



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR RESEARCH & INNOVATION

The Director-General

Brussels,

***By registered letter with
acknowledgment of receipt:***

Leonid Schneider
Taunusstr 11
63526 Erlensee
Germany

Advance copy by email:
ask+request-5880-
c910c50a@asktheeu.org

**Subject: Your application for access to documents – Ref GestDem No
2018/4723**

Dear Mr Schneider,

I refer to your message of 28 August 2018 via which you submitted, within the framework of Regulation (EC) No 1049/2001¹, a request for access to documents, registered on 30 August under the abovementioned reference number.

With reference to *the UCL-led clinical trial INTENS ... Work Package 5 the "transplantation of engineered intestine" in patients, to take place at UCL (London, UK) and in UCLA (California, USA)*, you requested access to documents which contain the following information:

- *any issued ethical approvals for clinical trials on patients*
- *any approvals issued by EMA*
- *any recruiting clinical trials*
- *any transplantations already performed.*

¹ Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p. 43).

We regret to inform you that the Commission does not hold any documents that would correspond to the description provided in your application.

The Horizon 2020 project INTENS (INtestinal Tissue ENgineering Solution) does not have any deliverables related to clinical trials on patients under Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC.

As specified in Article 2(3) of Regulation 1049/2001, the right of access as defined in that Regulation applies only to existing documents in the possession of the institution. Given that no such documents corresponding to the description provided in your application are held by the Commission, we are not in a position to handle your request.

In accordance with Art 7(2) of Regulation 1049/2001, you are entitled to make a confirmatory application requesting the Commission to review this position. Such a confirmatory application should be addressed within 15 working days upon receipt of this letter to the Secretary-General of the Commission at the following address:

European Commission

Secretariat-General

Unit SG.DSG2.B.4 - Transparency

BERL 5/282

B-1049 Brussels

or

by email to: sg-acc-doc@ec.europa.eu

Yours sincerely,

Jean-Eric Paquet