
STATUTORY INSTRUMENTS

2007 No. 1523

**The Human Tissue (Quality and Safety
for Human Application) Regulations 2007**

PART 2

**LICENSING OF ACTIVITIES RELATING TO THE
USE OF TISSUE FOR HUMAN APPLICATION**

Information and confidentiality

13.—(1) It shall be a condition of every licence under Schedule 1 that all necessary arrangements are made to ensure that all information which is collected in pursuance of the licence or a third party agreement in relation to the licence—

- (a) is available for the purpose of tracing donations;
- (b) is kept up-to-date and corrected without delay where any discrepancy relating to such information is identified; and
- (c) is held securely and subject to safeguards against unauthorised additions, deletions, modifications or transfer of information.

(2) Any information which is collected in pursuance of a licence under Schedule 1 or a third party agreement, and from which a donor (living or deceased) or recipient of tissue or cells may be identified, shall not be disclosed except where such disclosure—

- (a) is of information which has been rendered anonymous so that neither the donor nor recipient is identifiable,
- (b) is made in accordance with an order of a court,
- (c) is otherwise required by law,
- (d) is made to a person as a member or employee of the Authority,
- (e) is made to a person who is otherwise acting on behalf of the Authority in the exercise of its functions under these Regulations, including in particular its functions under Part 5 of these Regulations,
- (f) is made to a tissue establishment for the purpose of tracing a donation from donor to recipient or recipient to donor,
- (g) is made to a licence holder or a person to whom a licence applies for the purposes of his functions under the licence,
- (h) is made to a third party in relation to a licence for the purposes of his functions under a third party agreement,
- (i) is made pursuant to any consent to disclosure given by the person, being the donor or recipient of the tissue or cells, whose identity would be disclosed,
- (j) is necessary—
 - (i) for any purpose preliminary to proceedings,

- (ii) for the purpose of, or in connection with, any proceedings,
 - (iii) for the purpose of reporting a suspected offence,
 - (iv) for the purpose of cooperating with a police investigation,
 - (v) for the purpose of investigating a serious adverse event or serious adverse reaction,
- (k) is made by a licence holder or designated individual in accordance with directions given to that person by the Authority under section 23(1) or 24(1) of, or paragraph 2(4) of Schedule 3 to, the 2004 Act, as applied by regulation 8, or
- (l) is of information which has been lawfully made available to the public before the disclosure is made.
- (3) References to proceedings in paragraph (2)(j) include any formal procedure for dealing with a complaint.
- (4) Where a disclosure is made to a person pursuant to paragraph (2)(d) or (e), that person shall not further disclose the information received unless the disclosure—
- (a) is made in accordance with paragraph (2), or
 - (b) is made by the Authority for the purpose of its obligations under regulations 17 and 20.