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 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.

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, Article 94.