

## Standard Procedures in Handling Data Request Application from External Parties

Requests for patient data or information from the Hospital Authority (HA) are considered on a case-by-case basis. Factors including the relevance of the requested data to the purpose of study, data availability, data limitations, personal data privacy issues, and the resources involved in extracting the data, etc. would be taken into account when processing the request.

The Standard Procedures are applicable to all applications from external parties for clinical or administrative data related to patients and patient care for research purpose.

- 1. The requestor has to submit to HA the project information sheet / research protocol and the Data Request Application Form (Form A or B), which will be assessed in terms of the relevance of the requested data to the purpose of study, the availability and limitation of data, as well as the feasibility of data extraction. HA is obliged to caution the requestors on the data limitations, including issues relating to the consistency and completeness of data when the request is for a time series of data. In this connection, the application may not be entertained if there are reservations on the data completeness or data comparability over time or across all HA institutions and so forth.
- 2. Requirements of the Personal Data (Privacy) Ordinance must be strictly adhered to. If patient-based records are requested, assessment should be made regarding the need to suppress certain sensitive data which may potentially disclose the personal identity, and with due consideration on whether patient's informed consent has been or will be obtained during the conduct of the research study as stipulated in the research protocol.
- 3. When the study requests for identifiable patient-based records, documentary proof of research ethics approval from all the relevant Cluster Research Ethics Committee(s) or the HA Central Institutional Review Board for the study has to be provided to HA by the requestor. If the study only requests for de-identified patient-based records, documentary proof of approval from at least one locally recognized research ethics committee is required.

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- 4. HA will, where appropriate, inform or consult its relevant Clinical Coordinating Committee (COC) / Central Committee (CC) on any issues related to such application.
- 5. Should there be a need to revise the research protocol during HA's assessment of the application, and such revisions are agreed by both parties, then the revised protocol has to be submitted to the relevant research ethics committee(s) for approval where appropriate. Documentary proof of such approval has to be provided to HA.
- 6. A charge will normally be imposed on the requestor for the provision of data, calculated based on the agreed data requirements and resources required for generating the dataset.
- 7. If the data requirements, data limitations, timeframe and cost of data extraction are agreeable to both parties, the requestor will have to complete an Undertaking Form and send it to HA.
- 8. After receipt of the payment, the signed Undertaking Form and all the required documents, HA will generate the data and write it in a CD, with password protection. The requestor or his/her delegate will collect the CD in person from HA office. Further enquiries shall be made to HA within three months of receipt of the data.
- 9. The data must not be transmitted or released, in whole or in part and in whatever form or media, to any party or place outside Hong Kong.
- 10. The charge quoted is for a one-off data extraction exercise. Any further rerun with or without additional data items will be considered separately, in accordance with these standard procedures.
- 11. The requestor is obliged to destroy such data requested and to send to HA the Declaration of Data Destruction, duly signed, within 12 months of the Study Completion Date. Data retention for five years or above requires justification and is subject to review as needed.
- 12. An application shall be considered dormant if HA did not hear from the requestor within six months of last communication.

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