shAIRe
Scientific and Health Data Assets In Respiratory Research

Future Research Consent Information

Introductory:

Many scientific journals now require that data be openly shared and the Canadian Institutes of Health Research (CIHR) and funder of these Lung Health Team Grants "believes that research data collected through the use of public funds should be responsibly and securely managed and be, where ethical, legal and commercial obligations allow, available for reuse by others."
https://science.gc.ca/site/science/en/interagency-research-funding/policies-and-guidelines/research-data-management/tri-agency-research-data-management-policy

To align practice with these policies it is essential that prospective studies include explicit language in consent forms to seek permission for coded data/samples to be shared with others for secondary data analyses.

At the time of writing, there is no universal future research consent language being implemented across our Canadian Research Ethics Boards (REBs) that informs participants about the sharing of their coded data.

Below are 3 different approaches being used at Canadian institutions. We encourage all investigators to include one of these methods in their project to ensure that coded data and samples being collected can be shared and used in future research.

1. The language on 'Future Research' is included in the main consent form. E.g. Clinical Trials Ontario and other Ontario REB's encourage the following paragraph to be inserted into the main consent form.

   Other Future Research
   If de-identified data or samples may be used or shared for future research, include the following:

   Your coded study data and/or coded samples may be used or shared with other researchers (inside and outside of Canada) for future studies. "Coded" means that directly identifying information (such as your name and date of birth) will be replaced by a randomly generated number, which will be applied to the study data and/or samples. This may include storing the coded study data and/or samples in controlled-access databases/biobanks, for which access is limited to researcher(s) who submit a study plan and who sign an agreement to use the coded study data and/or coded samples only for that research.
   Very limited coded study data may also be placed in an open access, publicly accessible database. The goal of sharing is to make more research possible.

However, the code matching your study data and samples with your name and other directly identifying study data will not be shared.
You will not be asked if you agree to take part in future research studies using your study data and/or samples. You or your study doctor will not be told what type of research will be done. You will not be given reports or other information about any research that is done with your study data and/or samples.

b. Another institution has the following clause in their main consent form:

When the study is done, the Sponsor may place your coded study data into a secure database. The coded data may then be used to answer other research questions in the future. Only researchers who have the training and experience to do the research (also known as "qualified researchers") will be allowed to use the data. {State whether or not data will be anonymized (i.e. No way to link back to individual ever) or de-identified (link remains at study site) and state how long it will be stored for future use.}

2. Separate consent form – e.g. **Additional Research Using Coded Data or Samples**. In addition to the main consent form, a 'separate consent' or 'optional research consent form' is provided to the participant. The information about sharing the data and future research using the coded data/samples is explained in a separate consent form and the participant agrees to their coded data/samples being used by signing the consent form. E.g. *I authorize the use, access, and sharing of my Coded Data including my sample(s) and data as described in this document.*

3. Opt In or Opt Out Approach: The language is included in the main consent form where the participant is given the choice.

   E.g. **Use Of Data [And/Or Biospecimens] For Future Research:**

   It is your choice whether or not to let researchers share your data and biospecimens for research in the future. If you say "yes," you can change your mind later, but your data and biospecimens might still be used if they have already been shared.

   My [identifiable / de-identified] research data [and/or specimens] may be kept for use in future research to learn about, prevent or treat other health-related problems.

   ❑ *YES*
   ❑ *NO*

More information:
TCPS2 https://ethics.gc.ca/eng/policy-politique_interpretations_consent-consentement.html#8