

<p>2.11.4</p>	<p>Data Protection Impact Assessment ('DPIA')</p> <p>From the previous section it has been determined that the personal data you are collecting requires a Data Protection Impact Assessment ('DPIA').</p> <p>'Data protection by design' means embedding data privacy features and data privacy-enhancing technologies directly into the design of a project at an early stage. This will help to ensure increased protection for individual data privacy throughout the lifecycle of a research project. A key component of data protection by design is the DPIA.</p> <p>The purpose of a DPIA is to assess and demonstrate compliance with data protection legislation.</p> <p>The DPIA also provides evidence that the risks to individuals have been considered and sufficient measures have been taken to protect those individuals.</p> <p>The DPIA assesses the activity to be carried out against all the principles of data protection and determine whether the processing of personal data is both necessary and proportionate or whether changes to the process or additional controls are required.</p> <p>What is a DPIA and why may it be required / beneficial for a Research Project?</p> <p>A DPIA is a process designed to identify risks arising from of the processing of personal data and to manage these risks from as early as possible during the lifecycle of the project. It also demonstrates compliance with the GDPR.</p> <p>It is a mechanism for assessing the impact of new initiatives or new technologies and implementing measures to minimise or reduce associated risks.</p> <p>DPIA completion is frequently required as a key component of research project design.</p> <p>A DPIA is particularly important in instances where the research utilises new technologies or, taking into account the nature, scope, context and type of processing, <u>is likely to result in a high risk to the rights and freedoms of individuals.</u></p> <p>The DPIA process and outcomes will help to improve the design of a research project and enhance communication about data protection risks with relevant stakeholders such as research partners, third parties and participants.</p> <p>Please review the Questions and associated Guidance in the section below carefully.</p>		
	<p>Question</p>	<p>Help Text</p>	<p>Guidance</p>
<p>2.11.4.4</p>	<p><i>Are you capturing explicit consent for the use of your special category data?</i></p>		<p>If you are relying on explicit consent to support your research then you should ensure that the consent meets certain criteria in order to be valid.</p> <p>'Explicit consent' is valid when an individual gives an express statement of their consent to participate in a research study.</p> <p>An explicit consent statement should specifically refer to:</p> <ul style="list-style-type: none"> • the particular data set that is to be processed, • the precise purpose of processing (including any automated decision-making), • any risks and/or implications that might arise for the data subject as a result of the data processing, and

			<ul style="list-style-type: none">• any other relevant and specific information that might influence the decision of a data subject to give or not give their consent. <p>The Health Research Regulations 2018, Regulation 3(1)(e) states that explicit consent is one of the mandatory "suitable and specific measures" that must be in place for the processing of data for health research purposes unless the researcher has been granted a consent declaration under Regulation 5 or under the transitional arrangements (Regulation 6).</p> <p>However...</p> <p>Explicit consent should not be relied upon as the de-facto Article 9 GDPR Condition for processing special categories of personal data. It is a requirement under the Health Research Regulations which should be provided in addition to a separate Article 9 GDPR Condition.</p> <p>The GDPR prohibits data transfers to third countries or international organisations, where there is no adequacy decision (Article 45) or appropriate safeguard (Article 46), except where the data subject has been adequately informed of the risks of consenting to these kinds of transfers because of the lack of, among others, an appropriate safeguard as is mentioned in Article 49 and have given their explicit consent to the transfer anyway.</p> <p>For further information please see https://www.hrb.ie/funding/gdpr-guidance-for-researchers/gdpr-and-health-research/consent/explicit-consent/ or contact dataprotection@tcd.ie.</p>
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