





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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