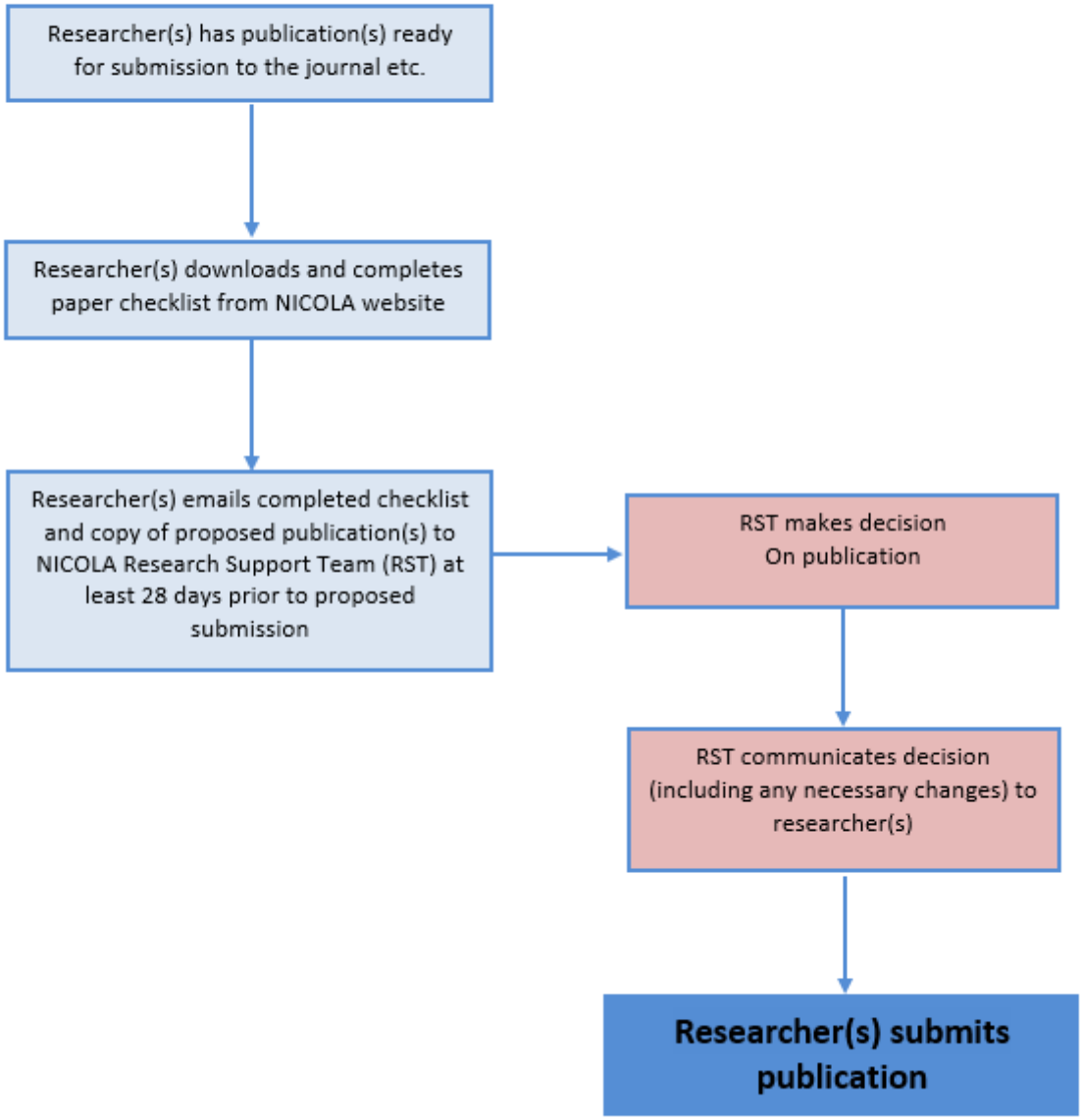
Appendix Two: Flowchart showing the process of applying for access to NICOLA data



Appendix Three: Flowchart showing the process for Statistical Disclosure Control (SDC) screening of NICOLA outputs created in the safe setting



Appendix Four: Flowchart showing the process for the screening of NICOLA publications



Appendix Five: Policy updates

This appendix will detail the changes made to this Data Access policy since the release of v1.0 on 09/10/2018

Version 2, 23/09/2025

**********END OF DOCUMENT **********