

Guidance for Applicants

The following sections provide additional guidance on specific topics that may be relevant to research applicants.

Although this document is not intended to be used in a legal context, we define terms below in the legal manner simply for the sake of clarity.

- **Researchers.** All persons involved in a Substudy. When used in the singular, it usually means the main applicant or Principal Investigator (PI).
- **Resource:** All data, biological samples and other support provided to Researchers.
- **Data Access Committee (DAC):** the Airwave Study committee empowered to approve or decline access to the Resource.
- **Substudy:** the research project approved by the Data Access Committee.
- **Trusted Research Environment (TRE).** The working environment where your Substudy will be conducted.
- **Derived Data** are data and methods created by the Substudy which evaluate some property, characteristic or trait of individuals or groups of individuals. For example, for a Substudy aiming to compute participants' metabolic age, these ages will be Derived Data. Within this definition we are including computer codes and other methods resulting from or created by a Substudy.

General Conditions of Use

The formal conditions by which Researchers must abide by when using the Resource are defined in contracts of employment and / or the Data Access Agreement of the TRE. Without in any way compromising these agreements, we set out below certain expectations that bear repeating:

1. Do not use the Resource for any purpose other than that which has been approved (i.e. the Substudy). We will be delighted to be asked to approve, for example, exploratory investigations that may lead to further applications and study grants; but please ask first.
2. Do not make datasets derived from the Resource available outside your research team without our prior agreement.
3. If you have access to datasets from us (even anonymised versions), please manage those with the same care that you would your own confidential research data. For example, restrict access to your Substudy team members, store data only on encrypted media, restrict access to backups, and transfer data via secure methods.
4. If the Researcher (the main applicant) relocates to another institution, please tell us as far in advance as is reasonable, especially if you want to continue your Substudy at the new institution. Alternatively, please advise who will be the replacement. We reserve the right to terminate a substudy in these circumstances but will make all reasonable efforts to avoid doing so.
5. At the conclusion of the Substudy, any locally held data (i.e., off-TRE) must be securely erased or archived in a location to be agreed by us.

6. Data Processing Impact Assessments (DPIA): In general, Researchers will not need to conduct their own DPIAs. One exception is cases where the Resource is used to invite Airwave participants to join their own research study, managed separately from Airwave with its own ethics approval. Within Imperial College, the obligation to make a DPIA is fulfilled by completing a [Data Activity Risk-assessment Tool](#) (DART) application. Other institutions will have their own internal processes. The Researcher is responsible for completing their own DART (we'll help where we can) and we may require evidence of a successful application before granting access to the Resource.
7. We try hard to ensure that Airwave datasets are as accurate as possible, and that biological samples have been collected and stored in a manner likely to preserve their integrity. However, we provide no formal guarantees of this and will not be liable to the Researcher or any other third party for losses you or they may suffer that results from errors we or anyone else who has contributed to the Resource may have made.
8. Researchers should not normally find themselves in a position where they have sufficient information to identify a participant. Please tell us if you do find such identifying data within the Resource, even if it's because the person identified is someone about whom you have access to confidential information on. You should never make efforts to identify a member of the cohort, even in principle.
9. Please write to use via the Secretary of the DAC with occasional updates on progress with your Substudy, especially near its completion. It doesn't need to be long and formal; a few hundred words annual will normally suffice.

The remainder of this document addresses topics and expectations that require a little more narrative.

Invitations

Applicants requesting an introduction to Study participants have a wider responsibility when they or their staff are dealing with participants.

When a Substudy is approved which invites our participants to join their study, the invitation will be sent by Imperial College as correspondence from the Airwave PI. It will provide copies of, or pointers to, that study's REC-approved materials relating to the study. Should the participant wish to join the study, they will need to contact the Applicant directly.

You will most likely need to complete your own DPIA when processing data for your own separately managed Substudy.

Responding to Questions

In certain circumstances, a participant may respond to an invitation to join a particular study with questions relating to the reason for the invitation. This may happen, for example, where a Substudy interested in a certain health-condition has invited participants whose existing genotype is believed to confer high susceptibility to the condition. Usually, the invitation will not disclose whether the invite is because they are part of the susceptible group or a control group. However, the invitee may already have reason to be concerned about their own susceptibility, perhaps because of diagnoses occurring to blood relatives.

In these cases, neither the applicant nor the Airwave Study itself should disclose further information regarding the reason that a participant was included as part of the invitation. This applies whether the participant chooses to join the study or not.

Feedback to Individual Participants

The content of any feedback sent by a Substudy shall be stated clearly within its protocol. In general, Researchers are encouraged to make available the outcome of measurements taken in the presence of the participants, such as height, weight, blood pressure, etc. They may also choose to disclose subsequent results, such as laboratory assays or the results of other analyses, if it is reasonably certain that the benefits of disclosure clearly outweigh any possible risks to the participants or their families. This will arise when three conditions are met:

- There is clear indication of an existing health problem.
- Any health problem identified would be amenable to referral to a relevant specialist.
- The participant has indicated beforehand that they wish to be notified if such a problem is identified.

In providing feedback, studies should present sufficient supporting information that the recipient can assess whether their result suggests that they should consult their primary care provider. Often this will be by providing the reference-range for the assay. Other information relating to the assay may also be provided, such as links to reliable resources on the Internet.

We want participants to be informed about the significance of their results, but researchers cannot take the place of primary care providers. We are not aware of all the factors affecting a participant's test results, and so we cannot give specific advice.

Applicants should make clear that participants will not be provided with feedback on assays, re-interpretations of results, or other assessments that may be conducted in the future.

Feedback to Participants as a Whole

We are committed to communicating the outcomes of research to members of the cohort and the wider community. This means providing accurate, dependable, and engaging interpretations of research results that are accessible to a general audience with no specialist scientific knowledge.

The main purpose is to demonstrate to cohort members the value of the contribution they make in remaining active members, and to keep them informed of progress on the Study. We also aim to inform the wider public on the developments in science, given that most research is paid for by public money.

We therefore request that, at the conclusion of each research project, the Researcher writes a summary of their results for a general audience. The Airwave Study team may publish these reports on our website and in other general communications, making modifications to improve clarity by agreement. Reasonable embargo conditions will be respected.

Publications

As part of their substudies we expect applicants to place all research findings in the public domain via publication in peer-reviewed literature.

Pre-publication drafts of papers should be submitted to DAC for comment according to the terms of the Data Access Agreement of the TRE where the research was conducted. For researchers using CSRE – Imperial's local TRE – the DAC should be notified at least four weeks in advance of intended publication.

Researchers should notify DAC if, in their opinion, there is a reasonable chance that their publication is likely to generate publicity amongst the wider public. DAC may then request the applicant provide a summary of their research in a form suitable for consumption by a lay audience via the Study website.

DAC may request the applicant delay submission of a publication for up to three months where, in its opinion, exceptional circumstances apply. Any such delay must be explained to the applicant in writing, and its duration must be no longer than is necessary.

Acknowledgements

Whether or not members of the Airwave research team are co-authors on a paper, publications arising from the use of the Airwave study should acknowledge use of Study data and other resources, including the contribution made by funders. Please contact the secretary of the DAC for specific forms of words to use, which may vary according to the specific datasets used.

The cohort was established by multiple funders, and it is a requirement that their contributions, as well as that of the participants, are acknowledged in any papers published using our data or samples. Please write to the DAC Secretary for the form of words to use.

Safe Outputs

Publications – including materials for internal consumption – and presentations must confirm to a disclosure control policy that ensures there is negligible risk of any member of the cohort being identified in results.

It is the responsibility of the researcher to produce safe outputs. Researchers must use their knowledge from the ONS Safe Researcher Training course (and other relevant training) to make a best endeavours commitment to ensure analytical outputs are anonymous before submitting them for review. Tables highlighting fewer than 10 participants in any aggregated result should normally be suppressed - always when ≤ 5 .

Applicants should respect the consents provided by study participants. Applicants should respect any special conditions made by third parties who have contributed to the Airwave resource and from which the applicant's research has benefitted.

Derived Data

Researchers benefitting from access to the Airwave Resource should expect to make their Derived Data available to the Airwave core team at the conclusion of their Substudy in a format directly linkable to the Study participants. These data will then be available for reuse by the Airwave core team and its community of researchers. Reasonable embargo periods will be respected. Researchers who benefit from Derived Data will acknowledge their source in publications.

It is appreciated that the not all Derived Data are useful outside the context of the substudy within which they are created. We expect Researchers to make these limitations clear in supporting documentation.

Intellectual Property Rights (IPR)

The Airwave Health Monitoring Study supports the generation of new knowledge and innovation through the responsible use of its data and biosamples. Researchers granted access to Airwave resources to conduct a Substudy may develop IPR from their approved research activities. The Study does not claim ownership of downstream IPR created by Researchers, including patents, software, algorithms, or other proprietary outputs.

Researchers are encouraged to pursue IPR protection where appropriate. Researchers should notify the Secretary of the DAC if pursuance of IPR protection may delay publication of research findings.

Whilst a Substudy retains its IPR to any original methods created to compute the Derived Data, should the Derived Data be subsequently used by us or any third party approved by DAC to derive secondary IPR, Researchers agree to waive claims on this secondary IPR. In certain circumstances, legal contracts may be required between the Researcher's institution and Imperial College before a Substudy can commence.

Biological Samples

Researchers using our biological samples should remember that this material may be covered by the Human Tissue Act. Please ensure it is stored in a properly regulated facility and that the DAC is aware of its physical location.

Any material unused at the conclusion of your work should be returned to us unless the remaining quantity of material is insufficient to be useful or has been in some way corrupted.

We may require you to destroy a sample if a participant revokes their consent.