# A black background with white text  Description automatically generated

# Data Protection Impact Assessment (DPIA)

## Why do I need to complete a DPIA?

The Irish Health Research Regulations require researchers to assess the data protection implications of health research. In particular, Data Protection legislation requires that a DPIA is undertaken where the processing of personal data poses a high risk to the privacy rights of data subjects.

A DPIA is an assessment of the data protection risks associated with the processing of personal data for your research study. These risks may include the risk of a data breach, loss of data or unauthorised access to data. **Remember that data protection risks may** **not be the same as clinical risks.** **For example, an observational study may pose no clinical risk to the participant but, if the data were shared with a commercial company, there could be privacy risks to an individual.**

A [DPIA Pre-Screening](https://www.maynoothuniversity.ie/data-protection/dpia-data-protection-impact-assessment-0) Questionnaire will help you to identify whether your research could pose high data protection risks. A DPIA is not required where the Pre-Screening Questionnaire determines that data protection risks are not high.

The University’s Data Protection Officer has templates for the [DPIA Pre-Screening](https://www.maynoothuniversity.ie/data-protection/dpia-data-protection-impact-assessment-0) Questionnaire and [DPIA](https://www.maynoothuniversity.ie/data-protection/dpia-data-protection-impact-assessment-0).

Who should carry out the DPIA?

A DPIA must be undertaken by the organisation that is the Data Controller for the research purpose. It is usually the responsibility of the Principal Investigator to carry out the DPIA. The DPIA must be completed during the design phase of your research before you finalise the study protocol/operating instructions and usually before you apply for approval from an ethics committee.

For large or multi-site studies where organisations may be acting as Joint Controllers, a single DPIA should be carried out with each Joint Data Controller being given an opportunity to contribute. This would normally be coordinated by the lead organisation’s Principal Investigator.

### Benefits of completing a DPIA

A DPIA assists you as a researcher to reflect upon and fine tune your research protocol, to identify and mitigate the data protection risks for your research and helps to demonstrate compliance with data protection legislation including the Health Research Regulations.

The DPIA helps you to:

* assess the feasibility of your research protocol and identify potential issues that need to be addressed, including bringing ethical issues to light when considering consent;
* clearly identify what personal data is processed, for what purpose and how the personal data will be managed;
* identify the specific measures required to safeguard your research data;
* identify the roles of any third parties and what data protection agreements may be required with these parties;
* prepare your participant information leaflet and consent form;
* evidence compliance with data protection legislation to the ethics committee;
* complete the data management plan which is, increasingly, a requirement of many funders;
* demonstrate that you have considered any data protection risks arising from your research.

Additional Resources

Data Protection Commission (DPC) [DPIAs](https://www.dataprotection.ie/en/organisations/know-your-obligations/data-protection-impact-assessments)

European Data Protection Board (EDPB) [Guidelines on DPIAs](https://ec.europa.eu/newsroom/article29/items/611236/en)