**DATA PROTECTION Checklist**

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| **Protocol #** |  |
| **Protocol Title** |  |
| **Protocol Version No. and Date** |  |
| **Sponsor-Investigator / Project Lead Name** |  |
| **Sponsor** *(if applicable)* |  |
| **Trial Coordinator / Project Manager** |  |

**INSTRUCTIONS ON HOW TO USE THIS CHECKLIST:**

**Question 1**: Points contained in Question 1 should be considered when drafting Participant Information and Consent Forms (PICFs) for participating/collaborating sites based within the EU.

**Questions 2 to 9**: Questions 2 through to 9 should be considered when completing the sections in the ethics application forms referring to the Managing and Handling of Personal and other Research Data, as well as, when developing your concise Data Management Plan (DMP) for your research/project.

**Should you require any further assistance, please feel free to contact:**

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| **Melbourne Children’s Trial Centre (MCTC)** [MCTC@mcri.edu.au](mailto:MCTC@mcri.edu.au) | **Clinical Epidemiological & Biostatistics Unit (CEBU) for Data Management related enquiries:** [luke.stevens@mcri.edu.au](mailto:luke.stevens@mcri.edu.au) |
| **MCRI Data Protection Officer** [legal@mcri.edu.au](mailto:legal@mcri.edu.au) |  |

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| **TRANSPARENCY** | | **Yes** | **No** | **NA** | **If No, Specify Action taken or comment** |
| 1. **Does the Information Sheet (i.e. Patient Information Sheet & Consent Form) to be provided to participants include:** | | | | | |
| **1.1** | The purposes for which their [personal data](https://gdpr-info.eu/art-4-gdpr/) / [special category](https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/lawful-basis-for-processing/special-category-data/#:~:text=Special%20category%20data%20is%20personal,not%20have%20to%20be%20linked.) data will be processed? |  |  |  |  |
| **1.2** | The legal basis for the processing of their personal data/special category data?  *NB. For the majority of MCRI research, it is recommended that `consent’ is the appropriate legal basis.* |  |  |  |  |
| **1.3** | State that their personal data/special category data will be transferred internationally into an Australian maintained and hosted database?  *NB: Example text is provided below for inclusion in Section 14: What will happen to information and data about you/your child/baby?*  *In this study, your coded data must also be sent to countries outside the EU because this study is conducted in collaboration with the Murdoch Children’s Research Centre in Melbourne Australia. In Australia, EU legislation for the protection of your personal data does not apply. However, your privacy will be protected* *under the Australian Privacy Act and you will have enforceable rights under this law.*  *[Optional text if your project intends to use the Florence eTMF/eISF software, is provided as follows]: The study team also uses a third party software platform for the management of study-related documents. In doing so, some limited personal information such as your child/babies’ name, initials and date of birth may be securely stored off site within this platform. This platform is hosted in Europe and has been carefully chosen by the Murdoch Children’s Research Institute so that your personal information will be stored securely and processed only in accordance with applicable data protection and privacy laws and regulations including the Australian Privacy Act and the European General Data Protection Regulation (GDPR). The vendor of the platform is required to comply with strict confidentiality obligations and is not permitted to share your personal information with any third parties whatsoever.* |  |  |  |  |
| **1.4** | The people or organisations that their personal data/special category data will be shared with, including any onward transfers to third-parties, if applicable? |  |  |  |  |
| **1.5** | When their personal data/special category data will be erased/deleted?  *NB. The GDPR requires that data is not kept as identifiable personal data for longer than is necessary in relation to the purposes for which it is processed. However, personal data processed solely for research purposes may be stored for longer periods, provided there are appropriate safeguards, such as pseudonymisation. This longer period is not defined in the GDPR. You will also need to comply with the MCRI’s Research Data Management Policy which stipulates that research data and records should be retained for a minimum of 25 years after the end of the research, or longer if required by research funders and regulators.* |  |  |  |  |
| **1.6** | Their rights under the GDPR? |  |  |  |  |
| **1.7** | The following declaration regarding cross-border data transfers, included on the Consent form signed by the Parent/Guardian/Child:   * *I understand that my personal data will be sent outside the European Union because this study is conducted in collaboration with the Murdoch Children’s Research Institute (MCRI) in Australia. I understand that Australia has privacy laws which are not considered as strong as the General Data Protection Regulation (GDPR) or other local privacy/data protection law, but that nonetheless my privacy will be protected under the Australian Privacy Act, and that I will have enforceable rights under that law. I consent to this data transfer to the MCRI.* |  |  |  |  |

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| **DATA MINIMISATION** | | **Yes** | **No** | **NA** | **If No, Specify Action taken or comment** |
| **2** | Are the items of personal data/special category data to be collected the minimum necessary to achieve the research objectives? |  |  |  |  |
| **3** | Has the potential for using anonymised or pseudonymised data been considered? |  |  |  |  |
| **4** | Will access to the personal data/special category data of participants be restricted to authorised persons? |  |  |  |  |
| **5.** | Will participant data be kept in the form of fully identifiable data for a fixed period of time? |  |  |  |  |
| **6.** | Is there a clear rationale for the length of time data will be kept as fully identifiable data? (Refer to Q 1.5 above) |  |  |  |  |

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| **DATA SECURITY** | | **Yes** | **No** | **NA** | **If No, Specify Action taken or comment** |
| **7.** | Will personal data/special category data be collected, transmitted, and stored securely? |  |  |  |  |
| **8.** | Is the level of security to be provided appropriate to the risks represented by the processing? |  |  |  |  |
| **9.** | Will arrangements be put in place for the secure disposal and or destruction of personal data/special category data when it is no longer required? |  |  |  |  |

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| **OTHER SAFEGUARDS** | | **Yes** | **No** | **NA** | **If No, Specify Action taken or comment** |
| **10.** | If the data is planned to be shared with another organisation, will there be a written agreement with the other organisation, setting out each one’s respective roles and responsibilities, and how individuals may exercise their rights in respect of their data? |  |  |  |  |
| **11.** | Will the personal data/special category data of participants be used for measures or decisions with respect to individual participants? [[1]](#footnote-2)  *Note: If the answer to this question is ‘Yes’, the processing of the personal data will not comply with GDPR.* |  |  |  |  |
| **12.** | Is it likely that your use of personal data/special category data will cause substantial damage or substantial distress to any of the participants? |  |  |  |  |

1. Questions 11 and 12 reflect the requirement in the GDPR and the UK’s Data Protection Act that personal data may not be used for research purposes if: (a) it is processed for the purposes of measures or decisions with respect to particular individuals; or (b) it is likely to cause substantial damage or substantial distress to an individual. [↑](#footnote-ref-2)