

ISO/TS 17975:2015-09 (E)

Health informatics - Principles and data requirements for consent in the Collection, Use or Disclosure of personal health information

Contents		Page
Foreword		iv
Introduction		v
1	Scope	1
2	Normative references	2
3	Terms and definitions	2
4	Symbols and abbreviated terms	7
5	Consent requirements	7
5.1	General	7
5.2	What is Informational Consent?	8
5.3	Consent to Treatment versus Informational Consent	8
5.4	How consent relates to privacy, duty of confidence and to Authorization	8
5.5	Relationship of consent to OECD Guidelines	9
5.6	Relationship of consent to legislation	9
5.7	Expectations and rights of the individual	10
5.8	Consent Directives	10
5.9	Consent is related strongly to Purpose of Use	10
5.10	Consent to Collect and Use versus Consent to Disclose	11
5.11	Consent is applicable to specified data	12
5.12	Consent related to Disclosure	12
5.13	Exceptional access	12
5.14	Challenges associated with obtaining consent	13
6	Consent frameworks	13
6.1	Giving consent meaning	13
6.2	Types of consent	15
6.3	Detailed requirements	16
6.3.1	Express or Expressed (informed) Consent	16
6.3.2	Implied (Informed) Consent	18
6.3.3	No Consent Sought	19
6.3.4	Assumed Consent (Deemed Consent)	20
7	Mechanisms and process: Denial, Opt-in and Opt-out, and Override	21
7.1	Express or Expressed (and Informed) Denial	21
7.2	Opt-in and Opt-out	22
7.2.1	Opt-in	22
7.2.2	Opt-out	22
7.3	Override	22
8	Minimum data requirements	22
Annex A (informative)	Consent framework diagrams	24
Annex B (informative)	Jurisdictional implementation examples	30
Bibliography		34