C2d. Checklist- Start a research project based on biobank samples

This checklist shows the administrative steps a researcher must make before the start-up of new research projects / sample collection for research / clinical trials that will use biobank samples taken in health care activities. When a new research project starts, it needs to be planned administratively, financially and operationally.

It is important at an early stage to reflect over and decide whether to use existing sample in health care or set up a new sample collection.

Costs are related to if existing or newly collected samples will be used. Applied research fundings should therefore be specified (see example on costs in article 6).

Consultation: To maximize the usability of collected samples and obtain guidance and information on completion of forms and applications, it is recommended to contact the Biobank Coordinator or the Biobank early in the planning phase of new research projects.

The following is needed for research involving biobank samples

1. **Information for patient/research participants with the informed consent form (unless the Ethical Review Board decides otherwise)**
   - Guidance and examples, designed and approved by Ethical Review Board (EPN in Swedish) and the National Biobank Council (NBR in Swedish)
     - Information for research participants: www.epn.se.
     - Example of information for research participants, document K3: www.biobanksverige.se

2. **Approved ethical application**
   - The Review Ethics Board approve the research project including information for research participants and informed consent of patient/sample donor**.**
     - Application form and guidance to application: www.epn.se.

3. **Register the sample collection in a biobank through the national application form or the multicenter application form**
   - Application for access to sample and personal data for research should be made by the researcher who desires samples from healthcare. The national application form L1. "*Access to sample collection and personal data for research*" is used.
     - Form (L1) and instruction for completion (K4) can be found at: www.biobanksverige.se
     - Contact the biobank coordinator or the biobank for any inquires related to the application, access to sample collection and/or access to personal data for research

- The application for access to newly collected samples and personal data for multi center studies should be made by the researcher who initiate a multicenter study with newly collected samples where the sample collection will be released. The Regional Biobank Centre (RBC) in the region where the ethical review was approved will conduct the processing of the application.
  - Form (N1a) and instruction for completion (M3) can be found at: www.biobanksverige.se
  - Contact RBC for any inquiries regarding multicenter studies: www.biobanksverige.se
- Please note, if samples are sent abroad for analysis a "MTA - *Agreement on the transfer of biological material"* (document L2a), must be established. If samples are sent for analysis within Sweden, either the MTA (L2a) or a simplified version *"Överenskommelse avseende destruktion eller återlämnande av prov efter analys"* (L2b) can be used.
  - Instructions (document K5), template for MTA and the simplified agreement can be found at: www.biobanksverige.se

4. Report personal data files to data controller/ data protection officer

- When a new file is created for a new research study or new sample collection, it must be reported to the Data Controller/Data Protection Officer. Data Controller is the Research Principal which determines the use and processing of personal data.
  - See on-site instructions about reporting to Data Protection Officer at the current Research Principal, University or County Council/Region.

5. Establish agreements on extended access to sample after completed research study

- Prolonged access to samples that shall be stored after a study has been completed is handled differently at biobanks in Sweden. Contact your local biobank coordinator or biobank for more information on how samples that are saved for future use are regulated between the responsible biobank and responsible person for the sample collection.

6. Costs linked to biobank sample (existing or newly collected)

- Keep in mind that there are several costs linked to a biobank sample that needs to be considered. Below is a list of expenses that could be relevant for your study. Contact the biobank coordinator or the biobank for more details regarding:
  - Sampling (for newly collected sample)
  - Startup fee (for newly collected sample)
  - Sample handling
  - Storage
  - Allocation (newly collected sample)
  - Withdrawal and preparation (existing sample)
  - Transmission of sample material
  - Extraction of files