

Q1. Am I the Data Controller/joint controller of the health research study? *

Yes
↓

No → Consult with your Data Controller

Q2. Am I processing personal data for health research?

My Processing activity is: eg
Collecting, Retaining/Storing, Analysing, Deleting,
Anonymising, Transferring/sharing

Personal data is: eg
Associated with Bio-samples/ Archival tissue, Clinical data,
Demographic data, Health administrative data, other health
categories

Personal data is:
Pseudonymised or de-identified personal data

Or

I am Processing:

Irrevocably anonymised data

You do not need to apply for a consent declaration for
processing anonymised data as it falls outside the scope of
GDPR and the Health Research Regulations

Yes
↓

Q3. Do you have '*explicit consent*' for the purpose of processing the data for your health research?

No
↓

Yes → You should not need to apply for a consent
declaration. All other elements of GDPR and Health
Research Regulations 2018 must be observed

Q4. Do the amendments made to the Health Research Regulations (S.I. 18 of 2021) apply to my study, including the criteria and safeguards? (e.g., deferred consent amendment, low risk retrospective chart review study etc.)

No
↓

Yes → You should not need to apply for a consent
declaration. All other elements of GDPR and Health
Research Regulations 2018 must be observed

Q5. Is it the view of the Data Controller, that the public's interest in carrying out the Health Research significantly outweighs the public interest in seeking explicit consent?

Yes – **Apply**

No → Unless you are processing anonymised data, steps
should be taken to ensure data protection compliance

*It is essential to establish correct Data Controller and Data Processor designation. These terms have the meaning ascribed to them in GDPR

Please consult <https://hrcdc.ie/> for additional guidance and clarifications.

For further queries, please contact: Secretariat@hrcdc.ie