**CLINICAL TRIALS: GDPR CHECKLIST**

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| **Study Name/Title:** |  |
| **Sponsor:**  *(if Clinical Trial)* |  |
| **Protocol Number/Name:** |  |
| **PIL/CF Version No & Date:** |  |

**\*NOTE:** The criteria below are specifically listed in Article 13 of EU GDPR as information to be provided when personal data is collected from a data subject. Article 13 of EU GDPR can be referenced, if required, to inform authors/owners of PIL/CFs of their obligations to EU patients. This review form should not be sent to external parties.

**\*NOTE:** This review form only covers PIL/CF compliance with GDPR requirements. It does not cover requirements as defined under GCP or other local requirements.

| **Criteria** | **Advice** | **✓ Please confirm document and section**  *(Add comment where appropriate)* |
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| 1. **Identity and contact details of the data controller** | *This will be local to the site where the subject is providing their personal data & where it is stored - usually the local institution. The Data Controller should be specifically listed alongside details of the Data Protection Officer (as per Criteria 2).*  *If required, it may be appropriate to list multiple Data Controllers, e.g. Hospital Data Controller for personal data at the hospital, and Data Controller for coded data at sponsor/external party.*  *A note should be added to the document to state that the first point of contact for any data protection issues should be the local trial site (as they hold their identifiable personal data), and that contacting the external data protection officers carries the risk of losing their anonymity/identifying their coded personal data.* |  |
| 1. **Contact details of the Data Protection Officer** | *This will be local assigned person to the site where the subject is providing their personal data & where it is stored. The contact details of the Data Protection Officer should be listed – a general contact email or telephone should be listed, e.g.* [*DPO@hospitalname.ie*](mailto:DPO@hospitalname.ie)*, rather than a specific DPO name, to avoid updates if DPO changes in the future.*  *As above, it may be appropriate to list multiple Data Protection Officers, e.g. Hospital Data Protection Officer for personal data at the hospital, and Data Protection Officer for coded data at sponsor/external party.*  *A note should be added to the document to state that the first point of contact for any data protection issues should be the local trial site (as they hold their identifiable personal data), and that contacting the external data protection officers carries the risk of losing their anonymity/identifying their coded personal data.* |  |
| 1. **Purpose(s) of the processing and the lawful basis for the processing** | *Generally this is explained by describing why you are obtaining consent to collect the data for the study and what will be done with the research data, i.e. their consent is being collected to participate in the research study and to collect data relating to their participation.* |  |
| 1. **Where processing is based on the legitimate interests of the controller or a third party, the legitimate interests of the controller** | *Not Applicable to Informed Consent Forms - processing is based on the consent provided by the subject* |  |
| 1. **Any other recipient(s) of the personal data** | *This is usually indicated by informing subjects that an external monitor or external auditor could review their personal data at the site for the purposes of monitoring quality & safety of subjects in the trial; also need to indicate if any other recipients will receive or view their personal data such as an external lab or vendor (i.e. where data is****not****anonymised prior to sending)*  *If required for the study, it should also be noted that pseudonymised/coded data may leave the study site and the recipients and reason for transfers should be mentioned.* |  |
| 1. **Where applicable, details of any intended transfers of personal data to a third country (non-EU member state) or international organisation and details of adequacy decisions and safeguards** | *Where applicable, if any personal data will be leaving the EU (i.e. where data is****not****anonymised prior to sending), the subject must be informed of this and details of the decision making and safeguards in place should be described. This applies also to pseudonymised/coded data which may leave the EU.* |  |
| 1. **The retention period (how long an organisation holds onto personal data) or, if that is not possible, the criteria used to determine the retention period** | *This should be determined at study start and should be communicated to all subjects in the informed consent form - each site should agree to the retention period, e.g. 15 years* |  |
| 1. **The existence of the following rights: - Right of access - Right to rectification - Right to erasure - Right to restrict processing - Right to data portability - Right to object** | *To cover 8, 9, 10 & 11 a sentence can be added to this effect; e.g. that subjects "have the right to access, rectify, erase, restrict processing, portability, object or withdraw consent of use of your personal data at any time in accordance with GDPR, national regulations and the local hospital/clinic regulations. There is no obligation to provide your data - if you decide you do not want to provide your data, there will be no impact on the normal standard of care you may receive. You also have the right to lodge a complaint with data protection authority if you feel it necessary"* |  |
| 1. **The right to withdraw consent at any time, without affecting the lawfulness of processing based on consent before its withdrawal** |  |
| 1. **The right to lodge a complaint with a supervisory authority** |  |
| 1. **Whether the provision of personal data is a statutory or contractual requirement, necessary to enter into a contract, an obligation, and the possible consequences of failing to provide the personal data** |  |
| 1. **The existence of any automated decision making processes that will be applied to the data, including profiling, and meaningful information about how decisions are made, the significance and the consequences of processing** | *Assess per study - generally explained by describing why you are collecting the data for the study; may need to discuss randomisation process or whether this information will impact on treatment or diagnosis* |  |

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