Australian
Clinical
Trials
Alliance

4 June 2021

Ms Angelene Falk
Australian Information and Privacy Commissioner
The Office of the Australian Information Commissioner
GPO Box 5218
Sydney NSW 2001
Via Email: privacy.rules@oaic.gov.au au

Dear Ms Falk,

Re: Consultation on the National Health (Privacy) Rules 2018 Review

The Australian Clinical Trials Alliance (ACTA) is the national peak body supporting and representing networks of clinician-researchers conducting investigator-initiated clinical trials, maintaining clinical quality registries, and operating clinical coordinating centres within the Australian healthcare system.

We are grateful for the opportunity to comment on the Review. We are particularly interested in the use of identifiable claims information for medical research and have restricted our comments to this as identified in Question 25 of the Review.

We are aware of ongoing problems with accessing data for our community even where they have been granted approval by a Human Research Ethics Committee (HREC) as outlined in the Rules. We include an excerpt below for our reference.

12 Disclosure of identifiable claims information for medical research purposes

(1) Claims information that identifies an individual may only be disclosed for medical research if:

(a) the Department of Human Services is satisfied that the individual to whom the information relates has given their informed consent to the use of that information in the research project; or

(b) the disclosure is made for the purposes of medical research to be conducted in accordance with guidelines issued by the National Health and Medical Research Council under section 95 of the Privacy Act 1988.

(2) Before disclosing claims information under section 12(1), the Department of Human Services must obtain a written undertaking from the researcher that the claims information will be securely destroyed at the conclusion of the research project.

The Review asks whether this provision is still necessary, and we wish to state that it is. If medical research is not explicitly identified as a permissible use, then there is a likelihood that the omission will lead to interpretations preventing such use, notwithstanding that the Privacy Act permits it. In practice, we have

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been told by our members that Services Australia (formally Department of Human Services) has imposed their own interpretations of what is required for disclosure to research participants when they are asked for their consent. These are often in conflict with the requirements approved by HRECs. Such inconsistency could be interpreted in two ways;

1) Australian HRECs are not operating appropriately in terms of the requirements for consent.
2) Services Australia requires elements of consent not consistent with Australian ethical practices.

Rule 12 (1) (a) indicates that the DHS must be satisfied that the individual has given their informed consent. We contend that HRECs are the best arbiter of deciding the level of disclosure required and that the NHMRC Certification and NMA schemes have established very high standards of operations that confirm this. If Services Australia disagrees with the HREC approved Patient Information and Consent forms, then they should publish a clear directive on this. However, HRECs have extensive experience, including lay member and consumer representation, and ACTA suggests that the level of disclosure they approve accurately reflects community expectation in fulfilment of Rule 12 (1) (a). We suggest that Rule 12 (1) (a) be changed to

(a) the Department of Human Services is satisfied that there is appropriate Human Research Ethics Committee approval for the consent to use claims information in the research project;

ACTA notes that Rule 12 (1)(b) relates to a Waiver for the requirement of consent and as such HRECs are empowered to approve this under the Guidelines approved under s95 of the Privacy Act and Services Australia should not make any further requirement on top of this.

With respect to Rule 12 (2), we would note that there is an obligation to store clinical trial data for specified time periods set out either by the NHMRC or the Therapeutic Goods Administration Act. Our members report that this may not always have aligned with Services Australia's requirements. The conclusion of a research project may be more than 20 years in some instances. We suggest that Rule 12 (2) be amended to include the following statement at the end of the sentence "…project or as required by other regulatory requirements…". We also note that where a person withdraws their participation in a trial, the regulatory bodies will still require access to their data up to the time they withdrew and sometimes beyond for safety reasons. This is disclosed to participants as part of their consent and is widely accepted in practice and routinely approved by HRECs.

We thank you for the opportunity to comment.

Yours sincerely,

Professor Nik
On behalf of
Australian Clinical Trials Alliance

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