

DICA regulations

Scientific and efficiency research

** Translation from article 13, 14 and 15 of the Dutch "DICA Regulations", in the event of discrepancies between the English and Dutch text, the Dutch text will prevail. **

13. Benefits in kind

13.1 DICA may provide pseudonymized data to third parties for conducting scientific research under the conditions laid down in these regulations.

13.2 A register of the benefits for scientific research is kept by DICA. In this register at least the following is stated for each provision: a description of the data, the date, to whom and for what purpose the provision was made. The participant has the right to inspect this register.

14. Application and assessment of the application

14.1 The third party must submit a written request for the pseudonymized data to DICA. The application must at least state the identity of the applicant, the reasons for the application, the research question and the nature of the information requested. The third party may also be asked to send the research protocol.

14.2 The application is first assessed by the Clinical Audit Board of the Clinical Audit concerned and then by the Privacy Committee. These advise DICA.

14.3 DICA does not take a decision that deviates from a negative opinion of these committees.

14.4 The Clinical Audit Board of the Clinical Audit concerned assesses a request on the following grounds:

- a. whether the provision and subsequent use of the data by the applicant can reasonably lead to a responsible publication;
- b. whether it is plausible that the information to be provided is relevant for the purpose intended by the applicant;
- c. whether it is likely that the applicant will make responsible use of the data to be provided.

14.5 The Privacy Committee, after receiving a positive recommendation from the Clinical Audit Board of the Clinical Audit concerned, assesses a request on the following grounds:

- a. whether the disclosure is in accordance with the purpose of the Clinical Audit;
- b. whether the protection of patients' privacy is sufficiently guaranteed;
- c. whether it is likely that the applicant will make responsible use of the data to be provided;
- d. whether the provision does not endanger the continuity of the Clinical audit;
- e. whether or not the information to be provided is traceable to the participants.

14.6 The Privacy Commission will draw up guidelines specifying which datasets generally meet the conditions stated in Article 2.5. Requests that fall within these guidelines can be handled by DICA without consulting the Privacy Commission. The Privacy Commission receives an annual overview from DICA of the applications that have been processed in this way with explanatory notes.

14.7 The Privacy Commission can advise to attach conditions to the provision.

15 Decision to provide

15.1 DICA decides whether or not to provide the data within 3 weeks of receiving the advice from the Privacy Commission. This period can be extended once by 3 weeks.

15.2 DICA may set additional conditions for the provision in relation to the conditions proposed by the Privacy Commission.

15.3 DICA can deviate from a positive advice from the Clinical Audit Board and the Privacy Committee if:

- a. the applicant does not want to commit to the conditions set;
- b. DICA believes that providing information entails the real risk that the Clinical audit will suffer damage;
- c. DICA is of the opinion that providing the real risk of business damage for DICA entails.

15.4 A decision that deviates from a positive recommendation must be sufficiently substantiated.

15.5 A decision to provide is communicated in writing to the Clinical Audit Board of the Clinical Audit concerned and the Privacy Commission.

15.6 After the decision to provide information, an agreement is concluded with the applicant before the information is provided. This will in any case include the conditions attached to the provision by the Privacy Commission and / or DICA and the Health Research Code of Conduct will be imposed bindingly.

15.7 The applicant owes the actual costs of accessing the data.