

Dealing with requested amendments to the Patient Information Consent Form as part of Human Research Ethics Applications

Following the implementation of the European Union's General Data Protection Regulation (**GDPR**), there has been an increase in the number of requests from sponsors of clinical trials to Human Research Ethics Committees (**HRECs**), for amendments to the standard Patient Information Consent Forms (**PICFs**). Proposed amendments to PICFs require approval from the relevant HREC as part of the application process for clinical trials conducted in Australia.

The template clinical trial research agreements require sponsors of clinical trials conducted in Australia to be Australian entities (**Local Sponsor**).

In their current form, PICFs require Local Sponsors and any person or organisation to whom a trial participant's personal information is transferred, to comply with Australian privacy laws, the *Health Records Act 2001* (Vic) and where applicable the Victorian *Privacy and Data Protection Act 2014* (Vic).

Requested amendments to the PICF to satisfy the GDPR, indicate the Local Sponsor's intention to provide the personal information (identifiable data) of trial participants to an organisation (such as the parent company of the Local Sponsor or international pharmaceutical companies) based in the European Union (**EU**). Any such disclosure and use of information would therefore be subject to European laws such as the GDPR.

Given the requirement that Local Sponsors are required to be Australian entities, there is no reason for PICFs to be amended to satisfy compliance with GDPR to facilitate the proposed disclosure of the personal information of trial participants to entities based in the EU. This is because the GDPR has no application to the collection, storage, use or disclosure of personal information within Australia.

Where the information to be provided to an overseas based entity is de-identified then the use and/or disclosure of such information is not captured under Australian privacy law or EU regulations, therefore there is no need for the PICF to be amended.

Where the Local Sponsor seeks to provide identifiable patient data to an entity based overseas, the privacy laws of the country where the entity is based, will need to be considered and the HREC will need to be satisfied that those laws are as strong or stronger than the privacy laws of Australia. The onus of establishing the strength of the privacy laws of another country should be placed on the Local Sponsor.

Requests to modify the PICF will need to be considered by the HREC on a case by case basis having regard to whether the requested amendments adequately:

- (i) address the proposed use and disclosure of a participant's personal information (including where and to whom such information will be provided); and
- (ii) provide the participant with sufficient information to enable them to make an informed decision as to whether they are willing to provide their consent to the proposed use of their personal information.

At a minimum, an amended PICF will need to include the following information:

- (a) the countries where the patient's data may be transferred;
- (b) who may be provided with access to the patient's data. This may include parent companies of the Local Sponsor, international pharmaceutical companies or national drug authorities of various countries;
- (c) in what circumstances the patient's data may be accessed; and
- (d) what safeguards will be put in place to protect the patient's privacy and prevent unauthorised access to the patient's information.