BOX1: Essential elements for the informed consent of biobanks and observational studies

- ☐ General (name of the PI, Institution, funding, duration, oversight, contact persons)
- ☐ Aims, research uses of data (e.g cancer research, RD research)
- ☐ Voluntariness of participation and possibility to withdraw
- ☐ Procedures involved in participation, including interviews, blood taking, etc.
- ☐ kinds of samples and data that will be collected;
- ☐ Potential physical, psychological and social risks
- ☐ Potential benefits
- ☐ Description of the coding system
- ☐ Protections in place locally to ensure the confidentiality of samples and data;
- ☐ Access to data/samples for research purposes: who will have access who should control and what the procedures in place (data access committee)
- ☐ Access to data/samples for purposes such as validation, quality control, etc.
- ☐ Study oversight
- ☐ Compensation/reimbursement
- ☐ Custodianship of samples;
- ☐ Study dissemination.

Core elements for the informed consent of studies participating to RD-Connect

- ☐ Hosting of the data in an open access database
- ☐ Access by industry if foreseen
- ☐ Possible linkage to different data (registries, medical records, etc)
- ☐ Possibility of large scale genome sequencing techniques
- ☐ Possibility of data sharing across research groups and national borders
- ☐ Return of incidental findings
- ☐ Withdrawal procedures, such as sample retrieval and/or destruction
- ☐ Prospects for third-party commercialization and intellectual property procedures;