HOP application form

Please complete this form if you want to conduct a data analysis on existing data in Hebon Resource or if you want to conduct additive data collection and/or analyze these data together with existing data in Hebon. The deadline for a Hebon research plan is 4 weeks prior to a Steering Group meeting. If approved, the project plan will be made available for Hebon members upon request. If approved, the applicant also agrees with providing a yearly status update on the research. The status update will be requested through an online form by Hebon.

1. **Investigators:**

   Note that one of the investigators should be a Hebon member.

2. **Contact person for this HOP:**

3. **Email address of the contact person for this HOP:**

4. **Phone number of the contact person for this HOP:**

5. **Which centers are involved in this HOP application?**

- ☐ Amsterdam UMC - locatie AMC
- ☐ Amsterdam UMC - locatie VUMC
- ☐ Erasmus MC
- ☐ LUMC
- ☐ MUMC+
- ☐ NKI-AVL
- ☐ Radboudumc
- ☐ UMCG
- ☐ UMCU

6. **Which departments are involved per center?**

   Example: PFT, NKI-AVL

7. **Application for**:

   - ☐ Analysis
   - ☐ Grant project proposal

8. **Title of the proposed project:**

9. **Background:**

   (Maximal 100 words)

10. **Study aims:**

    (Maximal 100 words)

11. Study design:

(Maximal 100 words; include a description of the eligible group)

12. Definition study population:

Please, define as specific as possible, e.g. age range, sex, mutation status.

Hebon participant status

Eligible Hebon participants can be classified with one of the following statusses:

- Participant
- Non-responder
- Refuser
- Deceased prior to invitation

Non-responders are individuals that have received the invitation for the Hebon study and two reminders, but have not responded to these letters. In accordance with regulations regarding the protection of personal data, limited data concerning these non-responders can be obtained.

13. Do you request data of non-responders or deceased persons?

(Please, be note that you will need IRB approval)

☐ Non-responders ☐ Deceased persons

☐ Not applicable

14. Will additional data collection be conducted?

If yes; is identifying data necessary for the additional data collection?

- ○ Yes, and identifying data is necessary for the additional data collection.
- ○ Yes, but no identifying data is necessary for the additional data collection.
- ◉ No additional data collection will be conducted.

➔ *If yes, but no identifying data is necessary; continue to question 16.*

➔ *If no; continue to question 21.*

15. Which identifying data (name, address, etc) is necessary for the additional data collection?

If identifying data is necessary, please be aware that the Steering committee will decide whether this data may be made available for this study.

16. Is a link with the BRP necessary?

The BRP (Basisregistratie Personen) contains personal data of Dutch citizens. Address data may be required when an invitation for participation in a study needs to be sent to Hebon participants. The BRP can also be consulted to check if individuals in the target population are deceased.

- ◉ No
- ○ Yes

Additional data collection

In case of additional data collection please, be aware that METC/IRB approval may be necessary and centers may opt-out for the data collection (even if the Hebon Steering group has accepted the proposed project).

Please be aware that the "HOP-specifieke Studie Overeenkomst" requires you to make available the existing or new data, which you use for this HOP, for the Hebon database and other Hebon research.

17. Plan of additional data collection:

Please, indicate what new data (type: questionnaire, treatment, e.g. PALGA) you will collect, who will conduct the data collection and, if applicable, your plans for a pilot study. Please, also indicate how the distinction between personalized and coded or anonymized data will be organized.

(Maximal 500 words).

18. Timeline for pilot study and data collection.

Only if you are planning to invite members of the Hebon study population to participate in your study (e.g. questionnaire).

19. Target number of participants included in additional data collection:

After acceptance of the HOP, Hebon Centraal can provide exact numbers of eligible participants.

20. Which centers will be involved in the additional data collection?

- ☐ Amsterdam UMC - locatie AMC
- ☐ Amsterdam UMC - locatie VUMC
- ☐ Erasmus MC
- ☐ LUMC
- ☐ MUMC+
- ☐ NKI-AVL
- ☐ Radboudumc
- ☐ UMCG
- ☐ UMCU

21. Analysis plan:

Please, include clear outlines of the methods of analysis. Note that the data should be kept at the digital environment of one of the Hebon sites.

(Maximal 500 words).

22. Time plan:

Please, be aware of the General Hebon terms of data delivery, such as the Data Transfer Agreement (DTA), the timeframe to claim the subject et cetera.

23. Type of data required:

- ☐ Summary data (e.g. estimated hazard ratios and p-values)
- ☐ Primary data (from variables in our codebook)
- ☐ Power analysis

24. Please specify what type of summary data you need and for which variables:

25. Please specify what type of primary data you need and for which variables:

Click here for the codebook

Mark the required variables with an "X" in the last column. Please, send the document with required variables to hebon@nki.nl.

26. Please specify the required statistical power analysis:

27. Please specify funding for this research:

☐ Funding:

☐ Not applicable

28. If accepted by the Hebon Steering Committee:

There is adequate funding and personnel available.

☐ Yes

☐ No, because:

29. Writing committee:

Please be noted that the author list of the manuscript should adhere to the requirements as listed in the Hebon collaboration agreement.

Thank you for your application!

If this Hebon Research Plan (HOP) will be approved by the Hebon Steering Committee, you will be granted access to the Hebon data after signing the 'HOP-specifieke Studie Overeenkomst' including this HOP. You will have to indicate that your research protocol and practice is in accordance with the Hebon Protocol, the Hebon Privacy Document, the Code of Adequate Secondary Use of Data (2004) and Code of Adequate Secondary Use of Tissue (2011).

Do not forget to send the Excel with your required variables to hebon@nki.nl!