ADDITIONAL INFORMATION in case of research projects with biological samples

If samples are stored for future research in a repository abroad:

Information on the repository's policy must be sent to the CEIm, which must show compliance with the rules set out in "*Recommendation CM/Rec (2016)6 of the Committee of Ministers to member states on research on biological materials of human origin*". The CEIm must specifically be informed of the following:

- that the biobank/repository has independent supervision that guarantees the protection of patient data and interests,
- that there is an independent revision (ethical and scientific) of the various studies to be carried out with the samples and,
- that biological samples will not be transferred to third parties and samples will not be sold.

Access to Biobank: Section "Core Facilities" on the website.

REQUEST TO THE CREC FROM HUVH FOR A FAVOURABLE REPORT ON A PROJECT WITH CREATION OF A BIOLOGICAL SAMPLE COLLECTION

New project including the use and storage of biological samples as a COLLECTION

Samples obtained outside a project approved by the CREC?

Yes

No

Submit to the CREC:
1. **RESEARCH PROJECT** report, specifying a line of research

2. Research project PIS/IC specifying that samples will be stored as a Sample Collection (CREC PIS/CI forms).

Submit to the CREC:
1. **RESEARCH PROJECT** report, specifying the line of research.
2. Research project PIS/IC specifying that *samples will be stored* as a Sample Collection (CREC PIS/CI forms) to contact study subjects again and request their consent, or IC exemption request to the CREC to be able to use those samples (according to Art. 24 RD 1716/2011).

Research project approved by the CREC whose samples will be stored as a Sample Collection

Are subjects still being recruited for the study and biological samples obtained?

Yes

No

Did the project PIS/CI approved inform on the future use of samples and who is responsible for their storage?

Yes

No

RESEARCH PROJECT AMENDMENT to create a COLLECTION. Submit to the CREC:
1. RP approval reference.
2. Project report (highlighting changes that indicate that samples will be stored as a collection).
3. PIS/IC used to obtain samples already collected.
4. New PIS/IC to obtain samples from future subjects or to update consent of subjects already recruited.
5. IC exemption request for subjects already recruited (justify reason if consent will not be updated, Art. 24 RD 1716/2011).

Did the project PIS/CI approved inform on the future use of samples and who is responsible for their storage?

Yes

No

RESEARCH PROJECT ADDENDUM to create a COLLECTION. Submit to the CREC:
1. RP approval reference.
2. Appendix to project indicating that samples will be stored as a collection.
3. PIS/IC used to obtain samples already collected.
4. New PIS/IC to update study subject consent or request IC exemption (according to Art. 24 RD 1716/2011).

Researcher responsible for the COLLECTION:

1. Register the collection in the National Biobank Register.
2. Notify HUVH of the Biobank register reference.

Art. 37. RD1716/2011

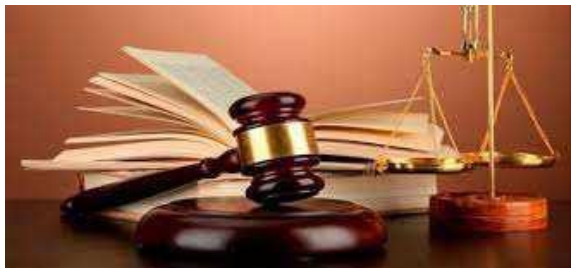
Art. 28. RD 1716/2011

END

Registration in the National Register of Sample Collections and Biobanks:
https://biobancos.isciii.es/NuevaColeccion.aspx

Notification to HUVH Biobank:
biobanc@vhir.org

Biomedical research projects with samples of human origin conducted by researchers at Vall d'Hebron require ethical-methodological evaluation and **authorisation from the hospital Clinical Research Ethics Committee**.



The following were approved in order to regulate the correct collection, storage and use of biological samples of human origin, and to promote their use in biomedical research following suitable ethical and scientific practices:

- Biomedical Research Act (Act 14/2007, of 3 July, on Biomedical research) and subsequently,
- Royal Decree 1716/2011 implementing the Biomedical Research Act.

These can be downloaded from the "more information/legislation" section of our website.