

Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010
on standards of quality and safety of human organs intended for transplantation

CHAPTER III

**DONOR AND RECIPIENT PROTECTION AND
DONOR SELECTION AND EVALUATION**

Article 16

Protection of personal data, confidentiality and security of processing

Member States shall ensure that the fundamental right to protection of personal data is fully and effectively protected in all organ donation and transplantation activities, in conformity with Union provisions on the protection of personal data, such as Directive 95/46/EC, and in particular Article 8(3), Articles 16 and 17 and Article 28(2) thereof. Pursuant to Directive 95/46/EC, Member States shall take all necessary measures to ensure that:

- (a) the data processed are kept confidential and secure in accordance with Articles 16 and 17 of Directive 95/46/EC. Any unauthorised accessing of data or systems that makes identification of donor or recipients possible shall be penalised in accordance with Article 23 of this Directive;
- (b) donors and recipients whose data are processed within the scope of this Directive are not identifiable, except as permitted by Article 8(2) and (3) of Directive 95/46/EC, and national provisions implementing that Directive. Any use of systems or data that makes the identification of donors or recipients possible with a view to tracing donors or recipients other than for the purposes permitted by Article 8(2) and (3) of Directive 95/46/EC, including medical purposes, and by national provisions implementing that Directive shall be penalised in accordance with Article 23 of this Directive;
- (c) the principles relating to data quality, as set out in Article 6 of Directive 95/46/EC, are met.