Sample questions for Rare Disease Biobanks

Please find below a set of example questions that may be asked in the rare disease biobank Assessment Form via the RD-Connect ID-Card.

1	**OVERVIEW ON THE BIOBANK**
1.1	General information
1.2	Type of biobank – Host institute – Type of Host institute
1.3	Source of funding
1.4	The number of rare disease samples collected
1.5	Target population
1.6	Listing in other biobank inventories/networks
2	**COLLECTION OF DISEASES**
2.1	What percentage (%) of your biological sample are from rare diseases?
2.2	Which rare diseases do you collect?
3	**TYPE OF BIOLOGICAL RESOURCES**
3.1	Does your biobank *collect* (select all that apply: whole blood, cells, tissue, urine, fluids)
3.2	Does your biobank prepare (select all that apply: cells, cell lines, DNA, RNA, protein, etc)
4	**USE AND ORIGIN OF THE BIOLOGICAL SAMPLES**
4.1	In what context were your collections sampled/used? (Research/Diagnostics/Therapeutics)
4.2	What type of associated data could you provide with the samples? (Clinical/Molecular/Other)
4.3	List of recent scientific publications based on samples from your biobank
5	**QUALITY ASSURANCE**
5.1	Does your biobank have a quality assurance system? (i.e. ISO 9001, OECD guidelines, other specific guidelines)
5.2	Does your biobank adopt dedicated standards for sample acquisition?
5.3	Does your biobank perform molecular tests to ensure sample integrity?
5.4	Does your biobank adopt a dedicated SOP for sample processing/storage?
6	**DATA MANAGEMENT**
6.1	Does your biobank have a catalogue for collections? If so, is it published on a website?
6.2	Does your biobank maintain an updated database?
6.3	Does your sample management system contain a data identification system?
6.4	Which software does your biobank use?
6.5	Is the collection database exportable?
7	**ACCESS TO SAMPLE COLLECTION**
7.1	Is there a restriction on which user may access samples held in your biobank?
7.2	How many samples do you distribute per year?
7.3	Does your biobank require the users to sign a Material Transfer Agreement?
7.4	Is there a cost recovery system in place?
7.5	Is there a dedicated policy for the return of the results from users?
8	**ETHICAL, LEGAL AND SOCIAL IMPLICATIONS (ELSI)**
8.1	Do you have an Ethical Committee approval for your biobanking activity?
8.2	Are the biological samples collected with an informed consent from the patients?
8.3	Does the informed consent include the option for patients to withdraw sample at any time?
8.4	Is international exchange of samples considered in the informed consent?

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