**Contents**

1. Purpose and scope
2. Reference documents (standards)
3. Responsibilities
4. Description of the procedure
5. Related documents

**A-Purpose and field of application**

This procedure describes the organisation defined for the management of any request made to CeRBiM.

**B. Reference documents**

Standard NF EN ISO 20387: General requirements for biobanking

ISO 9001 standard: Quality management system - Requirements

**C. Responsibilities**

The CeRBiM coordinator is responsible for applying this procedure.

The quality manager ensures that the document is kept up to date.

**D-Description of the procedure**

 **☞D-1 Operational requests**



**🡺** All operational requests are :

- recorded and the actions traced in the "Follow-up of operational requests" spreadsheet

- analysed as a team

- discussed +/- with the people involved

- submitted to the weekly team meeting with the coordinator for approval

**🡺** For industrial applications: organise a meeting with DRCI to discuss regulatory issues

 **☞D-2 Other requests**

🡺Request related to a study: finance, monitoring, other

 Request communicated to the team and tracked in the study file

🡺 Requests for information, complaints, other :

* Discussed at a team meeting
* Traced, depending on the subject, in the server's reports **and/or** operational file **and/or** in accordance with the non-conformity management procedure **and** recorded via the EDM.

**E. Related documents**

Via Kalilab