

Q1. Has health research commenced **after** August 8<sup>th</sup>, 2018?\*

Yes ↓

No ▶ Consult with your DPO

Q2. Am I the Data Controller? \*\*

Yes ↓

No ▶ Consult with your Data Controller

Q3. 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**

Bio-samples, Archival tissue, Clinical data, Demographic data,  
Health administrative data, other health categories



**Personal data is:**

Pseudonymised or de-identified personal data

Yes



Or

**I am Processing:**

Irrevocably anonymised data, or pseudonymised data that is  
anonymised in the hands of the Data Controller carrying out the  
health research. Specifically, there is no means or no intention  
to process the data in a manner that could identify the data  
subject



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

Q4. Do you have '**explicit consent**' for the purpose of processing the data for health research?

No



Yes ▶

You do 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 compliance with GDPR  
and the Health Research Regulations

- Provide a letter of approval from relevant REC(s)
- Provide a Data Protection Impact Assessment (DPIA) with DPO feedback
- Outline why obtaining explicit consent, in line with GDPR was not demonstrably feasible.
- Outline the reasons why the public's interest in carrying out the health research significantly outweighs the requirement to seek consent

\*Commencement of research is deemed to be the date REC approval has been granted. [Regulation 4\(1\)](#)

\*\*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](mailto:Secretariat@hrcdc.ie)