

**The following are commonly occurring issues / omissions in Patient information leaflets (PILS). Please ensure that you review your PILS to ensure these have been addressed, before submitting to the HRCDC. Delays with your application are likely if these issues have not been addressed.**

**This is a guideline only, the HRCDC may, at its meetings, have additional requirements, as needed for an individual application. This document should not be considered as any form of legal advice.**

**Please ensure:**

- Names and locations of all known data controllers and processors involved in the study data are available to participants in the study and / or those providing proxy assent. (ensure locations outside Ireland are also clearly noted).
- The name and contact details of the Principal Investigator / Point of Contact in Ireland is provided for any data protection queries.
- Names, details, locations of any third parties to whom the personal data will be shared is outlined clearly in the PILS. Undefined terms such as industry bodies, external consultants, health insurers, other parties etc should not be used.
- Duration of the study and data retention times are clearly outlined.
- The process of what happens to the personal data if the participant withdraws / proxy withdraws from the study is clearly outlined. If it is not possible to delete data after a participant withdraws, the PILS needs to clearly outline the reasons for this. If the study wishes to continue to process data after withdrawal, then specific, clear, and separate proxy assent/participant consent should be obtained and recorded for this continued post-withdrawal processing.
- References to sub studies should be removed if they do not apply to the research study in the HRCDC application.
- For international / multisite trials, the PILS are tailored for use in Ireland and each facility, as needed.
- Please ensure tick boxes or yes / no options are available in all consent forms.

**Other points to note:**

- Ensure consent and assent terms are used appropriately. Proxy Assent is the correct term when referring to seeking permission from a suitable individual to process personal data of the participant.
- Proxy assent should be provided from a person that understands the will and preference of the participant in the study.
- It is considered good practice that separate documents are used when seeking consent/consent to continue from the participant versus seeking proxy assent on their behalf from a suitable individual.
- In studies where a deferred proxy assent model is in place, the personal data of the participant should be deleted if proxy assent is not obtained within a specified timeframe. This timeframe will need to be specified in the PILS / HRCDC application. If the study wishes to continue to process the data where deferred proxy assent cannot be obtained after this time, this should be outlined in the study documents and a justification for this specified in the HRCDC application.
- *Terms such as 'If there is no known objection by your relative being in this study' and 'Do you have any objection to your relative taking part...'* should be avoided and replaced with more positively phrased questions to ask if they thought the participant would be willing to be included in this research.