Investigator Initiated Studies (IIS) Governance References

All applicable industry codes, local or regional, regulating IIS should be observed. Examples include but not limited to below list.

APACMed Code of Ethical Conduct for Interactions with Health Care Professionals 2020
https://apacmed.org/content/uploads/2020/05/APACMed-Code-of-Ethical-Conduct-2020.pdf

Australia – Code of Practice 2020
https://www.mtaa.org.au/sites/default/files/uploaded-content/field_f_content_file/code_of_practice_e11_-_2020_revised.pdf

Brazil – Abimed Code of Conduct 2018
https://abimed.org.br/wp-content/uploads/2022/07/CodigoCondutaEN.pdf

Canada Medtech Code of conduct 2019
https://medtechcanada.org/files/Code_of_Conduct/2019_Medtech_Canada_Code_EN.pdf

Europe - MedTech Europe Code of Ethical Business Practice 2022
https://www.medtecheurope.org/resource-library/medtech-europe-code-of-ethical-business-practice/

New Zealand – Code of Practice 2016
https://mtanz.org.nz/filescust/CMS/Training/Code_of_Practice_2016.pdf

US - AdvaMed Code of Ethics on Interactions with Health Care Professionals 2020
https://www.advamed.org/member-center/resource-library/advamed-code-of-ethics/

Europe for pharmaceuticals - EFPIA Code of Practice
https://www.efpia.eu/relationships-code/the-efpia-code/

Regulation 2016/679 European Union General Data Protection Regulation (GDPR)

Health Insurance Portability and Accountability Act of 1996 (HIPAA Privacy Rule)

ISO 14155:2020 Clinical investigation of medical devices for human subjects – Good clinical practice (GCP)

ICH E6(R2) Good Clinical Practice (GCP)

WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects as last amended 2013
http://www.wma.net/en/30publications/10policies/b3/

The Nuremberg Code – Principles for absolute requirement of voluntary informed consent (P1) and the right of the subject to withdraw (P9)

National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research. The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research

Article 4 of Directive 2010/63/EU “Principle of 3R’s (Replacement, Reduction, and Refinement)