



## EuroDSD Standard Operating Procedure (SOP) for Handling and coding of biological samples

### Prerequisites for the exchange biomaterials

- EuroDSD is a European consortium working on the elucidation of the pathophysiology of Disorders of Sex Development in a collaboration of clinical centers with research partners. It involves entry of pseudomized patient data into a central registry. Data entry requires patient consent. The registry will contain information if biological material (blood or its derivatives, tissue, urine) is available from the patient at the initiating clinical center.
- The registry must contain information if informed consent for exchange of biomaterials of patients between clinical centers and research partners is available.
- Consent forms must be available to the coordinator of EuroDSD upon request.
- Only materials where consent has been obtained will be exchanged.
- The exchange of biomaterials is solely for the purpose of DSD research as agreed upon within the EuroDSD grant agreement with the European Commission.

### Coding of Biomaterials

- Patient entry into the central registry will lead to creation of a unique identifier.
- Only the entering clinical center will be able to link patient personal data to unique identifier. Personal data will be strictly kept away from the central registry, an outside link will not be possible.
- Biomaterials will be coded only with the unique identifier once exchanged within the EuroDSD consortium. Any exchanged biomaterial must not contain personal information of the patient. This is the legal responsibility of the clinical center.

### Handling of Biomaterials and Research Information

- The Clinical center will provide information on the storage of the biomaterials according to the biological SOPs provided within EuroDSD.
- The research partner will provide any research results on biomaterials obtained within EuroDSD into the virtual research environment which is part of the work package 1 in association with the central registry.
- The clinical centers will be able to view relevant summary conclusions on research data accumulated from biomaterials from their patient solely for the purpose of relating relevant information to the patient.
- Any scientific exploitation will be made in accordance with the consortium agreement within EuroDSD and the agreements made within the Project Governing Board and the Project Council.
- Materials will be stored by the recipient only for the research purposes within the agreed scientific project. Excess materials will be returned to the initial clinical center upon finishing the research project or destroyed if requested by the clinical center or as required by the national ethical review of center and partner.