

FIVE SAFES FRAMEWORK

What is the Five Safes framework?

The Five Safes framework is a set of established principles which enable studies such as NICOLA to provide safe research access to your data and biological samples e.g. blood, urine. The framework originated from the Office for National Statistics and has become best practice in data protection whilst fulfilling the demands of open science and transparency.

What are the Five Safes?

Safe data: data is treated to protect my confidentiality concerns.

Safe projects: research projects are approved by data owners for the public good.

Safe people: NICOLA staff and approved researchers are trained and authorised to use data safely.

Safe settings: a secure environment prevents unauthorised use of data.

Safe outputs: screened and approved outputs from us and from researchers that are non-disclosive.

Find out more about the 5 Safes by clicking on this link
<https://youtu.be/MIn9T52mwj0>

What does this mean for NICOLA?

By following the Five Safes, NICOLA provides controlled access to sensitive or confidential data to approved researchers, meaning they access and use datasets in a secure and responsible way. The Five Safes work in parallel with ‘our commitment to you’ processes detailed within the NICOLA Privacy Notice.

The following is an explanation of each Safe process:

SAFE DATA

The data is de-identified – names, addresses and any other details that would directly identify you are removed. These details are replaced with a unique research ID number before we make it available to a researcher for analysis. All our data is prepared using disclosure control procedures to ensure anonymity therefore ensuring that an individual cannot be identified in each dataset.

SAFE PROJECTS

If a researcher would like to access any NICOLA data, they have to submit a research proposal to the NICOLA Data Access Committee. In order for access to data to be granted, the researcher needs to demonstrate that their proposal is an appropriate and ethical use of the data, and the purpose is consistent with the aims and ethics of the original study.

SAFE PEOPLE

Only ‘bona fide’ researchers can access your data and they must sign a data user agreement which commits them to maintaining participant confidentiality. By ‘bona fide’ we mean a person with the professional expertise and experience to conduct ‘bona fide’ research and have a formal relationship with a ‘bona fide’ research organisation that requires compliance with appropriate research governance and management systems. The ‘bona fide’ researcher must agree to adhere to current legislation regarding data protection and declare that they understand the controls and policies that must be in place at their Institution in order to keep data safe.

They and their institution (typically the University they are employed by) are required to sign a Data Access Agreement which binds them to these terms and conditions, including the requirement to maintain the confidentiality of study participants.

SAFE SETTINGS

When NICOLA data is shared with researchers, they access it via a secure server using unique login details. As part of the access terms and conditions, researchers are not permitted to transfer or disclose NICOLA data either in

whole or part to any third party, except as permitted in their original research proposal.

Data received with your consent from the NHS or other government departments are held securely in our Data Safe Setting which has secure office space and secure server use. The safe setting can only be accessed by designated NICOLA staff that are specifically trained in processing confidential data and ensure that all data is de-identified prior to research use.

SAFE OUTPUTS

All data made available to approved researchers is de-identified. We only share data that is relevant and appropriate to answer the aims and objectives of the approved research proposal. Data is encrypted and securely transferred to the researcher. Researchers who are submitting research findings in the form of a paper or report for publication are required to submit their output to the NICOLA Research Support Team for approval prior to submitting it for publication. This is to ensure that participant confidentiality is protected and to ensure that the paper will not bring the study into disrepute.