Data Access Policy v1

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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 approximately 8,500 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 such as those, mentioned above and including Healthy Ageing in Scotland (HAGIS). 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 of NICOLA was granted from the School of Medicine, Dentistry and Biomedical Sciences Research Ethics Committee, Queen's University Belfast (QUB, Ethics Reference 12.23).

Baseline data collection (Wave 1) for NICOLA commenced in December 2013, with data collected from 8504 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 is underway with data collection due to complete early to mid 2019. Follow-up measurements (Wave 3, Wave 4…) will take place every 2-3 years over a period of at least 10 years.
Interview and self-completion questionnaires data (Wave 1) includes: socio-economic and socio-demographic 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 **not** being carried out for 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 Steering Committee (NSC) 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 NSC 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 NSC has decided that data will only be accessed through an in-house '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. 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, provides copies of the survey materials (e.g., the computer assisted personal interview (CAPI) questionnaire, self-completion questionnaire, dietary questionnaire, and health assessment) 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 is a PDF document which is fully searchable and details information on the NICOLA data that are 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. The data dictionary/codebook will become available on the website in due course.

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. 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. You may also be directed towards local NICOLA subject leads to discuss your proposed research. The Committee will aim to respond in writing within 15 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 in accessing the required data. You will also be invited to meet the Data Manager (by Skype if necessary) in order to receive induction into the procedures and policies relating to NICOLA. At the end of the induction 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.

Stage 4) Data Access: Following the induction process, the applicant can arrange a suitable time and date to attend the NICOLA data office and access the data from a 'safe setting' which will be located within the Centre for Public Health, QUB. Access to this room is only permitted when the study proposal has been approved and the Data Access Agreement and Confidentiality Form have been signed.

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
- Any additional data required
- Change in funding source

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.

1.4 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 Frank Kee (NICOLA Scientific Director). 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:

- *Chronic illness, disability, biomarkers: Prof Frank Kee (QUB)*
- *Finance: Prof Michael Moore (QUB)*
- *Multi-omics: Dr Amy Jayne McKnight (QUB)*
- *Mental Health & Health Services Research: Prof Michael Donnelly (QUB)*
- *Nutrition: Prof Jayne Woodside (QUB)*
- *Physical activity: Prof Mark Tully (Ulster University)*
- *Socio-economic and socio-demographic health, healthcare utilisation: Prof Dermot O'Reilly (QUB)*
- *Social environment: Dr Paula Devine (QUB)*
- *Vision health: Dr Ruth Hogg (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 Frank Kee, Dr Amy Jayne McKnight, Prof Dermot O'Reilly, Dr Paula Devine, Dr Charlotte Neville, Mrs Amanda Coulter and Mrs Angela Scott. 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 RST is led by the Data Manager who is responsible for maintaining the security of data and ensuring confidential access to data. The Data Manager ensures that the rules of the Data Access Policy are adhered to and that data is managed according to the Data Protection Act 1993 (superseded by General Data Protection Regulation [GDPR] from 25th May 2018) and is effectively protected against access by unauthorised individuals. The Data Manager carries the responsibility for the ongoing quality, integrity, security and accessibility of the data and is responsible for preventing the improper disclosure of information when stored, transmitted, received and archived. The Data Manager functions as a liaison between the DAC and the data management staff that carry out the data management tasks. The RST are responsible for managing and curating the research data generated from NICOLA. This includes cleaning NICOLA data received, validating linkages and performing other internal quality and validity checks, preparing documentation about the datasets, handling metadata, securely providing access to the NICOLA data resource, archiving data, screening output data and syntax files generated by researchers and incorporating newly derived variables into the original dataset.

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 2 of NICOLA has been agreed and therefore the NSC will not be accepting requests for new forms of data collection for Wave 2.

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.).

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 biosamples data

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 biosamples 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 Genomics data

Full details of the type of genomic 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), and gene expression data (RNA-Seq by next generation sequencing) on a subset of NICOLA participants.

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

2.3 Potentially identifying data

The following safeguards have been implemented 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)
    a. the data can only be accessed via a "safe setting" located within the NICOLA premises at the Centre for Public Health, QUB (other than in exceptional circumstances and after consultation with the NICOLA DAC).
    b. the RST will take all measures possible to ensure that any NICOLA data, located within either the UK Data Service or within the NICOLA database will not be disclosive.
    c. there will be no access to data which could indirectly disclose identifying material e.g. postcode, employment codes.
    d. potentially identifiable data such as retinal images, facial images and genomic data will be kept separate from other data and will not be linked directly to the accessible data resource.
    e. the use of IT devices to save/transfer data will not be permitted within the "safe setting". It is not possible to use devices such as pen drives, USB drives, external hard drives, modem and other electronic modes of data transfer. There is no internet access available on the PCs that are used within the 'safe setting'.
2. Data will be safeguarded against unauthorised modification (integrity)
    a. the RST reserve the right to check syntax files used by researchers.
    b. 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)
    a. all researchers requiring access to the data will be required to sign a confidentiality agreement and data access agreement prior to accessing the data.
    b. data which are deemed by the 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 year of birth is released as standard. The age of any data collection sweep is always computed and made available. Exact dates of birth will not be given to research collaborators. We recognise that there are times when this information is important for deriving variables (such as season of birth). In these circumstances we will work with the researcher to correctly derive their variable as follows: (a) the researcher will be provided with a limited dataset containing a collaborator ID, pseudo date of birth, and any other essential data; (b) the researcher will use this dataset to write syntax that correctly generates any derived variables; (c) the researcher will send this syntax to the NICOLA RST (in SPSS or Stata format) and (d) the NICOLA RST will run the syntax to create the derived variables.

2.3.3 Other potentially sensitive data

NICOLA collects a variety of 'clinically interpretable 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 genetics data.

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. On approval of your project you will receive an email requesting that you make contact with the NICOLA Data Manager to arrange a suitable date/time for your first visit to the safe setting. The NICOLA data will have been cleaned previously by the NICOLA RST 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 assigned a username and password by which they can log into the allocated desktop computer or a project when the first dataset is provided. The 'safe setting' will be supervised by a member of the RST. This supervisor will assist with login and data access but will not provide statistical, methodological or other support. The following computer programs will be available to use: SPSS, Stata, R/R Studio, Microsoft Excel. All outputs generated from your data will be screened for statistical disclosure by the RST 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 the PC to which you are assigned.

3.2 Confidentiality form

Protecting the confidentiality of the study participants is a primary concern of the NSC. 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 pre-requisite 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 Data access

Researchers must adhere to the NICOLA access policy and confidentiality form at all times. 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.

4.3 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';
- Disclosure of 'safe setting' username/login details to unauthorised persons;
- Failure to comply with any of the statements as detailed in the Data Access Confidentiality Agreement

4.4 New variables and derived variables

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.

4.5 Intellectual Property

QUB has ownership over the NICOLA resource in its entirety, including any data generated and biosamples collected. As such, any requests to access the data must be made through the NICOLA Access Committees. 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 biosamples 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.

4.6 Publications and dissemination of research data and results

4.6.1 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 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 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 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 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 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 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.

4.6.1.1 Rules on Open Access

4.6.1.1.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.

4.6.1.1.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).

4.6.1.1.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.

4.6.2 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.

4.6.3 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.

4.6.4 Conference Proceedings

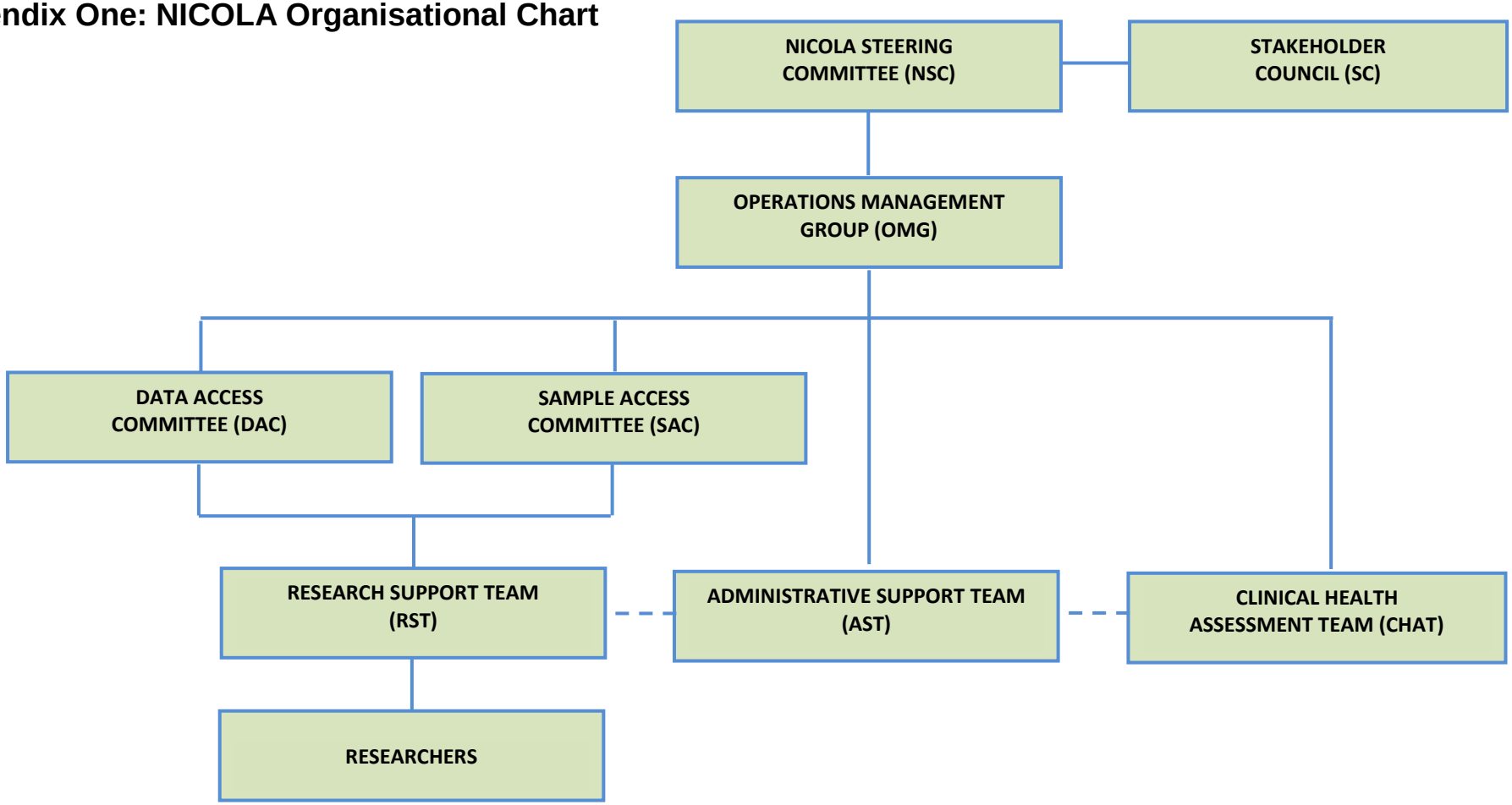
Conference abstracts do not have to be submitted to the RST prior to the conference but must be sent to the RST prior to being published in conference proceedings or journals.

4.7 The Media

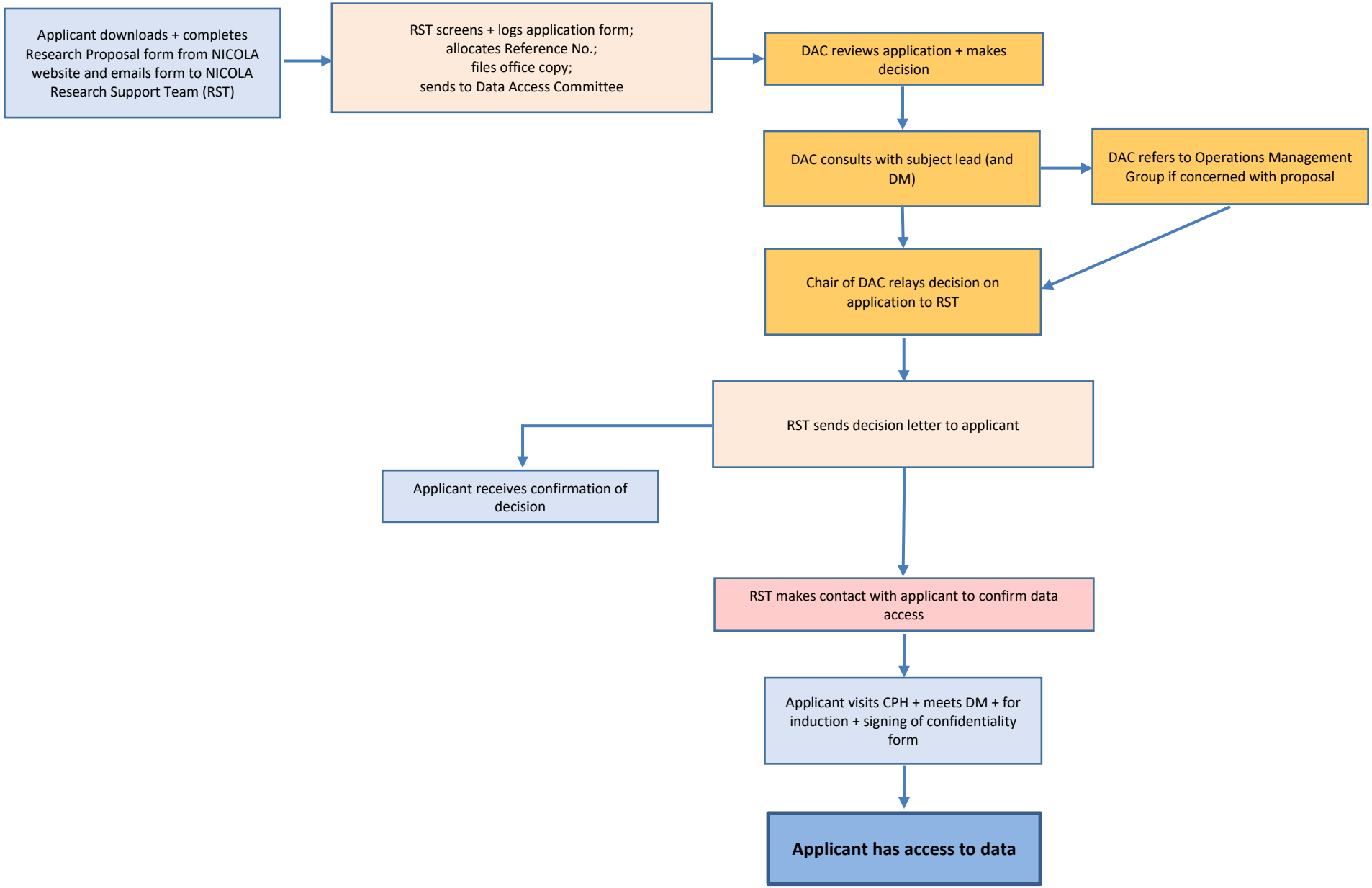
All press releases on research arising from the study must be written in conjunction with NICOLA Operations Management Group and under the guidance of QUB communications team. We reserve the right to publish

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.

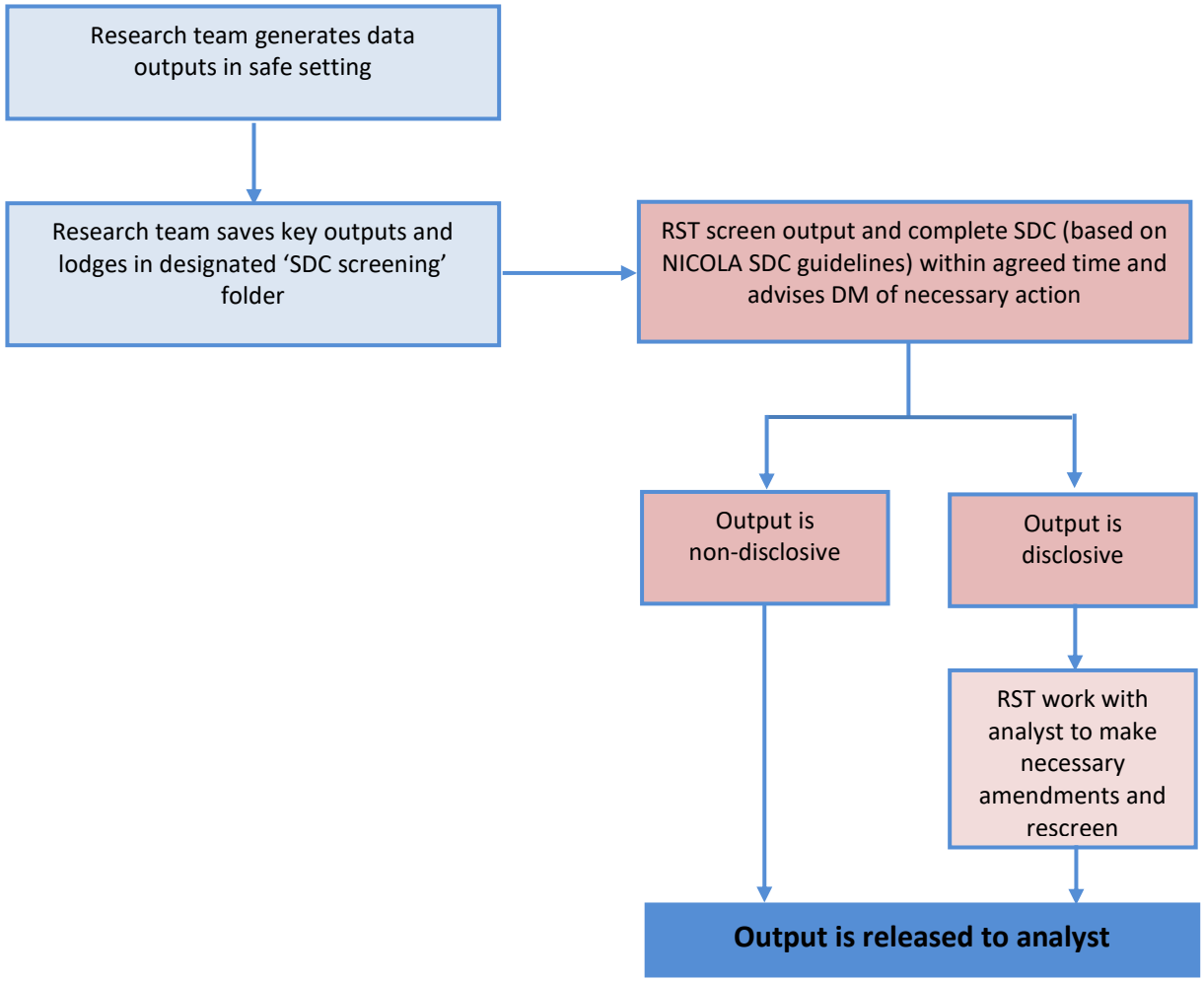
Appendix One: NICOLA Organisational Chart



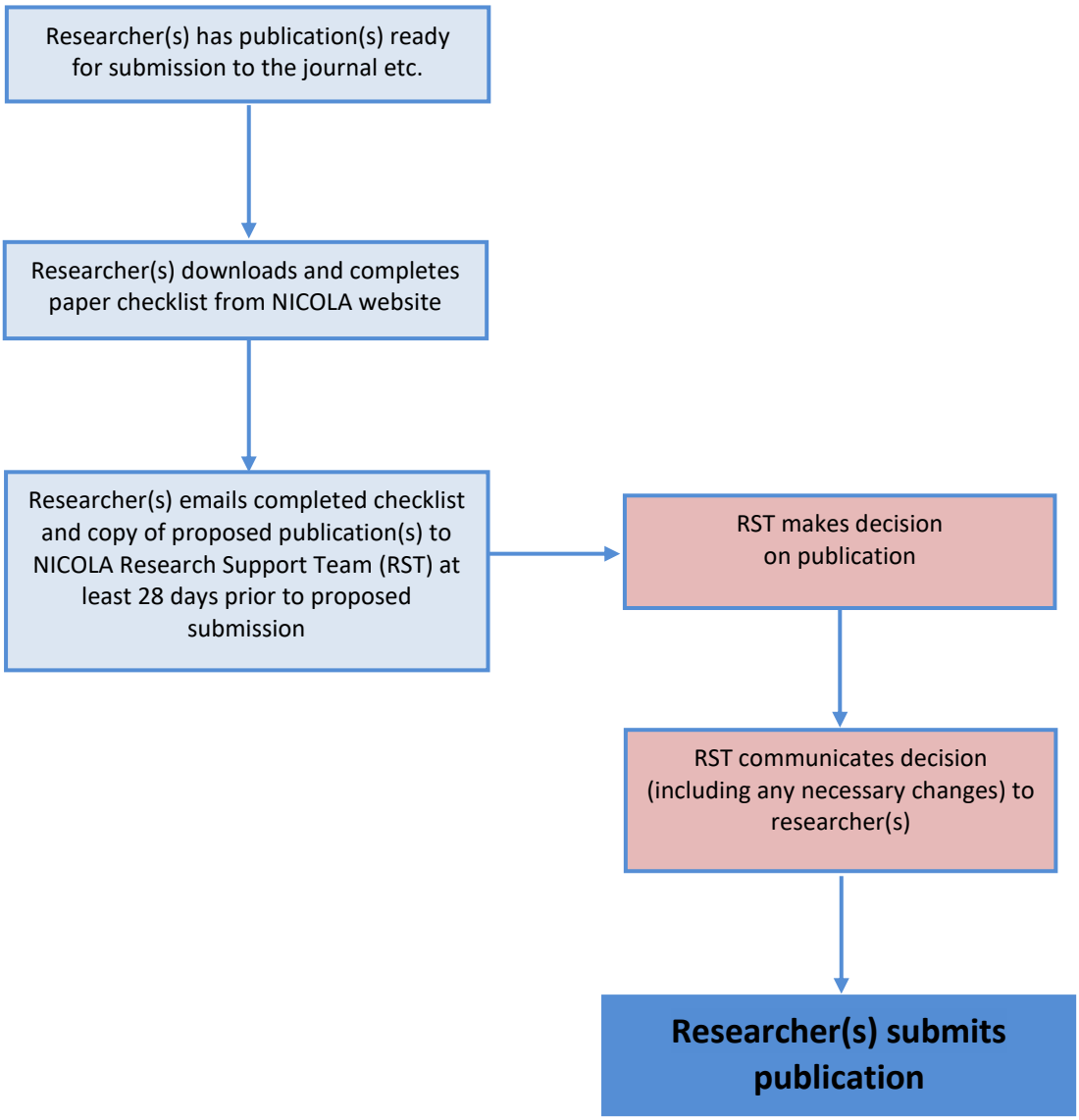
Appendix Two: Flowchart showing the process of applying for access to NICOLA data



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 Sample Access policy since the release of v1.0 on 09/10/2018