SingHealth CIRB: Illuminaté
"To Énlighten... Ethics, above all"
Adapted version for researchers, investigator and study

SingHealth
Defining Tomorrow's Medicine

Issue 13
Jul 2023

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Research Involving De-identified Data

1. Exemption vs IRB Determination >>>

	Exemption	IRB Determination
IRB Review	Submission to IRB is required. IRB approval will be granted if research meets any of the Exemption Categories 1 to 6.	Submission to IRB is not required. They do not meet the definition of human subject research.
Type of study	• Category 1: Research involving Normal Educational Practices and Settings • Category 2: Research involving Anonymous Educational Tests, Surveys, Interviews, or Observation • Category 3: Research involving Identifiable Subjects in Special Circumstances • Category 4: Research involving Collection of Existing Data • Category 5: Public Benefit or Service Programs • Category 6: Taste and Food Evaluation and Consumer Acceptance Studies	• Service Evaluation • Clinical Audit • Surveillance • Outbreak Investigation • Research involving only unidentifiable/ de-identified data or samples *Please refer to the Table for Differentiating Research from Other Research-like Activities for more information.

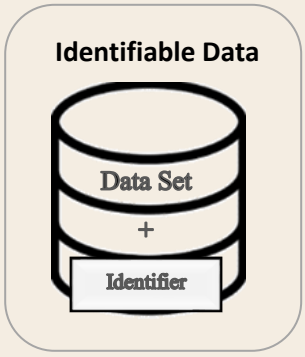
2. Identifiable Data vs De-identified Data >>>

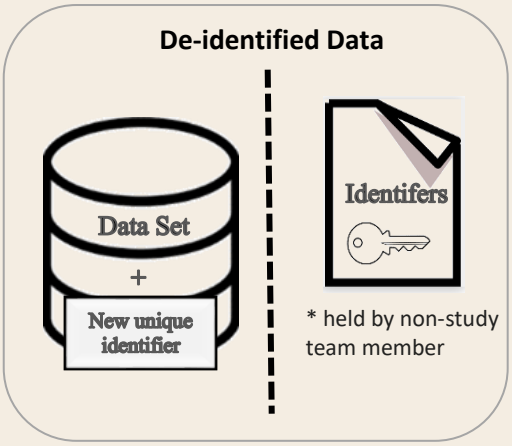
Anonymised Data: Data set where all direct identifiers had been removed, and the data cannot be re-associated with the underlying individuals.

- Not considered as "individually identifiable health information" under the Human Biomedical Research Act (HBRA).

Identifiable Data: Data is considered identifiable if identifers are present.

- Considered as "individually identifiable health information" under the Human Biomedical Research Act (HBRA).
- Research studies involving identifiable data must be submitted to IRB for review.





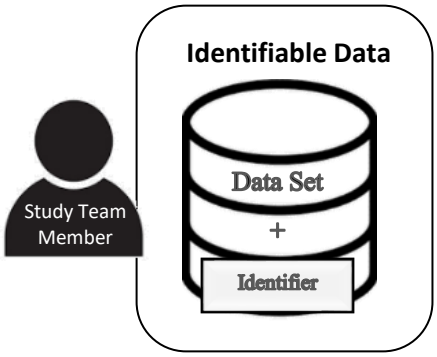
De-identified Data: Data sets where personal identifiers had been extracted and re-association with any of the individuals in the original records would not be allowed.

- De-identified data sets often contain a newly-created unique identifier which separates any identifying characteristics from the original study data sets.
- This identifier should not identify the individual, except through a Record Linkage Data. The record linkage data should be held by an individual who is not in the study team.
- Not considered as "individually identifiable health information" under the Human Biomedical Research Act (HBRA).

3. Research involving the Use of Identifiable Data >>>

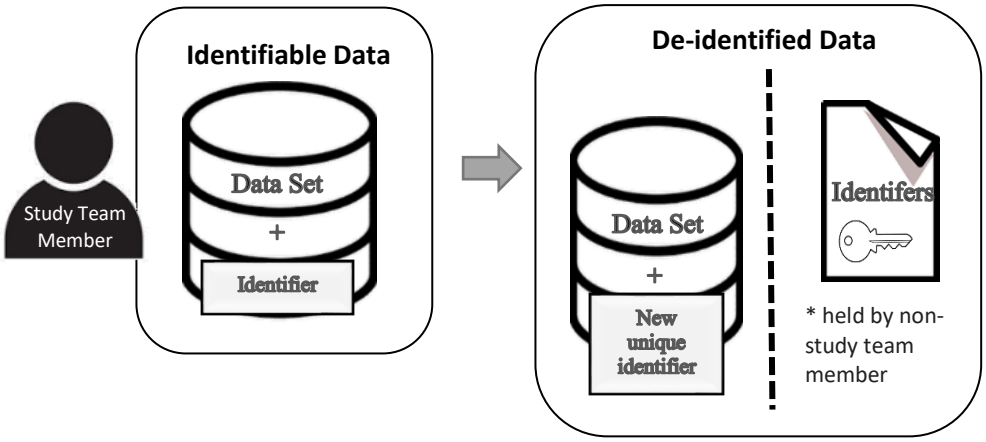
This section will describe the various scenarios where research invoves the use of identifiable data.

Example 1: Study team member extracts identifiable data from source.



Example 2: Study team member extracts identifiable data from source. Data is then de-identified by non-study team member. The research is considered to be using identifiable data if:

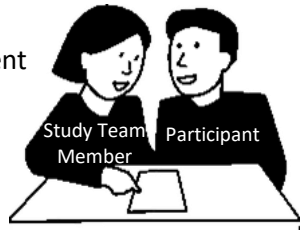
- **Study team member have access to the data source.**
- **Data provider is part of the study team.**



For research study involving the use of identifiable data, the study team must apply for one of the following:

1) Consent to be obtained from participants.

Study team obtained consent from participants for prospective/ retrospective collection of data.



To submit inform consent document for IRB review

- To include HBRA S12 (1) elements, if study is Human Biomedical Research.
- To include HBRA S12 (2) elements, if study is Human Biomedical Research and it involves collection of human tissue.

2) Wavier of consent to be requested if no consent would be obtained from participants.

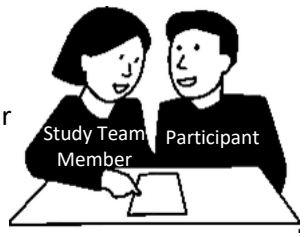
To provide justification for wavier of consent for IRB Review:

- For Human Biomedical Research, study will need to fulfill the criteria stated in HBRA Fifth Schedule.
- For non-Human Biomedical Research, study will need to fulfill the criteira stated in the IRB application form.

IRB reviews and grants the wavier of consent.

3) Consent was obtained from participants previously.

Participants consented previously in other studies, for the use of the collected data, to be used for future research.



Note:

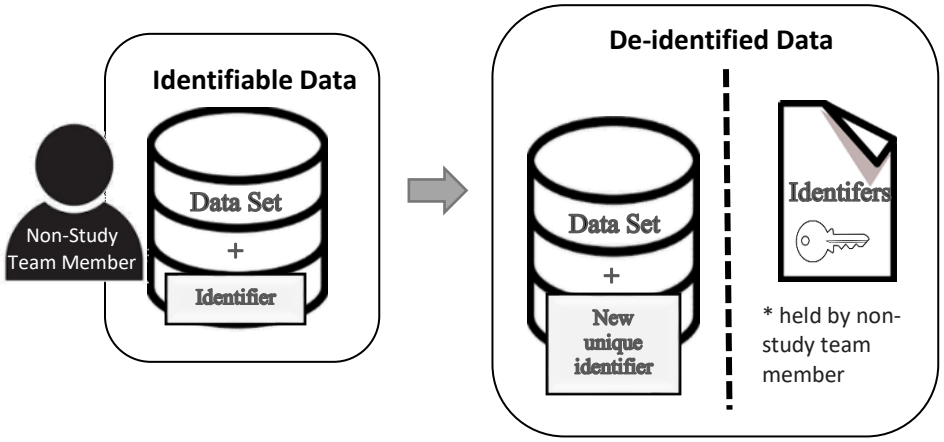
- Participants provided consent to use the data collected from other study.
- Research study should only be using the collected data from other study. It should not collect additional data from source.

To provide the following for IRB review:

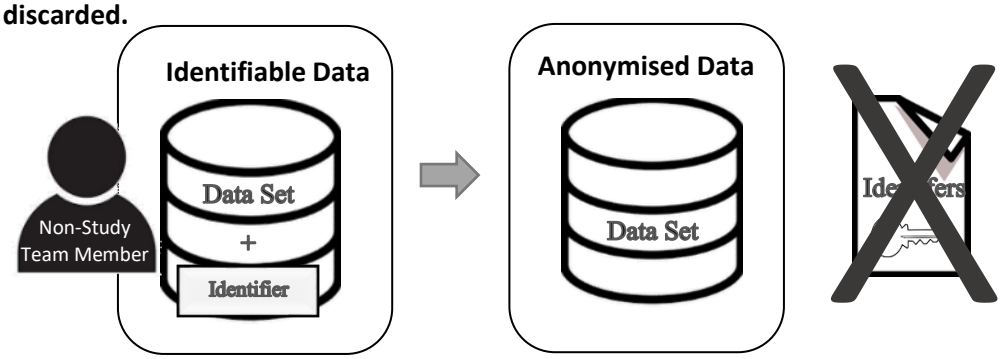
- CIRB Reference and Protocol Title of approved studies.
- Consent document (template) of the approved studies, where consent for the use of data/ samples for future research had been obtained.

4. *Research involving Use of De-identified/Anonymised Data >>>*

Example 3: **Data extracted and de-identified by non-study team member.**



Example 4: **Data extracted by non-study team member, identifiers are removed/ discarded.**



For research study involving the use of de-identified/anonymised data, submission to IRB is not required as it does not meet the definition of human subject research.

- Note: Data set received by study team at the beginning of the study must be de-identified/ anonymized data.
- If submission is submitted for IRB review, IRB determination letter would be issued if further ethical delibration is not required.

Takeaway message...

It is important to understand whether the research involve the use of identifiable data or de-identified data.
For research involving the use of identifiable data, either consent or wavier of consent must be requested.
For research study involving the use of de-identified/anonymised data, submission to IRB is not required as it does not meet the definition of human subject research.

If you have any questions, please contact CIRB at irb@singhealth.com.sg