To the Chair of EC Research,

I confirm that artificialized/extracted HBM (Human Bodily Material) will be used in the scientific research project [*title*] and that

□ only already existing artificialized/ extracted HBM will be used

□ it will not be applied in humans

□ no genetic research on the artificialized/ extracted HBM will be performed

Only if you tick all checkboxes, the adapted procedure will apply.

In this adapted procedure, it is sufficient to submit the research project and its objectives to EC Research. If EC has not expressed any objections within 28 calendar days after receipt of the research project and this filled-in statement, the scientific research can be started. A submission to the Biobank UZ/KU Leuven is not necessary, nor a registration of this MLM.

If it concerns artificialized/ extracted HBM produced in Belgium after 18 March 2022 please confirm that

□ the traceability towards the donor is lifted

□ the donors have been informed of the possible production of the artificialized/ extracted HBM and the potential consequences thereof (art. 10, §5, 2nd indent of the Law of 19 December 2008 (HBM Law)) including the lifting of traceability of the material.

For artificialized/ extracted HBM (especially which is made in-house), the researcher should always consider whether it is appropriate to select this flow, as this would make future genetic research inadmissible.

For research involving **new** production of artificialized/extracted HBM, the standard flow in accordance with the HBM Law (including submission to biobank) still applies.

Yours sincerely

Name and signature of PI

Date:

**Legal definitions:**

human body material: any biological body material, including human tissues and cells, gametes, embryos, fetuses, as well as the substances extracted from them, whatever their degree of processing is, excluding substances of non-human origin

Application in humans: the use of human body material on or in a human receiver, including the extracorporeal application

Artificialized material: human body material produced or cultured outside of the human body

Extracted material: material extracted from human body material, but which no longer contains any cells

Genetic research: ‘scientific research, without application on humans, that is performed on genetic material such as DNA, RNA, irrespective whether the genetic material was isolated from other body material or not.