REC 000000000000000000000000000000000000
0000000000 REC 0000000000000000000000000
REC 000000000000000000000000000000000000
REC
REC 000000000000000000000000000000000000
REC 000000000000000000000000000000000000
REC 000000000000000000000000000000000000

REC 0000 SOP 000000000000000000000000000000
- 000000000000000000000000000000000000
REC 000000000000000000000000000000000000

000000REC 000000000000000000000000000000
0000 (000000000) 0000000000000000000000
REC 000000000000000000000000000000000000
- 000000000000000000000000000000000000
REC
REC 000000000000000000000000000000000000

00000000000000000000000000000000000000
00000000000000000000000000000000000000
000000 (00000000) 00000000REC 000000000000000000000000000
REC 000000000000000000000000000000000000
SOPSOP
- DDDDDDD.

- **-** 0000000;
- **-** 000000000;
- **-** 00000000

00000000000000000000000000000000000000
 European Commission (2006). Detailed guidance on the application format and documentation to be submitted in

• European Commission (2006). Detailed guidance on the application format and documentation to be submitted in an application for an Ethics Committee opinion on the clinical trial on medicinal products for human use. Brussels: European Commission. Retrieved 12 July, 2021, from:

https://ec.europa.eu/health/sites/default/files/files/eu dralex/vol-10/12_ec_guideline_20060216_en.pdf



- World Medical Association (2013). Declaration of Helsinki — Ethical Principles for Medical Research Involving Human Subjects. Retrieved 12 July, 2021, from: https://www.wma.net/policies-post/wma-declaration-of-hel sinki-ethical-principles-for-medical-research-involvinghuman-subjects/
- 2. European Parliament and the Council (2009). DIRECTIVE 2001/20/EC on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use. Retrieved 12 July, 2021 from: https://ec.europa.eu/health/sites/default/files/files/eu dralex/vol-1/dir_2001_20/dir_2001_20_en.pdf



A2-4.15-V1.1