**Guidance for Researchers**

**Health Research - Participant Information Leaflet**

**Please read carefully before drafting your Information Leaflet and Consent Form**

The Trinity College Dublin Data Protection Office has prepared this guidance document to help researchers conducting [health research](https://www.tcd.ie/dataprotection/healthresearch/) in Ireland to draft an information leaflet which complies with national and European data protection law.

In Ireland, health research is governed by the GDPR[[1]](#footnote-2), the Data Protection Acts 1988 -2018 and the Health Research Regulations 2018 (as amended).

If your research is health research on Irish participants, you must obtain explicit consent from the participants for a specific area of research.

**Explicit consent is informed consent which you have a record of.**

## Further Guidance

Consent Form templates and further guidance materials are available from [www.tcd.ie/dataprotection/research/](http://www.tcd.ie/dataprotection/research/).

## Instructions

This template is intended for research studies which are non-interventional.

For any interventional study, including studies which involve the use of residual samples, please contact our office for additional template clauses.

Please bear in mind that this template is intended to address multiple scenarios. Some sections may therefore not apply to your research.

You may also need to include additional sections in your information leaflet, depending on your study.

All advisory text should be deleted before finalising the document.

# Introduction

An information leaflet is an important document for a number of reasons:

* It provides potential participants with all the information they need to fully understand what taking part in a research study means for them (including any risks and benefits);
* It provides potential participants with information on where to get additional information if needed, and outlines how they can withdraw their consent; and
* It ensures that the participant and Trinity as an organisation have a record of the information provided to the participant.

## Process

It is important that participants are given enough time to consider the information leaflet.

After reading the information leaflet, participants should be encouraged to ask any questions that they may have or discuss any worries or concerns regarding the research. Informed consent can only be provided once participants confirm that all of their questions have been answered and the researcher is assured that participants understand the following three points:

1. what the research is about
2. what participation will entail, and
3. any risks that may be involved[[2]](#footnote-3)

Best practice is that participants provide their written consent to participate. The information leaflet and consent form together provide written evidence of informed consent.

You must keep records of the information leaflet and consent form provided to research participants to evidence compliance with data protection law.

## Tips for Drafting an Information Leaflet

Researchers should pay attention to the content, length and appearance of the information leaflet.

1. Content

Keep it simple. We recommend that you draft your information leaflet to a reading age of a 12 year old.

**Use clear and plain English so that the information is easy to read. Do not cut and paste directly from a Research Ethics application or study protocol.**

If you need to use abbreviations or acronyms, spell them out.

Define unavoidable medical language such as ‘inclusion’, ‘exclusion criteria’, ‘controls’ etc.

Be consistent with any terms you use in your documents. For example, if you call something a research study, use this term and not ‘project’ . It can confuse your readers if you use different words for the same thing.

Tailor the information to the individual that is providing the consent. For example, if a parent/guardian of a child is consenting on their behalf, please tailor your information leaflet to that situation.

2. Length

Keep the information concise. Ensure that there is no avoidable repetition. It may be useful to cross-reference to other section(s) to avoid repetition.

Keep sentences to an average of 15 to 20 words.

Break up long paragraphs and complex information. Use bullet points and subheadings.

3. Appearance

The National Adult Literacy Agency has provided useful [plain English writing tips](https://www.nala.ie/plain-english/plain-english-tips/).

Use a clean and clear font (Calibri, Arial, Verdana or Tahoma work well). A good standard size is 12 points.

Use visuals to add to your message.

Use **lower case bold** to stress a point. Do not use block capitals.

**Researchers will need to tailor this template to their own research studies**

**Participant Information Leaflet - Template**

|  |  |
| --- | --- |
| **Study Title** | [INSERT DETAILS]  Guidance - use a simplified version of your study title which is understandable to a lay person. Do not cut and paste from the protocol or ethics submission. Please ensure that the same study title is used on your consent form. |
| **Research Site(s)** | [INSERT DETAILS] |
| **Principal Investigator(s) and Co-Investigator(s) (Study Team)**  (insert names, titles and contact details including Trinity School/Department/Unit) | [INSERT DETAILS] |
| **Study Organiser/ Sponsor**  (If applicable - delete if not required) | [INSERT DETAILS] |
| **Data Controller** | Trinity College Dublin (research data) |
| **Data Protection Officer (Research Data)** | Data Protection Officer  Secretary’s Office  Trinity College Dublin  Dublin 2 |
| **Data Controller (Hospital - medical records)**  (If applicable - delete if not required) | [INSERT DETAILS] |
| **Data Protection Officer (Hospital)**  (If applicable - delete if not required) | [INSERT DETAILS] |

# Introductory Statement

Guidance

You must provide an introductory statement which outlines the purpose of the research and makes it clear that participation is entirely voluntary. It should also outline the process of informed consent.

It should be clear that not taking part will have no negative consequences for the participant; for example, reduced care and treatment by a health practitioner providing care and treatment etc.

* Use clear and accessible language in your introduction.
* Explain that there are different sections to the information leaflet.
* Remind potential participants that they can also ask for assistance or further information at any stage.

**Sample Text**

*We would like to invite you to take part in a research study that is being carried out by [insert study team details] at [insert site details].*

*Before you decide whether or not you wish to take part, please take time to read this information leaflet carefully and discuss it with your family, friends or GP if you wish.*

*If there is anything which is not clear, or if you would like more information, please ask the researchers. . You should understand the benefits and any risks of taking part in this study so that you can make a decision that is right for you.*

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| **Do I have to take part?** |

Guidance

* The answer is ‘No’. It should be clear that taking part is entirely voluntary.
* State clearly that there will be no adverse/negative consequences if they do not take part - e.g. withdrawal will not affect clinical care if they are patients.
* Ensure that the participant knows they can change their mind and opt out later without giving a reason.

**Sample Text**

*No, you don’t have to take part in this study. It is entirely voluntary and up to you. If you decide not to take part, it won’t affect your current or future [insert as appropriate - e.g. medical care or education or employment]. Don’t feel rushed or under pressure to take part or to make a quick decision You can change your mind and opt out at any time even if the study has started.*

*This leaflet has six parts:*

*Part 1 - The Study*

*Part 2 - Data Protection*

*Part 3 - Approval, Organising and Funding*

*Part 4 - Future Research*

*Part 5 - Further Information*

*Part 6 – Next steps*

# Part 1 - The Study

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| **Why have I been invited to take part?** |

Guidance

Explain specifically why the potential participant has been invited to join the study - e.g. because they have a specific condition, they belong to a particular demographic etc, they are a healthy individual etc.

State how many participants you are intending to involve in the study and their characteristics - e.g. healthy volunteers, people with ‘X’ condition etc.

Make sure that people with no medical training or background understand the words you use. Do not assume participants will understand words and terms such as ‘inclusion’, ‘exclusion criteria’ or ‘control’.

**Sample Text**

# *We are interested in understanding experiences of adults aged 18 years and older relating to [insert detail]. You are being invited to participate in this study because you have experience in…. /work in … / you have responded to the flyer / social media advertisement and you have contacted us for additional information etc. We are hoping to have [insert number] participants in the study.*

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| **Why is this study being done?** |

Provide an outline of the purpose of your study in lay language.

**Sample Text**

*We are doing this study to understand…. / Explore the experiences of … / identify the appropriate supports that would improve….*

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| **What does taking part involve?** |

Guidance

**This is the most important section** as itdetails what will be involved in the research study from a participant’s point of view, and in the order, they will experience it.

Consider:

* How long the participant will be involved in the research; how often they will need to attend a research session; and how long visits will be.
* If there are multiple study / site visits, describe them and the location, in the order the participant will experience them.
* Who will the participant be dealing with - will it be the PI or someone else?
* Outline any plans for long-term monitoring/follow-up.

For Interviews, consider:

* How long will the interview last?
* Who will be conducting the interview?
* Will it be a one-to-one interview? Will it be a group interview? (If yes, a confidentiality statement should be included in the Consent Form).
* Will the interview be recorded? If the interview is recorded will the participant receive a transcript, and will they be able to review it if they wish?

**Sample Text - All projects ( Consent Process)**

*If you decide to take part, a member of the research team will discuss this information leaflet and consent form with you. You will be given a copy of your signed consent form and this leaflet to keep.*

**Sample Text -Questionnaire**

*We will ask you to complete a questionnaire.*

*The questionnaire will ask your views/opinions on [insert topic].*

**Sample Text - Interviews**

*We will arrange a time and location ( online if possible) for your one to one interview with ( insert research team member). With your permission, the interviews will be audio recorded. During the interview you will be asked questions about [include as appropriate] e.g. barriers and enablers to your role as/your experiences as a [include as appropriate].*

*We will transcribe the interview .You will have an opportunity to check the transcript.*

**Sample Text - Study involving access to medical records.**

*If you consent,the hospital will also access your medical records to share data relevant to the research study (listed below in part 2)*

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| **What are the possible benefits of taking part?** |

Guidance

Explain what the potential benefits (if any) may be to the participant or if no direct benefit, state the public interests of the research.

Ensure that potential participants are aware that you do not know what the outcome will be, and this is why you are conducting the research.

**Sample Text - General**

*Taking part in this study may not directly benefit you. However, we hope that this research may help us to better understand [INSERT RESEARCH AREA] and may result in new policies/guidelines/tests, drugs or treatment approaches.*

**Sample Text – Longitudinal Study :**

*This is a long-term research project so the benefits of the research may not be seen for several years. By participating, you are helping to advance science and medicine/education for future generations.*

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| **Are there any possible disadvantages or risks from taking part?** |

Guidance

**This paragraph always applies**. Provide a fair and honest evaluation of the possible consequences of any potential risks or disadvantages.

Risks, including any discomforts, must be clearly explained.

* Potential breach of patient confidentiality should be considered as a risk.
* Questionnaires or interview questions that may cause distress: give an indication of kinds of questions you will be asking, and outline would happen if a participant becomes upset.

**Sample Text**

*There are no known risks involved in this study. At all times, the well-being of participants takes priority over research activities.*

*In the event of the interview triggering an emotional event, the interviewer will stop the session and advise you to contact X or will refer you to a* ***named*** *specialist or* ***named*** *counselling service [insert support information or advise if this is being included at the end of the leaflet].*

*Data Breach: we take many measures to ensure the confidentiality of all data and the risk to you of a breach of confidentiality is considered very low [amend as appropriate].*

*If you are harmed in any way, the researchers on this study are covered by insurance through [INSERT DETAIL]. This insurance will cover you in the unlikely event that you injured as a result of taking part in this study.*

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| **What will happen to the results of the study?** |

Guidance

Inform individuals if the information is being used in part fulfilment of a PhD, Masters etc.

Explain where the results/outcome from the research will be reported e.g. medical journals etc. Will the participant be provided with a copy of the report?

Make it clear that participants will not be directly identifiable in any publication.

**Sample Text**

*The results of the study will be reported in medical/scientific/educational journals and disclosed at medical/scientific conferences. No information which reveals your identity will be disclosed.*

*Some quotations from the focus group/interview/questionnaire etc. may be used in reports. However, no information which reveals your identity will be disclosed.*

# Part 2 - Data Protection

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| **What information about me (personal data) will be used for this study** |

Guidance

Describe what information about the participant (personal data) will be used for this study.

Please list all the different categories of personal data/information that you will be collecting and using in the study.

**Sample Text (Interviews)**

*We will use the following information about you (contact details to arrange an interview), the audio recording of your interview and the final transcript.*

**Will medical records be accessed? ( REMOVE IF NOT APPLICABLE)**

**Sample Text**

*Yes. A member of your clinical team will access your medical records to share the following information with us for this study (onset of disease, family history etc).*

*All information will be labelled with a code instead of your name to protect your identity.*

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| **Who will access my personal data?** |

Guidance

* Explain who will have access to the personal data - e.g. PI, research team, co-investigator, any collaborator etc. and for what purpose.
* Explain that any sharing of data with third parties, including any transfers outside of Ireland will comply with the GDPR.

**Sample Text - Access**

*Only the principal researcher (or named/nominated individual) will be able to identify you. They will keep the master file which links your identity to the research data. ( Transcript, health data etc.)*

*The PI will replace your name with a code on all research data.*

**Sample Text – Students**

*The study supervisor(s) may require access to the research data to ensure academic rigour.*

**Sample Text - Sharing (may not apply)**

*If you consent, we may share the research data collected from this study with other researchers within Europe and worldwide. Any sharing will require a legal agreement which complies with the General Data Protection Regulation (GDPR).*

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| **How is the information kept confidential and secure?** |

Guidance

State that you will code the research data and that the key to reidentify participants will be kept confidential and separate to the research data.

Explain that only TCD provided secure systems[[3]](#footnote-4) will be used .

If you are using any other systems to store data, state the data security of such systems.

Confirm that the researchers are bound by a professional code of secrecy (like doctors) or a contractual code of secrecy (that would mean disciplinary action for employees who disclosed or facilitated unauthorised access to the personal data) or some other arrangement that emphasises confidentiality (this may be applicable in the case of medical students).

Confirm that training in data protection law and practice has been provided to those individuals involved in carrying out the research.

Confirm that a Risk Assessment or a Data Protection Impact Assessment were carried out and provide an indication of the level of risk identified.

**Sample Text - General measures**

*Your privacy is important to us. We take many steps to make sure that we protect your confidentiality. We replace your name with a code at the hospital site ( other site) to ensure your confidentiality. Only the hospital site can link the research data back to you.*

*All research data is held securely on [insert detail e.g. TCD Microsoft Office 365 provided platforms[[4]](#footnote-5) or a restricted server in TCD, with restricted access to the research team listed above,*

*The PI and co-investigators are governed by a professional code of ethics to maintain your confidentiality.*

*A data protection impact assessment was carried out and the risk identified was ( low)*

**Sample text on Limitations on Confidentiality ( if applicable)**

*Confidentiality may be breached in circumstances in which the research team has a strong belief or evidence exists that there is a serious risk of harm or danger to you or another individual. Disclosure may also be required as part of a professional code, legal process, or Garda investigation. In such instances, information may be disclosed to significant others or appropriate third parties without permission from you being sought. Where possible, a full explanation will be given to you regarding the necessary procedures and the intended actions that may need to be taken.*

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| **How long will my personal data be needed??** |

Guidance

State the length of time the personal data will be kept, and why it is necessary to keep it for that period of time. If it is not possible to say how long you will keep it, include the criteria that will be used to determine the retention period - e.g. until you have published, for as long as you are funded by the HRB etc. in compliance with HSE policy ( 7 years).

**Sample Text – Data concerning health.**

*The research data ( insert type – for example coded transcripts, data concerning health shared from medical records etc.) will be retained for a period of [insert term the data will be held for] [and provide a rationale for the period] [e.g. legal/regulatory, publication, funder requirement, research best practice etc.]. At that point, the link between you and your personal data will be securely deleted.*

**Sample Text -Audio**

*The audio recording of the interview will be retained until it has been transcribed and the content verified after which it will be securely deleted.*

*The transcript will be retained for 3 years after the project end date in line with TCD’s retention policy.*

**Sample Text – Consent Forms**

*Your consent form will be retained for a period of [insert term] and then securely deleted (include rationale for the term).*

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| **What is the lawful (legal) basis to use my personal data?** |

Guidance

Identify the lawful basis for the processing of data by reference to [Article 6(1)(e)](https://gdpr-info.eu/art-6-gdpr/) and [Article 9(2)(j)](https://gdpr-info.eu/art-9-gdpr/) of the GDPR ( or consent ( Article 6 ( 1) ( a) and 9 ( 2) ( a) if parent/guardian)

**Sample Text - Legal basis**

*We will only use your personal data for this research project, (and if you consent, future research on (define area ) which we hope will improve (Insert public interest case here[[5]](#footnote-6). We will also ask for your consent as a requirement of Irish law ( Health Research Regulations), but we do not rely on this as our legal basis under GDPR.*

**Sample Text – Parent Guardian**

*We ask for your consent for your child to take part in this research project as their parent/guardian. ( Article 6 (1) ( a) and 9 ( 2) ( a) . If your child reaches 18 during the study, we will ask for their consent to continued use of any personal data collected.*

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| **What are my rights under Data Protection law?** |

Guidance

State the **rights** that individuals have regarding their personal data, noting that these rights are not absolute and are subject to certain restrictions.

**Sample Text - Rights under Data Protection law**

*You are entitled to:*

* *object to our use of your personal data or any further use;*
* *request access to your personal data and to receive a copy of it;*
* *request inaccurate personal data be corrected or deleted;*
* *request restriction of our use of your personal data ;*
* *request deletion of your personal data.*

*By law you can exercise the above rights in relation to your personal data, unless the request would make it impossible or very difficult to conduct the research. For example, if the study is about to be published then we may not be able to delete data as it would impact on the results.*

*You can exercise these rights by contacting your study researcher [INSERT CONTACT DETAILS] or the Trinity College Data Protection Officer, Secretary’s Office, Trinity College Dublin, Dublin 2, Ireland. Email: dataprotection@tcd.ie. Website:* [*www.dataprotection.ie*](http://www.dataprotection.ie)

# Part 3 - Approval, Organising and Funding

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| **Has this study been approved by a research ethics committee?** |

Guidance

State the name and contact details of the committee that gave ethical approval to the research and Include the date ethical approval was given

**Sample Text**

*Yes, this study has been approved by [insert name(s) of Hospital(s)] [Joint, if appropriate] Research Ethics Committee (REC). Approval was granted on [INSERT DATE]. An annual report will be provided to the REC and on completion of the study.*

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| **Who is organising and funding this study?** |

Guidance

Specify any person/collaborator who provides funding for, or otherwise supports, the study ( whether or not they will access the data).

Specify if the study is in part fulfilment of an academic qualification.

**Sample Text - Examples (Non-exhaustive)**

*This study is being undertaken by [insert name] as part of their academic studies / Masters / Ph.D. studies. It is self-funded.*

Or

*This study is being completed as part of a collaboration between [insert] and [insert]. Funding for this collaboration is being provided by [insert detail].*

Or

*This study is being funded by [insert detail]. They will be provided with an anonymous report. They will not access any personal data.*

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| **Will I be paid for taking part?** |

Guidance

State the costs of participation and any reimbursements or compensation to be provided (if any)

**Sample Text**

*No, we are not paying you to take part in the study.*

Or

*No, we are not paying you to take part. However, you will be reimbursed for travel expenses if you need to make any visits that you would not normally have made as part of your routine clinical care.*

Or

*Yes, we are paying you to take part. Detail if a ‘good will’ / token gesture is being given to participants*

# Part 4 - Future Research ( MAY NOT APPLY AND REMOVE IF IT DOES NOT APPLY)

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| **Will my personal data be used in future studies?** |

Guidance

In relation to the use of participant personal data for future studies, the DPO’s office interprets the Health Research Regulations as allowing researchers to seek participant consent to use their personal data for future health research purposes providing that consent is for a specified area ( for example dementia as this was your original study ), or more generally in that area ( for example infectious diseases v COVID) or a related area ( for example MS and ALS) .In all cases, you must specify the area or consent to future use cannot be considered to be valid.

For any future use of data by third parties, please consult the RDPO, as consent may not be in place for this, and there may be other considerations. ( researchdpo@tcd.ie)

Drafting Guidance

Make it clear that consent to future use of data is voluntary, and the participant can withdraw their consent to future research at any time.

Make it clear that this research will only take place if it has research ethics approval or subject to an approval process which includes ethical approval, legal agreement etc.

**Sample Text**

*With your consent we would like to keep data collected from you for this study for future research of ( same area of research) , for example we might revisit [insert detail] .*

Or

*With your consent we would like to keep data collected from you for this study for ( insert timeframe) for future research in the area of [general area of research]. We hope this will help researchers continue to examine and further understand the [insert study field] in the years to come.*

Or

*With your consent, we would like to share the data collected in this study with academic collaborators in Europe, and we may also wish to share with pharma companies who may manufacture and develop new medicines, tests and treatments in a highly regulated environment.*

*Academic researchers can make discoveries which identify the possibility of new medicines and treatments. Due to high-costs and the expertise involved, pharma companies must build on these discoveries to deliver these new medicines and treatments for patients. No identifiable data will be shared with companies.*

*To access any data held by the research team, researchers must get ethical approval from an independent research ethics committee and sign and adhere to a legal contract outlining how the data are to be used and kept confidential.*

*You can withdraw your consent to future use at any stage.*

# Part 5 - Further Information

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| **What happens if I change my mind?** |

Guidance

Explain that participation is voluntary, and participants may change their minds at any stage, and they do not have to give a reason .

State that withdrawal from the study will not affect the care that participants receive from any relevant service - e.g. for patients, from the HSE. If there are limitations on withdrawal from the study, this must be stated.

Ensure that participants know how to withdraw from the study.

**Sample Text**

*Your participation in this study is voluntary and you can change your mind even if the study has started.*

*You do not have to give a reason for changing your mind. This will not affect your [insert as appropriate e.g. medical care /education/treatment/education/employment] in any way.*

*If you would like to withdraw from the study, please contact [insert name and email/phone number] who can organise this for you.*

*We will discuss with if you are happy for us to continue to use information about you (personal data) which has already been collected. If you do not consent to your personal data being retained for this study, we will delete any information that could identify you.*

*Please note that we will not be able to remove personal data which has been shared or pooled for use in publication before your request for deletion.*

*We will not contact you again.*

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| **Who should I contact for information or concerns?** |

Guidance

# State who the participant should contact for additional information on the study, or if they have any concerns in relation to the study.

**Sample Text**

*If you have any concerns or questions, you can contact:*

*Principal Investigator: [insert name and email address]*

*If you have any questions in relation to your rights under data protection law, you can contact the Data Protection Officer, Trinity College Dublin: Data Protection Officer, Secretary’s Office, Trinity College Dublin, Dublin 2, Ireland. Email: dataprotection@tcd.ie. Website:* [*www.dataprotection.ie*](http://www.dataprotection.ie) *( remove if site DPO is contact point).*

*Under GDPR, if you are not satisfied with how your data is being processed, you have the right to raise a concern with the Office of the Data Protection Commission, 21 Fitzwilliam Square South, Dublin 2, Ireland. Website:* [*www.dataprotection.ie*](http://www.dataprotection.ie)

# Part 6 - Next Steps

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| **Will I be contacted again?** |

Guidance

* Explain if you will be contacting the participant again
* State how contact will be made e.g. via the gatekeeper/directly to the individual
* Ensure that the participant knows if they will be contacted again

**Sample Text**

*We will contact you in seven (7) days’ time, to give you time to consider your participation in the study. If we do not hear back from you, we will contact you on one further occasion and if we do not hear from you after that, we will not contact you again.*

Or

*If you would like to take part in this study, we will ask you to contact [insert contact details] and you will be asked to sign the Consent Form on the next page.*

**Thanks**

*Thank you for taking the time to read this Participant Information Leaflet.*

*You will be given a copy of this Leaflet and the signed Consent Form to keep. Please retain these in case they are needed for future reference.*

1. . Regulation (EU) 2016/679 (General Data Protection Regulation), the Data Protection Acts 1988 to 2018, and [↑](#footnote-ref-2)
2. . Extract from the Statement by the EU Commission (Ethics and Data Protection, November 2018). [↑](#footnote-ref-3)
3. TCD-provided software e.g. MS Teams or ZOOM (using a Faculty-provided ZOOM account), Qualtrics or other TCD Licenced software - this should be stated. [↑](#footnote-ref-4)
4. Note: If you are using other software/systems, you should include if due diligence has been conducted and whether there is a contract in place. [↑](#footnote-ref-5)
5. (Article 6(1)(e) and 9(2)(j) of the GDPR. [↑](#footnote-ref-6)