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Procedures for centralized secure material and data storage, in agreement with the GDPR requirements

According to the Human bodily Material (HBM) law and the UZ/KU Leuven biobank policies, any scientific research including the collection, storage and/or use of HBM at the Leuven Health Science Campus has to be approved by and registered with the UZ/KU Leuven biobank. The UZ/KU Leuven Biobank acts as the sole notified biobank of the Leuven Health Science Campus, with dr. Kristel Van Landuyt as Biobank Manager. The UZ/KU Leuven biobank:

- Complies to relevant (inter)national legislation (EC approval, FAMHP notification)
- Operates according to a quality management system (~ISO20387, ISBER)
- Insured as legally required
- Instated an access policy (balancing interests of custodian and sharing of material)
- Will install a financial model (cost recovery vs research budget burden)
- Reports bi-annually to EC (including information as registered in biobank registry)
- Is member of (inter)national biobank networks and organisations (BBMRI, ESBB, ISBER)

The biobank approval, which is an application to be submitted to the UZ/KU Leuven biobank as soon as the study is registered (i.e. S-number available) at the UZ Leuven clinical trial center (https://gbiomed.kuleuven.be/english/ctc) has been granted in the context of both the retrospective and prospective studies.
More information about the legal framework and associated approach of the UZ KU Leuven Biobank can be found on the website: https://www.uzleuven.be/en/node/16773.
In addition, KU Leuven is committed to high ethical standards for the processing of personal data in academic and other contexts. It adheres to the requirements of the General Data Protection Regulation (GDPR) and other applicable laws. The way in which KU Leuven processes personal data is explained in the privacy notice at https://admin.kuleuven.be/privacy/en.

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When starting up research involving human data, researchers fill in an online form, the so-called PRET (PRivacy and EThics) form (https://www.kuleuven.be/pret) or the CTC GDPR questionnaire (https://www.uzleuven.be/nl/clinical-trial-center/ctc-gdpr-questionnaire) , which both ensure that all research involving human data are correctly logged in the KU/UZLeuven GDPR register. These forms were approved in in the context of both the retrospective and prospective studies. The way in which KU Leuven processes personal data is explained in the privacy notice at https://admin.kuleuven.be/privacy/en.