

Medical Ethical Committee approval: What next?

Once the Medical Ethical Committee (CMO-light) grants approval to start a sub-biobank, several steps need to be taken before collecting patient samples to be stored in the Radboud Biobank. These steps are described below. **Please note that the following steps do not need to occur in chronological order.** Some of these steps (i.e. steps 3, 4, 5) may be undertaken simultaneously during preparation for the CMO-light review.

N.B. Please notify the Radboud Biobank a minimum of 2 weeks prior to beginning patient sample collection.

Step 1 Contact the Radboud Biobank (radboudbiobank@radboudumc.nl) and forward a copy of the CMO-(light) approval with the relevant accompanying documentation, i.e. sub-biobank protocol, patient information and informed consent.

Step 2 The Radboud Biobank ensures that:

- a. An appointment is made to sign the contract between the director of the Radboud Biobank and the person responsible for the sub-biobank (e.g. head of the department, health care chain, consortium of expertise center).
NB: For a consortium, power of attorney is granted to a representative on behalf of the consortium (in Dutch: *consortiumvolmacht*). A template is available via the Radboud Biobank.
- b. Request forms are drafted* by the senior lab technician and the biobank management system is formatted to include the new sub-biobank. *This is not necessary for the collection of tissue, which takes place via Epic order management.
- c. An appointment is made with the IT-coordinator and/or IT administrator regarding the data registration (e.g. options for data storage and biobank requirements). See also the "Notice for setting guidelines for clinical data" (this document is available in Dutch, 'Notitie richtlijnen vastleggen van klinische data').

Step 3 Register the sub-biobank in PaNaMa

(<http://portal.umcn.nl/organisatie/projecten/panama/Pages/home.aspx>).

Registering a sub-biobank in PaNaMa ensures university-wide uniformity and transparency in scientific research. As of November 1, 2016, the Executive Board requires the registration of a standardized minimum dataset in PaNaMa for all new research on human subjects (both WMO* and non WMO).

Once a sub-biobank has been registered in PaNaMa and PaNaMa has been formatted for the sub-biobank, the sub-biobank can be made visible in Epic.

(<https://portal.umcn.nl/organisatie/rz/Pages/Epicvooronderzoeksm medewerkers.aspx>).

*WMO, Wet Mensgebonden Onderzoek is the (Dutch) Medical Research Involving Human Subjects Act

Step 4 Draft the sub-biobank Process Flow (in Dutch: *Procesbeschrijving deelbiobank*; the Dutch template is available via the Radboud Biobank [website](#)) to ensure that the biobanking process runs smoothly and that there is transparency from the onset of patient inclusion to the publication of data. This entire process should be described in one document and contain the following information::

- a. Background information
- b. Responsibilities
- c. Patient inclusion

- d. Procedures for the collection and recording of clinical data
- e. Procedures for the collection and transport of human biomaterial
- f. Follow-up
- g. The procedure for withdrawal of consent
- h. The procedure for unsolicited findings

Step 5 We recommend drafting a sub-biobank rules and regulations manual (an example is available in Dutch via the Radboud Biobank). Define the terms and conditions regarding the collection and use of the biomaterial and clinical data in this manual.