A researcher's checklist for the ethical evaluation application

Below are instructions on the documents needed when a new study is submitted to the HUS’ Ethics Committee for an ethical evaluation. The instructions are Helsinki Biobank’s modification of the HUS General Guidelines (http://www.hus.fi/tutkijalle/tutkimusteettiset-komiteat/etettisenlausuntohakemus/Savut/lausuntohakemus1.aspx) and are only applicable to studies that solely use samples from a biobank. Studies in which a permit from Valvira is used or studies in which samples are collected to a biobank, the HUS General Guidelines should be followed. All documents should be sent as PDF files.

Application form (electronic on Tutkijan työpöytä, is filled in on-line)
- Helsinki Biobank can provide you with separate instructions for filling in this form.
- The official, easily understandable name of the study should be the same in all documents.
- Report a realistic timetable for the study. The permit from the Ethics Committee must be valid as long as the material is handled and the article is written.
- As a rule, research-based studies are not charged by a fee for the ethical evaluation. If the research has funding from a source that is not a charitable entity (eg a foundation), a fee is charged. The Ethics Committee, however, decides the fee on a case-by-case basis.

Appendix 1. Research plan
- The structure of the research plan should follow the general academic guidance (found for example via the link above)
- In biobank projects you should pay particular attention to the following issues and state them clearly in the research plan:
  - Only biobank samples will be used.
  - Biobank samples are delivered encoded. If there is a justified need to deal with personal identification numbers, this must be clearly stated in a research plan. It should be also stated how the personal identification numbers are handled and retained.
  - The benefit of the study for patients
  - The timetable for the study should be the same as in the application form

Appendix 2. Summary of the research plan
- A summary / short research plan in Finnish should always be submitted, also when notifying a change * (see below).

Appendix 3. The Principal Investigator’s (PI) ethical assessment of the study
- Must be submitted as a separate, signed attachment.
- In general, biobank projects do not pose any risks to the patients. The samples have already been collected and no additional involvement from the patient is needed. The patients have given their biobank consent, which means their samples can be collected, stored and used in medical studies. Therefore; a separate permission from the patient is no longer required in order to use the samples. The samples are also handed to the researcher encoded, reducing the risk of patient identity being revealed.
- Wider ethical considerations may be needed, for example, in studies where new therapeutic findings can be identified and the sample donor may directly benefit from the results. In this case, you can consider the potential benefits and risks for the patients and whether it might be necessary to contact the sample donors and in that case, how it should be done.
- A wider ethical assessment is always needed, when samples are collected to the biobank during the study.

Appendix 4. Privacy Policy Statement
- When processing personal data, a personal register is created, which requires a Privacy Statement.
- The Privacy Statement is a statutory public document prepared for the sample donors. A sample donor has the right to have a copy of the statement, so that he or she will understand what information is collected and how it is processed. Therefore, it must be written in layman’s terms. One Privacy Statement is sufficient.
• Helsinki Biobank can provide you with a Privacy Policy Statement form to be filled in.
• Normally in researcher-driven studies, the Register Controller is mainly HUS. However, in biobank projects, the researcher him/herself acts as the Register Controller. This is also stated in the General Terms of Access to Helsinki Biobank’s resources, which must be signed by the researcher before the samples are delivered (The link to the general terms can be found here: https://www.terveyskyla.fi/helsinginbiopankki/en/for-researchers/step-3-sample-request).

Appendix 5. Self-assessment of security risks
• The purpose of the risk assessment is, that based on it, the Ethics Committee can verify that the research material and the privacy of the sample donors are adequately protected.
• Helsinki Biobank can provide you with a risk assessment form to be filled in.
• You may also use a template used by your own organization, or the risk assessment can be written freely.

Appendix 6. Financing plan
• An indicative financing plan that tells how much money is reserved for the research, where the funding comes from and how the funds will be shared within the project.

Appendix 7. A description of the research team and the CV of the PI

Appendix 8. Helsingin Biobank’s statement of sample availability (= preliminary request form).

(Appendix 9. Cover letter)
• The application must be accompanied by a cover letter in case of a change*, a process being continued or when delivering a response to a request made by the Ethics Committee. The changes should be highlighted, and in the response, the requested matters should be presented one by one, specifying how the different requests have been solved. In a new study, a cover letter should be prepared only when necessary.

* A change or an amendment to the research plan
• Substantial changes to the research plan must be reported to the Ethics Committee.
• A change in the research plan is a case when the basic nature of the research remains the same, but there are some modifications or amendments made. (Section 3 of the Medical Research Act).
• Changing the research into a biobank project (for example, if samples have been previously gained with a permission from Valvira) is a change that requires a new ethical evaluation.