Supplemental Table 1: Analysis of policy frameworks

## Country-Specific Provisions

### UNITED STATES

The Food and Drug Administration have formally proposed an amendment to its regulations to allow an alteration or waiver of consent for FDA-regulated clinical investigations, thereby harmonizing provisions for non-regulated and regulated trials.

**Simplified consent**
No requirement to include all elements of Good Clinical Practice in either the Common Rule or Food and Drug Administration (FDA) regulation.
No requirement for written informed consent. Ethics committees may separately waive the requirement to document consent for both non-regulated and regulated trials.

**Alteration/waiver of consent**
For non-regulated trials, alteration and waiver of consent is permitted under the Common Rule. For regulated trials, a proposed rule in the Federal Register harmonizes the requirements with the Common Rule under the 21st Century Cures Act. These provisions are promulgated in Food and Drugs Administration Guidance which may be applied before its regulations are revised.

**Waiver of consent to use/disclose protected health information:** Permitted under the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule if: The use or disclosure involves no more than minimal risk, is impracticable without access to protected health information and there are adequate provisions to protect the privacy and maintain the confidentiality of data.

### AUSTRALIA

Provisions for non-regulated and regulated trials appear to permit harmonization through *de facto* provisions promulgated by the Therapeutic Goods Administration that permit regulated trials to default to the National Statement on Ethical Conduct in Human Research (the National Statement) if Good Clinical Practice requirements conflict with the National Statement.

**Provisions for both regulated and non-regulated trials**

**Simplified consent:** No requirement in the National Statement to include all elements of Good Clinical Practice or for consent to be written, signed and dated as long as participants’ decisions are clearly established.

**Alteration/waiver of consent:** In the absence of research-specific regulation, investigators must consider separate sources of information:

- **Alteration/waiver of consent to disclose trial participation:** The National Statement makes provision for waiver under (2.3.10); alteration through limited disclosure (2.3.1) and through opt-out (2.3.5).
- **Waiver of consent to receive a treatment:** Common law requires disclosure of the nature and purpose of the treatment and the material risks, benefits and reasonable alternatives.
- **Waiver of consent to collect/use/disclose data:** Permitted under Commonwealth privacy legislation if: Privacy risks are low, it is impracticable to seek consent, the research could not be carried out using de-identified information, and the public interest in the collection of
health information substantially outweighs the public interest in maintaining the level of privacy protection afforded by the Australian Privacy Principles.¹¹

**ENGLAND**

The requirements for non-regulated and regulated trials differ markedly and are detailed separately.

**Provisions for non-regulated trials**

**Simplified consent:** No legal requirement to include all elements of Good Clinical Practice and no requirement for written, signed consent.¹²

**Alteration/waiver of consent:** In the absence of research-specific regulation, investigators must consider separate sources of information:

- **Alteration/waiver of consent to disclose trial participation:** National guidance currently does not endorse or prohibit alteration or waiver of consent.¹²
- **Waiver of consent to receive treatment:** Common law requires disclosure of the nature and purpose of the treatment and the material risks, benefits and reasonable alternatives.¹³,¹⁴
- **Waiver of consent to process data:** The General Data Protection Act 2018¹⁵ implementing the General Data Protection Regulation (GDPR)¹⁶ requires a legal basis to process personal data. Although consent is one possible legal basis, an alternative legal basis may be used such as ‘task in the public interest’ or ‘legitimate interests’.¹⁷ In addition, for the common law duty of confidentiality to be set aside, support under Section 251 of the NHS Act (2006)¹⁸ must be obtained. Support may be granted if: It is impracticable to seek consent, the research cannot be carried out using de-identified information, and the research is in the public interest or in the interests of improving patient care.

**Provisions for regulated medicinal product trials - European Regulation No 536/2014¹⁹**

Existing clinical trials regulation for medicinal products will be replaced with European Regulation No 536/2014 in 2019/20¹⁹ so we focus on the latter. If adopted ‘post Brexit’, this regulation will apply to all medicinal product trials, including products used within the terms of their marketing authorization.

**Simplified consent:** No requirement to include all elements of Good Clinical Practice. All trials will require written, signed and dated informed consent (with the exception of a sub-set of cluster trials under Article 30).

**Waiver of consent:** Not permitted.

**Alteration (of consent content):** Not permitted. Must include elements listed in Article 29.

**Alteration (of consent process):** Not permitted - except for a sub-set of cluster trials under Article 30 where an opt-out approach is permitted.

**References**


13. Chatterton vs Gerson: QB 431 1 All ER 257 (QBD), 1981.


