# 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 (Text with EEA relevance)

## CHAPTER XVIII

## MISCELLANEOUS PROVISIONS

### *Article 90*

### Specific requirements for special groups of medicinal products

This Regulation shall not affect the application of national law prohibiting or restricting the use of any specific type of human or animal cells, or the sale, supply or use of medicinal products containing, consisting of or derived from those cells, or of medicinal products used as abortifacients or of medicinal products containing narcotic substances within the meaning of the relevant international conventions in force such as the Single Convention on Narcotic Drugs of 1961 of the United Nations. The Member States shall communicate that national law to the Commission.

No gene therapy clinical trials may be carried out which result in modifications to the subject's germ line genetic identity.

### *Article 91*

### Relation with other Union legislation

This Regulation shall be without prejudice to Council Directive 97/43/Euratom[(1)], Council Directive 96/29/Euratom[(2)], Directive 2001/18/EC of the European Parliament and of the Council[(3)], Directive 2004/23/EC of the European Parliament and of the Council[(4)], Directive 2002/98/EC of the European Parliament and of the Council[(5)], Directive 2010/53/EC of the European Parliament and of the Council[(6)], and Directive 2009/41/EC of the European Parliament and of the Council.[(7)]

### *Article 92*

### Investigational medicinal products, other products and procedures, free of charge for the subject

Without prejudice to the Member States' competence for the definition of their health policy and for the organisation and delivery of health services and medical care, the costs for investigational medicinal products, auxiliary medicinal products, medical devices used for their administration and procedures specifically required by the protocol shall not be borne by the subject, unless the law of the Member State concerned provides otherwise.

*Article 93*

**Data protection**

1 Member States shall apply Directive 95/46/EC to the processing of personal data carried out in the Member States pursuant to this Regulation.

2 Regulation (EC) No 45/2001 shall apply to the processing of personal data carried out by the Commission and the Agency pursuant to this Regulation.

*Article 94*

**Penalties**

1 Member States shall lay down rules on penalties applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate and dissuasive.

2 The rules referred to in paragraph 1 shall address, inter alia, the following:

a non-compliance with the provisions laid down in this Regulation on submission of information intended to be made publicly available to the EU database;

b non-compliance with the provisions laid down in this Regulation on subject safety.

*Article 95*

**Civil and criminal liability**

This Regulation is without prejudice to national and Union law on the civil and criminal liability of a sponsor or an investigator.

(**1**) Council Directive 97/43/Euratom of 30 June 1997 on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure, and repealing Directive 84/466/Euratom (OJ L 180, 9.7.1997, p. 22).

(**2**) Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation (OJ L 159, 29.6.1996, p. 1).

(**3**) Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1).

(**4**) Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells (OJ L 102, 7.4.2004, p. 48).

(**5**) Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC (OJ L 33, 8.2.2003, p. 30).

(**6**) 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 (OJ L 207, 6.8.2010, p. 14).

(**7**) Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms (OJ L 125, 21.5.2009, p. 75).

**Status:**
Point in time view as at 31/01/2020.

**Changes to legislation:**
There are currently no known outstanding effects for the Regulation (EU) No 536/2014 of the European Parliament and of the Council, CHAPTER XVIII.