Resource Title: CIBERER Biobank, CBK
Website: http://www.ciberer-biobank.es

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Summary description of the resource (250 words max):
CIBERER Biobank, hereinafter CBK, is a public-non-profit-making biobank set up by the Centre for Biomedical Network Research on Rare Diseases (CIBERER) and located at the Centro Superior de Investigación en Salud Pública de Valencia, hereinafter CSISP. Through being an integral part of CIBERER, the Biobank has the institutional backing of the Spanish National Institute of Health (Instituto de Salud Carlos III) and thus of the Spanish Ministry of Economy and Competitiveness (for more information regarding CIBERER, please refer to Appendix 1).

CBK was founded in 2008 with clear aspirations to excellence and differentiation. It has set out to become a biobank centralizing the reception of samples connected with rare diseases in Spain. It actively involves the research and healthcare professionals providing samples to the biobank and disseminates them among national and international research groups working in rare diseases. It thus guarantees the scientific repercussion of the samples received.

CBK was founded with the aim of serving diagnostic and therapeutic research, facilitating the availability of high-quality biological material to carry this out. It was also set up to solve one of the main problems coming up in research into this type of pathologies: the dispersion of samples due to the low prevalence of rare diseases. This point is of special relevance at a time when the proliferation of different biobanks could hinder the concentration of cases required to carry out research into rare diseases.

Resource’s contribution to IRDiRC’s focus and mission (250 words max):
CBK forms part of the CIBER structure, a public consortium set up under the auspices of the Instituto de Salud Carlos III. Its Rare Diseases Area (CIBERER) was created to act as a reference, coordinate and promote cooperative research of excellence in rare diseases in Spain. CIBERER consists of sixty two
research groups, affiliated to 29 institutions in the consortium, including universities, hospitals, Spanish Research Higher Council (CSIC) Centers and other Public Research Bodies. Its mission is to become a center where priority and encouragement is given to collaboration and cooperation between basic and clinical research groups. Special stress is placed on the fields of genetic, molecular, biochemical and cellular research into genetic or acquired rare diseases. CIBERER’s aim is to improve knowledge on epidemiology, the causes and mechanisms producing rare diseases and investigate curative treatments. CIBERER’s researchers investigate into more than one hundred rare diseases and CIBERER gives them technological support for undertaking particular aspects of the research done thanks to Instrumental Transversal Platforms in RD (PITER) such as the CIBERER Biobank, a platform that provides services to them in addition to storing and providing RD samples.

Resource’s terms-of-use, licence policy (250 words max):

Responsible Custodianship
CIBERER Biobank adheres to principles for responsible custodianship which require planning and transparent policies to ensure long-term physical integrity of samples as well as maintaining their privacy and confidentiality.

Distribution protocol
Biospecimen distribution to researchers is based on principles of scientific merit and access in a timely and equitable manner. Any researcher who wishes to ask the CBK for a biological sample should fill in a sample request application form, enclosing a report on the research project for which this is required, as well as any relevant data on the evaluation of its viability (human and financial resources, infrastructure, etc.). Sample requests are opened to researchers worldwide.

The Ethics Committee and the Scientific Committee will proceed to evaluate the appropriateness of donating the biological sample requested and issue a report. If the decision is favorable, the sample will be sent to the applicant, after the researcher in charge has undertaken to comply with the conditions established by current legislation in Data Protection Act and Act 14/2007 on Biomedical Research by signing a Material Transfer Agreement. The commitment refers to the proper use of samples, given that they constitute scarce research material with high scientific value and to the confidentiality of the associated information or any that may stem from its study.

In addition, the biobank activity is monitored both internally and externally by CIBERER’s Management Committee and an International External Advisory Scientific Committee.

Process in place for quality control, life cycle management and scientific peer-review:
CIBERER Biobank has implemented a Quality Management System, based on UNE-EN ISO 9001:2008 standards and accredited in 2013 by ENAC, which apply to all the activities of the biobank (reception, processing, storage and supply of biospecimens) and which implies, among others: adherence to standard operating procedures (SOPs), recordkeeping, data management, equipment maintenance and staff adherence to continuous training. The biobank thus adheres to QC/QA policies and procedures for supplies, equipment, reagents, etc., has implemented biospecimen handling policies and procedures, a safety program, procedures for investigation, documentation and reporting of accidents, errors and complaints. All policies and procedures are in line with international organisms’ policies such as ISBER, OECD, NCI or BBMRI.
In order to ensure the processing and maintenance of high-quality samples, the Biobank personnel is well qualified and trained to adhere to standard operating procedures. All human biospecimens are potentially infective and biohazardous. Hence, biosafety precautions are taken by the biobank personnel. CIBERER Biobank also adheres to principles of general laboratory safety, implementing procedures regarding, chemical, electrical, fire and physical safety (ISBER 2008 Best Practices for Repositories).

The laboratory facilities were moreover specifically designed to fulfill the requirements of biosafety, sterility, ambient parameters, etc.. that the biobanking activity needs, and were designed to accommodate specific testing and quality control needs. Likewise, the biobank acquired highly specialized equipment for processing and storage of samples.

Recognizing the importance of moving forward evidence-based standards for the collection, processing and storage of biospecimens, CIBERER Biobank also participates in several biospecimen research working groups. CIBERER Biobank Best Practices will continue to evolve as the field of biospecimen biology advances, new scientific and technological practices develop and ethical and legal policies arise.

Core impact indicators (e.g. numbers of users per year, number of visits to site, number of downloads, number of partnerships):

- **Num. samples:** 301 (in the catalogue) from 33 different RD. Additionally, there are more than 300 samples from ongoing projects which will be incorporated in the catalogue as soon as they conclude. We would like to stress the fact that the Biobank is not located at a healthcare care center and that many researchers are obligated to deposit the samples they obtain at the Institution where they work, which makes having access to RD clinical samples more challenging even.

- **Service provision:** The biobank activities are not limited to biological samples custodianship and provision. It constitutes a platform offering services to CIBERER’s researchers and, in the near future, to a wider scientific community.

- **Participation in projects:** At present, the CBK is actively collaborating in 7 research projects, among which we highlight its strong implication in an IRDiRC Spanish initiative, the TREAT-CMT project, for which the biobank has processed, stored and facilitated hundreds of samples to researchers participating in the study. As for international projects, CBK is an associated partner in RD-Connect and participates in other European Projects such as Euro-WABB.

- **In this sense, this platform is aligned with the IRDiRC objectives and has proven to be a very useful platform at improving the efficiency of sample circuits necessary to the development of many research projects as well as handling all their ethical and legal aspects.**

- **Partnerships:** CBK collaborates with two national biobank networks (RVB, RNB) and has signed Collaboration Agreements with research centers (CSISP, CIPF), biobanks (BNADN) and patients associations (FEDER).

Size and constitution of the maintenance team, where applicable:

CBK has the following management organization scheme:

- **Scientific Management:** Francesc Palau, PhD, MD (Scientific Director of CIBERER)
- **Assistant Director:** José Mª Millán, PhD
- **Biobank Coordinator:** Virginia Corrochano, PhD
Laboratory Responsible: Salvador Martí, PhD

**Funding scheme (budget and sources):**
The contracted personnel working at the Biobank is funded by the Spanish Network for Research in Rare Diseases (CIBERER, see [http://www.ciberer.es](http://www.ciberer.es)), which depends on the Institute of Health Carlos III belonging to the Ministry of Economy and Competitiveness.

Additional technical staff is hired depending on the existence of external available funds. In 2014, an Agreement signed with FEDER, the Spanish Federation of Rare Diseases, allowed to hire an additional person.

The biobank’s annual budget in 2015 is 100,000 eurr approx, including two full-time contracts. The CIBER’s Rare Diseases Area (CIBERER) has financed the biobank activities since 2008 and plans to continue supporting this platform in the future. In addition the biobank has income support from collaborations, such as a 22,000 eurr donation in 2014 from the Spanish Federation of Rare Diseases to implement new services to provide to researchers in a non-profit basis.

Service provision also contributes to guarantee financial sustainability.

**Publication(s):**