

Guidelines for collaborators regarding use of HKU FAMILY Cohort data

Background

These guidelines aim to outline the dissemination procedures of the HKU FAMILY Cohort (FC) data to collaborators. The present guidelines are consistent with the data sharing policies of major studies, including the Nurses' Health Studies, National Health and Nutrition Examination Survey, and 'Understanding Society' household longitudinal study in the UK Data Archive. The principle is to make high quality available to those investigators who are interested in collaborating with the HKU FAMILY Cohort Research Committee on use of the FC data. The data released will be in as much detail as possible while maintaining HKU FAMILY Cohort participants' confidentiality. Interested parties will be required to meet the various mechanisms of data transfer and access described below.

A. Submitting a Proposal

A.1. Letter of intent

- Investigators wishing to develop collaboration with the HKU FAMILY Cohort Research Committee to use the data are asked to initially submit a brief (1-page) description of the proposed project ("letter of intent") to HKU FAMILY Cohort Research Committee (familyco@hku.hk). The letter of intent should briefly outline the following:
 - Primary Hypothesis being proposed
 - Scientific significance of the project

- Data variables taken from a list of variables made available by the FC that are required for analysis.
- A letter of intent may be submitted throughout the year. It will be reviewed by the HKU FAMILY Cohort Research Committee on a regular basis.
- Investigators will be invited to submit a proposal if the letter of intent for collaboration is approved, the following criteria will be used for assessments:
 - Such project is judged feasible (given database and team resources) and is of substantial scientific interest
 - The topic is not currently being pursued by another investigator, and is not currently under consideration by other applicants.
 - It is also possible that the applicant will be asked to submit additional information if it is unclear from the letter whether the proposed project fulfills the requirements.

A.2 Proposal

The proposal should include the following:

- Title
- Study Personnel and affiliations
- Funding source (if applicable)
- Lay Summary (includes significance) (up to 300 words)
- List of Variables requested

- Study Populations (up to 300 words)
- Primary Hypothesis for the Study
- Secondary Hypotheses (up to 2)
- Statistical Analysis Plan (up to 800 words)
- Expected Project Completion Date

B. Conducting analyses using HKU FAMILY Cohort data set

B.1. Undertaking on data transfer and access

- If the proposal is approved, an investigator from the HKU FAMILY Cohort Research Committee will be identified to work with the collaborator to facilitate the research.
- Collaborators will have to sign an undertaking on data transfer and access in the FC confirming that they have read the terms and conditions listed in this document and the undertaking, and that they agree to comply with them.
- Use of data from the FC is limited to the defined, specific project for which approval in the proposal has been obtained from HKU FAMILY Cohort Research Committee. If further research or analytic activities develop from the original project, the collaborator must obtain appropriate approval for such activities.

B.2. Dataset

- The data manager of the HKU FAMILY Cohort Research Committee will prepare and provide a data set which will contain variables required for analysis.

- A fee will be charged to cover staff costs and resources required to extract the relevant data sets.
- Collaborators will be required to provide documentation on any variables recoding in the data set to the HKU FAMILY Cohort Research Committee. It is possible for collaborators to request additional variables not stated in the proposal. They will be asked to submit further information to substantiate their request and such request is subjected to the approval from the Committee.

B.3. Progress reports

- Collaborator must agree to keep the HKU FAMILY Cohort Research Committee updated on the progress of the study by providing either a written or verbal report at least every 6 months. Failure to adhere to a reasonable progress schedule could lead to termination of the collaborative relationship.

C. Data Analysis and Publication Issues

C.1. Data transfer and security

- Collaborators will ensure that all data and analysis results must not be disclosed or transferred to any persons or parties who have not signed the undertaking on data transfer and access.
- Collaborators will also provide all security means to safeguard the data and prevent unauthorized use or access to it. It is of utmost importance that collaborators guarantee that no data and results would be saved in any portable storage devices.

- Collaborators will need to report to the HKU FAMILY Cohort Research Committee within 24 hours if the data has been compromised or leaked. This requirement includes any suspected data leakage as well.
- Any breach and suspected breach of the terms and conditions stated in the Collaborative agreement of data transfer and access in the FC must be reported to the HKU FAMILY Cohort Research Committee within 24 hours. Also, any breach will lead to immediate termination of access to the data and could result in legal action against the data user.

C.2. Presentation of results

- Presentation of results at a public meeting (including but not limited to scientific conference and media events) is encouraged but collaborators will be required to submit their results to the HKU FAMILY Cohort Research Committee before disseminating to the public.
- Collaborators must ensure that proper acknowledgement to both FC and the Hong Kong Jockey Club Charities Trust (who provided the funding for the FC) is given in all publications and any form of dissemination arising from analysis of the data.

C.3. Authorship and manuscript review

- Due to the complexity of the data and the FC investigators' understanding of the strengths and limitations of the database, substantial input is required of FC investigators to ensure valid and appropriate use of the data. Thus, at least one FC

investigator must be included as a co-investigator on any grant proposal where use of FC data is proposed.

- At least one FC investigator will be a coauthor on any manuscript resulting from this collaboration and, as such, will need to sign-off on any manuscript prior to its submission for publication. All manuscripts must also be submitted for review to the HKU FAMILY Cohort Research Committee and approval must be obtained before a manuscript can be submitted to a journal for publication.
- Any dispute regarding data interpretation may be brought to the HKU FAMILY Cohort Research Committee's attention, in which they reserve the right of final decision.

References

National Health and Nutrition Examination Survey. (2013). NHANES data release and access policy. http://www.cdc.gov/nchs/data/nhanes/nhanes_release_policy.pdf Accessed on October 4, 2013.

The Nurses' Health Study. (2013). Guidelines for external collaborators: use of the Nurses' Health Studies archived data. http://www.channing.harvard.edu/nhs/?page_id=471 Accessed on October 10, 2013.

University of Essex. (2012). End user licence of UK Data Archive. <http://data-archive.ac.uk/media/381244/ukda137-enduserlicence.pdf> Accessed on October 4, 2013.