

Supplementary material

1. INHERENT Ethics WG questionnaire

Contact Person Details (who fills in the survey):

Full Name:

Name of the institution:

Country:

Position in the institution:

Email address:

SECTION A – Data protection

1. Are there in your country any laws that regulate the processing¹ of personal data (e.g., name, age, contact details)?
- ☐ Yes
☐ No
☐ I don't know

If yes, please specify the following information for each document:

References: (title, year, releasing institution, ...)

Link to the official document/s:

Link to the English version (if available):

If the link is not available, please upload here the official document/s:

2. Are there in your country/institution any guidelines/recommendations for processing personal data?
- ☐ Yes
☐ No
☐ I don't know

If yes, please specify the following information for each document:

References: (title, year, releasing institution, ...)

Link to the official document/s:

Link to the English version (if available):

If the link is not available, please upload here the official document/s:

3. Health data represent a special category of personal data. Are there in your country any national laws and/or guidelines/recommendations for processing health data (e.g., data from clinical practice, clinical studies, Electronic Health Records, patient registries etc.)?
- ☐ Yes
☐ No
☐ I don't know

If yes, please specify the following information for each document:

References: (title, year, releasing institution, ...)

Link to the official document/s:

Link to the English version (if available):

If the link is not available, please upload here the official document/s:

4. Genetic data represent a special category of personal data. Are there in your country any national laws and/or guidelines/recommendations for processing genetic data?
- ☐ Yes
☐ No

¹Any operation or set of operations which is performed on personal data or on sets of personal data, whether or not by automated means, such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction (REGULATION (EU) 2016/679 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL)

☐ I don't know

If yes, please specify the following information for each document:

References: (title, year, releasing institution, ...)

Link to the official document/s:

Link to the English version (if available):

If the link is not available, please upload here the official document/s:

5. Do the existing laws and guidelines in your country include de-identification measures for personal data (including health and genetic data)?

☐ Yes

☐ No

☐ I don't know

If yes, please specify:

6. Do the existing laws and guidelines in your country require that an informed consent shall be obtained from the subject for data processing?

☐ Yes

☐ No

☐ I don't know

If yes, do the existing laws/guidelines in your country provide information to be included in the consent documents?

☐ Yes

☐ No

☐ I don't know

If yes, please specify:

7. Do the existing laws and guidelines in your country allow the secondary use of data?

☐ Yes

☐ No

☐ I don't know

8. Do the existing laws and guidelines in your country allow the transfer of data to third parties, including other countries?

☐ Yes

☐ No

☐ I don't know

If yes, is a data transfer agreement required?

☐ Yes

☐ No

☐ I don't know

9. Are ad hoc provisions for children included in the above-mentioned laws/guidelines?

☐ Yes

☐ No

☐ I don't know

If yes, please specify which provisions and provide the relevant law:

10. Is the authorisation from a National Competent Authority required for processing personal data for health research purposes?

☐ Yes

☐ No

☐ I don't know

If yes, please specify:

a. Name of the Competent Authority:

b. Contact details: (email, address, phone number, website)

11. Is the approval from an Ethics Committee required for processing personal data for health research purposes?

☐ Yes

☐ No

☐ I don't know

SECTION B – Clinical research

1. Are there in your country any laws that regulate clinical research?

☐ Yes

☐ No

☐ I don't know

If yes, please specify the following information for each document:

References: (title, year, releasing institution, ...)

Link to the official document/s:

Link to the English version (if available):

If the link is not available, please upload here the official document/s:

2. Are ad hoc provisions for children included in the existing laws in your country?

☐ Yes

☐ No

☐ I don't know

If yes, please specify which provisions and provide the relevant law:

3. Are there in your country/institution any guidelines/recommendations for conducting research involving adults?

☐ Yes

☐ No

☐ I don't know

If yes, please specify the following information for each document:

References: (title, year, releasing institution, ...)

Link to the official document/s:

Link to the English version (if available):

If the link is not available, please upload here the official document/s:

4. Are there in your country/institution any guidelines/recommendations for conducting research involving children?

☐ Yes

☐ No

☐ I don't know

If yes, please specify the following information for each document:

References: (title, year, releasing institution, ...)

Link to the official document/s:

Link to the English version (if available):

If the link is not available, please upload here the official document/s:

5. Do the existing laws and guidelines in your country allow the storage of collected sample for future research uses?

☐ Yes

☐ No

☐ I don't know

6. Is the approval from an Ethics Committee required to conduct research involving humans?

☐ Yes

☐ No

☐ I don't know

7. How many Ethics Committees are in place in your country?

☐ 1 (National)

☐ more than 1

☐ I don't know

8. Which type of studies requires an ethical approval?

☐ Interventional Clinical trials with drugs

☐ Non interventional Clinical studies

☐ Clinical studies on genetic data with/without drugs

9. Is the authorisation from a National Competent Authority required to conduct a research involving human subjects?

☐ Yes

☐ No

☐ I don't know

If yes, please specify:

a. **Name of the Competent Authority:**

b. **Contact details:** (email, address, phone number, website)

c. **Type of study requiring such an authorisation:**

Informed Consent

1. Do the existing laws and guidelines in your country require that an informed consent shall be obtained from study participants?

☐ Yes

☐ No

☐ I don't know

If yes, do the existing laws/guidelines in your country provide information to be included in the consent documents?

☐ Yes

☐ No

☐ I don't know

If yes, please specify:

2. Is the informed assent required for children/minors involved in the study?

☐ Yes

☐ No

☐ I don't know

If yes, do the existing laws/guidelines in your country provide information to be included in the assent documents?

☐ Yes

☐ No

☐ I don't know

If yes, please specify:

3. What is the legal age of consent in your country?

Please specify:

4. Do the existing laws and guidelines in your country foresee any confirmation/modification/withdrawal of the parental consent when the minor reaching the legal age of majority?

☐ Yes

☐ No

☐ I don't know

5. Do the existing laws and guidelines in your country require that an informed consent shall be obtained from the legal representative of the vulnerable study participants (such as subjects unable to provide consent due to mental disability)?

☐ Yes

☐ No

☐ I don't know

6. Do the existing laws and guidelines in your country require that a separate consent shall be obtained from study participants for genetic tests?

☐ Yes

☐ No

☐ I don't know

If yes, do the existing laws/guidelines in your country provide information to be included in the consent documents?

☐ Yes

☐ No

☐ I don't know

If yes, please specify:

SECTION C - Biosamples management

1. Are there in your country any laws/guidelines/recommendations on biosamples management?

☐ Yes

☐ No

☐ I don't know

If yes, please specify the following information for each document:

References: (title, year, releasing institution, ...)

Link to the official document/s:

Link to the English version (if available):

If the link is not available, please upload here the official document/s:

2. Are there in your country any provisions for the collection and management of biological material?

☐ Yes

☐ No

☐ I don't know

If yes, please specify which provisions and provide the relevant law:

3. Are there in your country any provisions on the storage of biological samples (e.g., duration, appropriate safety and confidentiality conditions, planned de-identification measures, etc)?

☐ Yes

☐ No

☐ I don't know

If yes, please specify which provisions and provide the relevant law:

4. Are there in your country any provisions for the transfer of biological samples to other countries?

☐ Yes

☐ No

☐ I don't know

If yes, please specify which provisions and provide the relevant law:

5. Are there in your country any specific measures for handling biosamples in paediatric and vulnerable populations (e.g., size-/age-appropriate tools, non-invasive procedure, maximum of blood)?

☐ Yes

- ☐ No
- ☐ I don't know

If yes, please specify:

6. Are there in your country any requirements for handling biological samples for genetic tests?

- ☐ Yes
- ☐ No
- ☐ I don't know

If yes, please specify:

7. Do the existing laws and guidelines in your country include measures for samples destruction, in case the consent is withdrawn?

- ☐ Yes
- ☐ No
- ☐ I don't know

If yes, please specify:

Is there any other reference person who can provide us with further information on above topics?

- ☐ Yes
- ☐ No

If yes, please specify:

- a. Full name:**
- b. Institution:**
- c. Email address:**

2. Supplementary tables and figures

Table S1. Official documents by topic.

Key topics	Official documents	Reference
Clinical research	United Nations Education, Culture and Science (UNESCO). International Declaration on Human Genetic Data.	[14]
	World Medical Association. Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects. 2013	[15]
	UNESCO. Universal Declaration on the Human Genome and Human Rights. 1997	[53]
	OECD Guidelines on Human Biobanks and Genetic Research Databases. 2009	[55]
	OECD. Recommendation on Health Data Governance. OECD Legal Instruments; 2017	[56]
	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. ICH Harmonised Guideline. E8(R1) - General Considerations for Clinical Studies. Final version, October 2021	[58]
	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. ICH Harmonised Guideline. E11(R1) - Addendum: Clinical Investigation of Medicinal Products in the Pediatric Population. Final version, August 2017	[59]
	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. ICH Harmonised Tripartite Guideline. E15 - Definitions for Genomic Biomarkers, Pharmacogenomics, Pharmacogenetics, Genomic Data and Sample Coding Categories. Current Step 4 version, November 2007	[60]
	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. ICH Harmonised Guideline. E18 - Genomic Sampling and Management of Genomic Data. Current Step 4 version, August 2017	[61]
	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. ICH Harmonised Guideline. E17 - General principles for planning and design of Multi-Regional Clinical Trials. Current Step 4 version, November 2007	[80]
	Council for International Organizations of Medical Sciences. Guidance on Clinical research in resource-limited settings. ISBN: 978-929036100-8. 2021	[62]
	Council for International Organizations of Medical Sciences in collaboration with the World Health Organization. International Ethical Guidelines for Health-related Research Involving Humans. ISBN 978-929036088-9. 2016	[63]
	Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (ETS No. 164) - Oviedo convention. 1997	[64]
	Council of Europe. Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research (CETS No. 195). 2005	[65]
	Committee of Ministers. Recommendation CM/Rec(2016)6 of the Committee of Ministers to member States on research on biological materials of human origin. May 2016.	[66]
	U.S. Department of Health and Human Services. International Compilation of Human Research Standards. 2021	[67]
	National Institutes of Health. Genomic Data Sharing (GDS) Policy. August 2014	[68]
	National Institutes of Health. Policy for Genome-Wide Association Studies (GWAS). January 2008	[69]
	National Institutes of Health. Informed Consent for Secondary Research with Data and Biospecimens: Points to Consider and Sample Language for Future Use and/or Sharing. May 2022	[70]

Key topics	Official documents	Reference
	National Institutes of Health. Guidance on Consent for Future Research Use and Broad Sharing of Human Genomic and Phenotypic Data Subject to the NIH Genomic Data Sharing Policy. November 2018	[71]
	U.S. Department of Health and Human Services, Office for Human Research Protections. Coded Private Information or Biospecimens Used in Research. January 2018	[72]
	U.S. Department of Health and Human Services, Office for Human Research Protections. Genetic Information Nondiscrimination Act (GINA): OHRP Guidance. March 2009	[73]
	Court in U.S. v Brandt. Nuremberg Code: Directives for Human Experimentation. 1947	[79]
	National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Belmont Report - Ethical Principles and Guidelines for the Protection of Human Subjects of Research. April 1979	[74]
	European Commission expert group on clinical trials in preparation for the implementation of Regulation (EU) No 536/20141 on clinical trials on medicinal products for human use. Ethical considerations for clinical trials on medicinal products conducted with minors. Revision 1, September 2017.	[81]
	European Parliament and Council of the European Union. Regulation (EU) 2016/679 of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation).	[25]
	United Nations Education, Culture and Science (UNESCO). International Declaration on Human Genetic Data.	[14]
	World Medical Association. Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects. 2013	[15]
	UNESCO. Universal Declaration on the Human Genome and Human Rights. 1997	[53]
	OECD. Recommendation on Health Data Governance. OECD Legal Instruments; 2017	[56]
	Council of Europe. Convention 108+ Convention for the protection of individuals with regard to the processing of personal data. 2018	[57]
	World Medical Association. Declaration of Taipei on Ethical Considerations Regarding Health Databases and Biobanks. October 2016	[76]
	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. ICH Harmonised Tripartite Guideline. E15 - Definitions for Genomic Biomarkers, Pharmacogenomics, Pharmacogenetics, Genomic Data and Sample Coding Categories. Current Step 4 version, November 2007	[60]
	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. ICH Harmonised Guideline. E18 - Genomic Sampling and Management of Genomic Data. Current Step 4 version, August 2017	[61]
Data protection	Council for International Organizations of Medical Sciences. Guidance on Clinical research in resource-limited settings. ISBN: 978-929036100-8. 2021	[62]
	Council for International Organizations of Medical Sciences in collaboration with the World Health Organization. International Ethical Guidelines for Health-related Research Involving Humans. ISBN 978-929036088-9. 2016	[63]
	Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (ETS No. 164) - Oviedo convention. 1997	[64]
	Council of Europe. Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research (CETS No. 195). 2005	[65]
	European Commission expert group on clinical trials in preparation for the implementation of Regulation (EU) No 536/20141 on clinical trials on medicinal	[81]

Key topics	Official documents	Reference
	products for human use. Ethical considerations for clinical trials on medicinal products conducted with minors. Revision 1, September 2017.	
	U.S. Department of Health and Human Services. International Compilation of Human Research Standards. 2021	[67]
	National Institutes of Health. Policy on Certificates of Confidentiality. October 2017	[77]
	National Institutes of Health. Genomic Data Sharing (GDS) Policy. August 2014	[68]
	National Institutes of Health. Policy for Genome-Wide Association Studies (GWAS). January 2008	[69]
	National Institutes of Health. Policy for Data Management and Sharing. January 2023	[78]
	National Institutes of Health. Informed Consent for Secondary Research with Data and Biospecimens: Points to Consider and Sample Language for Future Use and/or Sharing. May 2022	[70]
	National Institutes of Health. Guidance on Consent for Future Research Use and Broad Sharing of Human Genomic and Phenotypic Data Subject to the NIH Genomic Data Sharing Policy. November 2018	[71]
	U.S. Department of Health and Human Services, Office for Human Research Protections. Coded Private Information or Biospecimens Used in Research. January 2018	[72]
	U.S. Department of Health and Human Services, Office for Human Research Protections. Genetic Information Nondiscrimination Act (GINA): OHRP Guidance. March 2009	[73]
	OECD. Privacy Framework. 2022.	[75]
	U.S. Department of Health and Human Services, Food and Drug Administration. Certificates of Confidentiality - Guidance for Sponsors, Sponsor-Investigators, Researchers, Industry, and Food and Drug Administration Staff. September 2020	[79]
Biospecimens management	United Nations Education, Culture and Science (UNESCO). International Declaration on Human Genetic Data.	[14]
	UNESCO. Universal Declaration on the Human Genome and Human Rights. 1997	[53]
	International Society for Biological and Environmental Repositories (ISBER). Recommendations for repositories, Fifth edition. 2023	[54]
	OECD Guidelines on Human Biobanks and Genetic Research Databases. 2009	[55]
	World Medical Association. Declaration of Taipei on Ethical Considerations Regarding Health Databases and Biobanks. October 2016	[76]
	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. ICH Harmonised Tripartite Guideline. E15 - Definitions for Genomic Biomarkers, Pharmacogenomics, Pharmacogenetics, Genomic Data and Sample Coding Categories. Current Step 4 version, November 2007	[60]
	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. ICH Harmonised Guideline. E18 - Genomic Sampling and Management of Genomic Data. Current Step 4 version, August 2017	[61]
	Council for International Organizations of Medical Sciences. Guidance on Clinical research in resource-limited settings. ISBN: 978-929036100-8. 2021	[62]
	Council for International Organizations of Medical Sciences in collaboration with the World Health Organization. International Ethical Guidelines for Health-related Research Involving Humans. ISBN 978-929036088-9. 2016	[63]
	Committee of Ministers. Recommendation CM/Rec(2016)6 of the Committee of Ministers to member States on research on biological materials of human origin. May 2016.	[66]
	European Commission expert group on clinical trials in preparation for the implementation of Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use. Ethical considerations for clinical trials on medicinal products conducted with minors. Revision 1, September 2017.	[81]

Key topics	Official documents	Reference
	U.S. Department of Health and Human Services. International Compilation of Human Research Standards. 2021	[67]
	National Institutes of Health. Genomic Data Sharing (GDS) Policy. August 2014	[68]
	National Institutes of Health. Informed Consent for Secondary Research with Data and Biospecimens: Points to Consider and Sample Language for Future Use and/or Sharing. May 2022	[70]
	U.S. Department of Health and Human Services, Office for Human Research Protections. Coded Private Information or Biospecimens Used in Research. January 2018	[72]

Documents covering more than one topic were included more than ones

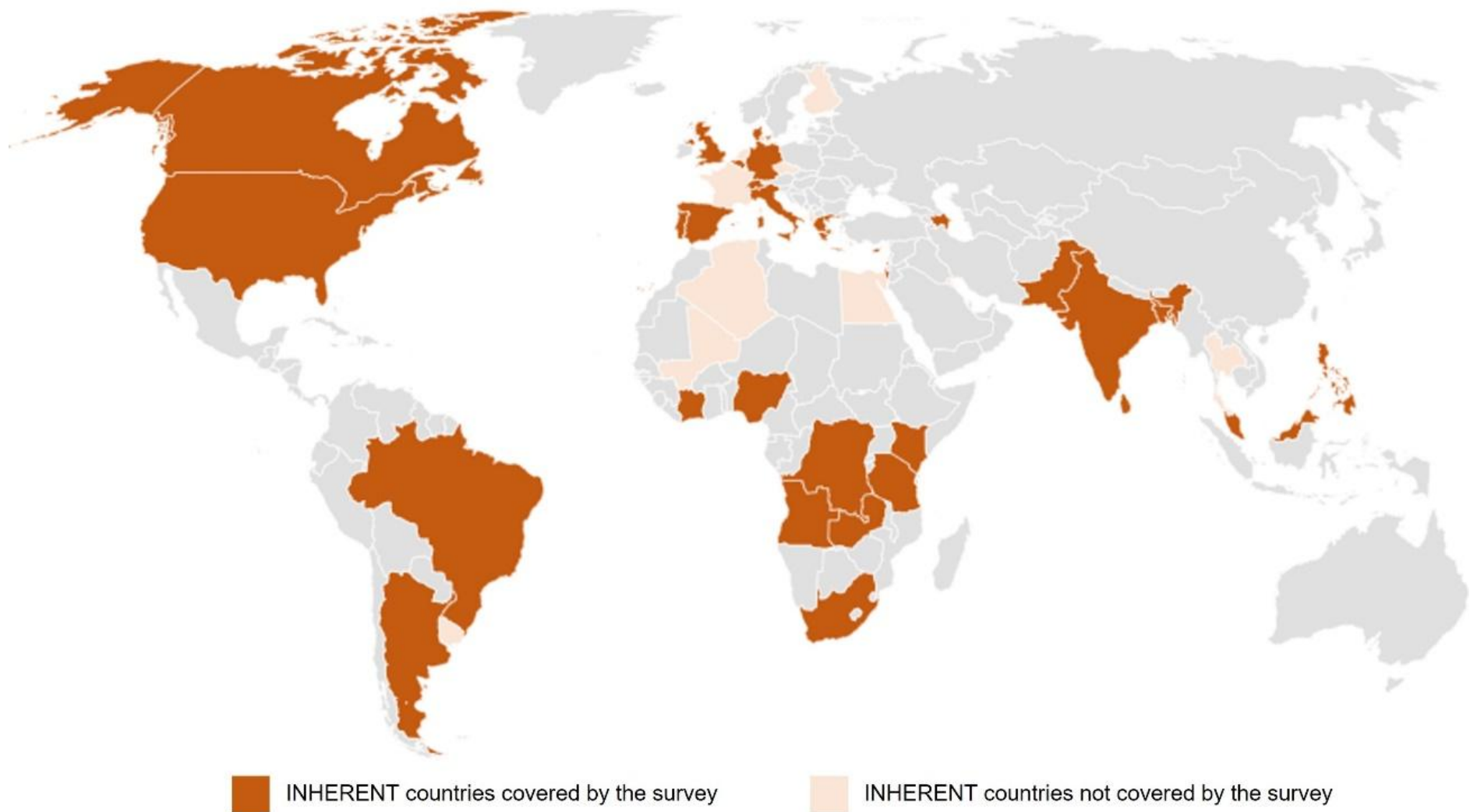


Figure S1. Geographical distribution of the received responses.

Table S2. Overview of the local framework on data protection

Countries	Applicable law/regulation/guidelines	Informed consent required	Secondary use	Data Transfer	Provisions for children	EC approval	CA authorisation
Angola	NA	yes	yes	yes	NA	yes	NA
Argentina	National Law 25326 10/30/2000	yes	yes	yes	yes	yes	yes
Azerbaijan	None ²	yes	yes	yes	NA	yes	no
Bangladesh	None ³	no	yes	yes	no	yes	no
Belgium	Belgian Law of 30 July 2018	yes	yes	yes	yes	yes	yes
Brazil	REV ASSOC MED BRAS. 2013; 59(1):72-77	yes	NA	yes	NA	yes	yes
Brunei	Data Protection Policy v2.2 - E-Government National Centre	yes	yes	no	no	yes	yes
Canada	Personal Health Information Protection Act, 2004	yes	NA	NA	NA	yes	NA
Côte d'Ivoire	NA	NA	yes	NA	NA	NA	NA
Cyprus	The Processing of Personal Data Law 2001; Law 125(I)/2018; The Safeguarding and Protection of the Patient's Rights Law, 2004; Law No. 25(I)/2021; Number 150(I) of 2001 Law Providing For The Establishment And Function Of The National Bioethics Committee	yes	yes	yes	yes	yes	yes
Democratic Republic of the Congo	Ministère de la Santé, DR Congo, PNDS 2016-2020	yes	NA	NA	yes	yes	yes
Denmark	Danish Data Protection Act, 2018	NA	yes	yes	NA	no	yes
Germany	Federal Data Protection Act (BDSG), 2021	yes	yes	yes	NA	yes	yes
Greece	NA	NA	NA	NA	NA	NA	NA

² Law No. 998-IIIQ 11 May 2010 on Personal Data does actually rule data protection in Azerbaijan. <https://natlex.ilo.org/dyn/natlex2/natlex2/files/download/86656/AZE-86656.pdf>

³ At the time the survey was conducted, no official document was available. However, in 2023, the 'Law No. 003-2023/ALT on the Protection of Personal Data' was issued. <https://www.dlapiperdataprotection.com/?t=law&c=BD>

Countries	Applicable law/regulation/guidelines	Informed consent required	Secondary use	Data Transfer	Provisions for children	EC approval	CA authorisation
India	Indian Council of Medical Research. National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017	yes	yes	yes	yes	yes	no
Israel	Details not available	yes	yes	yes	yes	yes	yes
Italy	D. Lgs. 10 Agosto 2018, N. 101; Garante della Privacy, Autorizzazione n. 9/2016	yes	yes	yes	yes	yes	no
Kenya	Public Health Act, 2012; Health Act, 2017; The HIV and AIDS Prevention and Control Act, 2006; Article 31(c) and (d), the Data Protection Act, 2019	NA	NA	NA	yes	yes	NA
Malaysia	Personal Data Protection Act, 2010; Malaysian Medical Council, Guidelines on Confidentiality, 2011; Clinical Research Malaysia Personal Data Protection Guidelines; Ministry of Health, Guidelines on Ethical Issues in the Provision of Medical Genetics Services in Malaysia, 2019	yes	yes	yes	yes	yes	yes
Malta	Chapter 586 Data Protection Act, 2018; Chapter 465, Public Health Act, 2007; Chapter 458, Medicines Act 2003; SL 528.10, Legal notice 263 on processing of personal data	yes	yes	yes	yes	yes	NA
Nigeria	Nigeria Data Protection Regulation, 2019; National Code of Health Research Ethics, 2007; National Health Act, 2014	yes	yes	yes	no	yes	yes
Pakistan	None ⁴	yes		yes	yes	yes	yes
Philippines	Republic Act 10173 – Data Privacy Act, 2012; National Privacy Commission of the Philippines. implementing Rules and Regulations of the Data Privacy Act of 2012	yes	NA	NA	yes	yes	yes

⁴ At the time the survey was conducted, no official document was available. However, in 2023, the “Personal data protection Bill” was released. <https://www.icnl.org/wp-content/uploads/Personal-Data-Protection-Bill-2023.pdf>

Countries	Applicable law/regulation/guidelines	Informed consent required	Secondary use	Data Transfer	Provisions for children	EC approval	CA authorisation
Portugal	Lei n.º 58/2019, de 08 de agosto, Portuguese Republic Assembly; Diário da República n.º 166/2014, Série I de 2014-08-29	yes	NA	NA	yes	yes	yes
South Africa	Protection of Personal Information Act, 2020; Presidency Republic of South Africa, National Health Act, 2004; Guidelines on Ethics for Medical Research: Reproductive Biology and Genetic Research	yes	yes	yes	yes	yes	NA
Spain	Organic Law 3/2018	yes	yes	yes	yes	yes	NA
Sri Lanka	Personal Data Protection Act No. 9, 2022	yes	yes	yes	yes	yes	yes
Switzerland	NA	NA	NA	NA	NA	NA	NA
Tanzania	NA	yes	yes	yes	yes	yes	no
United Kingdom	UK General Data Protection Regulation - Data Protection Act, 2018	yes	yes	yes	yes	yes	yes
United States of America	Privacy Act, 5 U.S.C. § 552a, 1974; Common Rule at 45 CFR 46.111(a)(7), 2018; HIPAA Privacy Rule, 45 CFR parts 160 and 164, Subparts A and C, 2002; HIPAA Security Rule, 45 CFR parts 160, 162, and 164, 2009; HIPAA Breach Notification Rule, 45 CFR §164.400-414; HHS, OCR, Health Insurance Portability and Accountability Act, 1996; Genetic Information Nondiscrimination Act, 2008	yes	yes	yes	yes	yes	no
Zambia	The Data Protection Act, 2021; The National Health Research Act, 2013	yes	yes	yes	yes	yes	yes

NA: Not available as respondents answered “I don’t know” to the related question

Details not available: respondents provided an answer without specifying the requested details.

Table S3. Overview of the local framework on clinical research

Countries	Applicable law/regulation/guidelines	EC approval	CA authorisation	Informed consent	Assent	Separate consent for genetic tests	Secondary use of samples
Angola	NA	Yes	NA	yes	yes	yes	yes
Argentina	National Law 25326 10/30/2000	Yes	yes	yes	yes	yes	yes
Azerbaijan	Hematology Ethics Committee Guidelines, 2021	Yes	no	yes	no	no	yes
Bangladesh	Bangladesh Medical Research Council Ethical. Guidelines for Conducting Research Studies Involving Human Subjects	Yes	no	yes	yes	no	NA
Belgium	Belgian Law of 7 May 2004; Belgian law of 7 May 2017;	yes	yes	yes	yes	no	yes
Brazil	NA	Yes	yes	yes	yes	yes	yes
Brunei	Brunei Darussalam Guidelines for Good Clinical Practice, 2021	Yes	yes	yes	yes	yes	yes
Canada	NA	Yes	NA	yes	NA	NA	NA
Côte d'Ivoire	NA	Yes	NA	yes	NA	NA	yes
Cyprus	Law N. 150 (I)/2001); Law of 2001 (70(I)/2001); The Medicinal Products for Human Use (Good	Yes	NA	yes	yes	no	yes

Countries	Applicable law/regulation/guidelines	EC approval	CA authorisation	Informed consent	Assent	Separate consent for genetic tests	Secondary use of samples
	Clinical Practice), P.I. 452/2004 and P.I. 318/2006; Cyprus National Bioethics Committee, K.A.Π. 175/2005; Cyprus, Center of Educational Research and Evaluation. Guidelines for the submission of the online application, 2014						
Democratic Republic of the Congo	Details not available	Yes	yes	yes	yes	NA	NA
Denmark	Details not available	Yes	yes	yes	yes	yes	yes
Germany	Arzneimittelgesetz in der Fassung der Bekanntmachung vom 12. Dezember 2005 (BGBl. I S. 3394), das zuletzt durch Artikel 3 des Gesetzes vom 27. September 2021 (BGBl. I S. 4530) geändert worden ist	Yes	yes	yes	yes	yes	yes
Greece	Details not available	Yes	yes	yes	yes	NA	NA

Countries	Applicable law/regulation/guidelines	EC approval	CA authorisation	Informed consent	Assent	Separate consent for genetic tests	Secondary use of samples
India	Office Memorandum: Guidelines for Exchange of Human Biological Material for Biomedical Research Purposes, 1997; New Drugs and Clinical Trials Rules, 2022; Guidelines for International Collaboration/Research Projects in Health Research; MoUs & HMSC Procedure, 2022; Handbook for Applicants & Reviewers of Clinical Trials of New Drugs in India, 2017; ICMR Guidelines for Good Clinical Laboratory Practices, 2021; National Ethical Guidelines for Biomedical and Health Research	Yes	no	yes	yes	yes	yes

Countries	Applicable law/regulation/guidelines	EC approval	CA authorisation	Informed consent	Assent	Separate consent for genetic tests	Secondary use of samples
	Involving Human Participants, 2017; National Ethical Guidelines for Biomedical Research Involving Children, 2017; National Guidelines for Gene Therapy Product Development and Clinical Trials, 2019; National Guidelines for Stem Cell Research, 2017; The Drugs and Cosmetics Act, 1940 and The Drugs and Cosmetics Rules, 1945 (Amended 2016)						
Israel	Details not available	Yes	yes	yes	yes	yes	yes
Italy	LEGGE 11 gennaio 2018, n. 3; DETERMINAZIONE AIFA - 20 marzo 2008; Errata-corrigere alla Determinazione	Yes	yes	yes	yes	yes	yes

Countries	Applicable law/regulation/guidelines	EC approval	CA authorisation	Informed consent	Assent	Separate consent for genetic tests	Secondary use of samples
	AIFA 20 Marzo 2008; DM 19 aprile 2018 - Costituzione del Centro di coordinamento nazionale dei comitati etici territoriali per le sperimentazioni cliniche sui medicinali per uso umano e sui dispositivi medici; DM 7 settembre 2017 - Uso terapeutico di medicinale sottoposto a sperimentazione clinica; DM 5 dicembre 2006 - Utilizzazione di medicinali per terapia genica e per terapia cellulare somatica al di fuori di sperimentazioni cliniche e norme transitorie per la produzione di detti medicinali; DM 15 luglio 1997 – Recepimento delle linee guida dell'Unione						

Countries	Applicable law/regulation/guidelines	EC approval	CA authorisation	Informed consent	Assent	Separate consent for genetic tests	Secondary use of samples
	Europea di buona pratica clinica per la esecuzione delle sperimentazioni cliniche dei medicinali; DM 18 marzo 1998 – Modalità per l'esenzione dagli accertamenti sui medicinali utilizzati per le sperimentazioni cliniche; DM 15 settembre 1998 - Integrazione al decreto 18 marzo 1998; DM 19 marzo 1998 - Riconoscimento della idoneità dei centri per la sperimentazione clinica dei medicinali; DM 7 ottobre 1998 - Integrazioni all'allegato al decreto 19 marzo 1998; DM 20 gennaio 1999 - Misure relative all'immissione in commercio ed alla sperimentazione						

Countries	Applicable law/regulation/guidelines	EC approval	CA authorisation	Informed consent	Assent	Separate consent for genetic tests	Secondary use of samples
	clinica di medicinali contenenti materiale di origine bovina; DM 13 maggio 1999 - Integrazioni al D.M. 18/03/98 e al D.M. 19/3/1998; DM 23 novembre 1999 – Composizione e determinazione delle funzioni del Comitato etico nazionale per le sperimentazioni cliniche dei medicinali; DM 28 dicembre 2000 - Misure finalizzate alla minimizzazione del rischio di trasmissione all'uomo, tramite farmaci, degli agenti che causano l'encefalopatia spongiforme animale; DM 10 maggio 2001 - Sperimentazione clinica controllata in medicina						

Countries	Applicable law/regulation/guidelines	EC approval	CA authorisation	Informed consent	Assent	Separate consent for genetic tests	Secondary use of samples
	generale e pediatria di libera scelta; DM 30 maggio 2001 - Accertamenti ispettivi sull'osservanza delle norme di buona pratica di fabbricazione e di buona pratica clinica; DM 17 dicembre 2004 - Prescrizioni e condizioni di carattere generale, relative all'esecuzione delle sperimentazioni cliniche dei medicinali, con particolare riferimento a quelle ai fini del miglioramento della pratica clinica, quale parte integrante dell'assistenza sanitaria; DM 12 maggio 2006 - Requisiti minimi per l'istituzione, l'organizzazione e						

Countries	Applicable law/regulation/guidelines	EC approval	CA authorisation	Informed consent	Assent	Separate consent for genetic tests	Secondary use of samples
	il funzionamento dei Comitati etici per le sperimentazioni cliniche dei medicinali; DM 21 dicembre 2007 - Modalità di inoltro della richiesta di autorizzazione all'Autorità competente, per la comunicazione di emendamenti sostanziali e la dichiarazione di conclusione della sperimentazione clinica e per la richiesta di parere al comitato etico; DM 7 Novembre 2008 - Modifiche ed integrazioni ai decreti 19 Marzo 1998, 8 Maggio 2003 e 12 Maggio 2006; DM 14 luglio 2009 - Requisiti minimi per le polizze assicurative a tutela dei soggetti partecipanti alle sperimentazioni						

Countries	Applicable law/regulation/guidelines	EC approval	CA authorisation	Informed consent	Assent	Separate consent for genetic tests	Secondary use of samples
	cliniche dei medicinali; DM 15 Novembre 2011 - Definizione dei requisiti minimi per le organizzazioni di ricerca a contratto nell'ambito delle sperimentazioni cliniche dei medicinali; DM 8 Febbraio 2013 - Criteri per la composizione e il funzionamento dei comitati etici; Circolare Ministeriale n. 6 del 8 aprile 1999; Circolare Ministeriale n. 16 del 12 ottobre 1999; DD 25 maggio 2000 - Trasmissione per via telematica dei dati inerenti le sperimentazioni cliniche dei medicinali; Decreto del Presidente dell'Istituto Superiore di Sanità del 26 aprile 2002;						

Countries	Applicable law/regulation/guidelines	EC approval	CA authorisation	Informed consent	Assent	Separate consent for genetic tests	Secondary use of samples
	Circolare Ministeriale n. 6 del 2 settembre 2002; Determinazione AIFA 23 Dicembre 2008; Determinazione AIFA 20 Settembre 2012; Determina AIFA 1/2013 del 7.01.13; Circolare Ministeriale N. 6 del 2 Settembre 2002; D. Lgs. 6 novembre 2007, n. 200; D. Lgs. 24 giugno 2003, n. 211; Decreto 07 settembre 2017; DPR 21 settembre 2001, n. 439; Regolamento di semplificazione delle procedure per la verifica e il controllo di nuovi sistemi e protocolli terapeutici sperimentali; D. Lgs. 14 maggio 2019, n. 52;						

Countries	Applicable law/regulation/guidelines	EC approval	CA authorisation	Informed consent	Assent	Separate consent for genetic tests	Secondary use of samples
	Comunicazione AIFA n. 2 del 7 aprile 2020						
Kenya	Guidelines for Conduct of Clinical Trials in Kenya, Pharmacy and Poisons Board, 2019; Health Laws Act, 2019	Yes	yes	yes	yes	NA	NA
Malaysia	Sale of Drugs Act, 1989; Sale of Drugs (Certificate of Analysis) Regulations, 1997; Control of Drugs and Cosmetics Regulations, 1985; Malaysian Medical Council, Clinical Trials and Biomedical Research, 2006; Malaysian Guideline for Good Clinical Practice 4th Edition 3. NIH Guidelines for Conducting Research in Ministry of Health Institutions and Facilities, 2021	Yes	yes	yes	yes	yes	yes

Countries	Applicable law/regulation/guidelines	EC approval	CA authorisation	Informed consent	Assent	Separate consent for genetic tests	Secondary use of samples
Malta	Clinical Trials Regulations, SL 458.43, 2004; Good Clinical Practice and Requirements for Manufacturing or Import Authorisation of Investigational Medicinal Products Regulations, SL 458.47, Regulation 3(6), 2006; Production of Cannabis for Medicinal and Research Purposes Act, Chapter 578, 2018; Production of cannabis for medicinal and research purposes (fees) regulations, SL 578.01, 2018; Mental Health Act, Chapter 525, Laws of Malta, 2014; Processing of Personal Data (secondary processing) (health sector) Regulation, SL 528.10, 2018; Data Protection	Yes	yes	yes	yes	no	No

Countries	Applicable law/regulation/guidelines	EC approval	CA authorisation	Informed consent	Assent	Separate consent for genetic tests	Secondary use of samples
	Act, Chapter 586, 2018; Health Ethics Committee, Guidance Notes for Clinical Trials in Malta, 2005; University Research Ethics Committee, University of Malta, Research Code of Practice, 2019; Ministry for Health, Charter of Patient's Rights and Responsibilities, 2016						
Nigeria	National Health Research Ethics Committee, 2007	Yes	yes	yes	yes	no	yes
Pakistan	Guidance on Clinical Trials Applications-For Applicants, 2022; National Guidelines for collection, usage, storage and export of Human Biological Materials, 2016	Yes	yes	yes	yes	NA	yes

Countries	Applicable law/regulation/guidelines	EC approval	CA authorisation	Informed consent	Assent	Separate consent for genetic tests	Secondary use of samples
Philippines	Department of Health Administrative, Order No. 2014-0034; FDA Circular No. 2012-007;	yes	NA	yes	yes	yes	yes
Portugal	Diário da República n.º 75/2014, Série I de 2014-04-16	Yes	yes	yes	no	no	yes
South Africa	National Health Act 61, 2003; Ethics in Health Research, Principles, Processes and Structures, 2015; South African Good Clinical Practice: Clinical Trial Guidelines, 2019	Yes	no	yes	yes	no	yes
Spain	Details not available	Yes	no	yes	yes	yes	yes
Sri Lanka	Ministry of Health, Health Research Governance Strategy, 2019; FERCSL Guideline, 2018; Guidelines of the College of Paediatricians in Sri Lanka	Yes	no	yes	yes	no	yes

Countries	Applicable law/regulation/guidelines	EC approval	CA authorisation	Informed consent	Assent	Separate consent for genetic tests	Secondary use of samples
Switzerland	NA	NA	NA	yes	NA	NA	NA
Tanzania	National Health Research Ethics Committee. Guidelines of Ethics for Health Research in Tanzania, 2009; National Institute of Medical Research. Standard Operating Procedures for the National Health Research Ethics Committee, 2014; Medical Research Coordinating Committee Ethical Guidelines	Yes	NA	yes	yes	no	yes
United Kingdom	UK Clinical Trials Regulations, 2004; GOV.UK guidance on authorisation of CTIMPs, 2022; GOV.UK guidance on regulation of ATMPs, 2015; GOV.UK guidance on legal requirements for children's medicines, 2020	Yes	yes	yes	yes	yes	yes

Countries	Applicable law/regulation/guidelines	EC approval	CA authorisation	Informed consent	Assent	Separate consent for genetic tests	Secondary use of samples
United States of America	Public Health Service Act, 1993; 45 CFR 46, Subparts A (the Common Rule), B, C, D, and E, 2018; OHRP, Human Research Protections Guidance, various; Protection of Human Subjects in Research Supported by USAID: A Mandatory Reference for ADS Chapter 200, 2015; Executive Order 12333, adopting 45 CFR 46 Subparts A, B, C, and D; United States Code Title 10, Section 980: Limitation on Use of Humans as Experimental Subjects; DoDI 3216.02, 2011; Food, Drug, and Cosmetic Act, 21 USC Sections 355 and 371, 2012;	Yes	no	yes	no	no	yes

Countries	Applicable law/regulation/guidelines	EC approval	CA authorisation	Informed consent	Assent	Separate consent for genetic tests	Secondary use of samples
	Public Health Service Act, 42 USC Section 262, 1998; 21st Century Cures Act, Section 3024, 2016; FDA, Regulations, Good Clinical Practice and Clinical Trials, various; FDA, Good Clinical Practice and Human Subject Protection in FDA-Regulated Clinical Trials; FDA, Drugs, Guidance, various; FDA, Biologics, Guidance, various; Food and Drug Administration Modernization Act, Section 113, 1997; Food and Drug Administration Amendments Act, Section 801, 2007; Clinical Trials Regulation and Results Information Submission, 42 CFR 11, 2016;						

Countries	Applicable law/regulation/guidelines	EC approval	CA authorisation	Informed consent	Assent	Separate consent for genetic tests	Secondary use of samples
	NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information, 2016; Genetic Information Nondiscrimination Act (GINA), 2008						
Zambia	National Health Research Act, 2013	Yes	yes	yes	yes	NA	yes
							NA: Not available as respondents answered "I don't know" to the related question Details not available: respondents provided an answer without specifying the requested details; USA: United States of America

Table S4. Overview of the local legal framework on biospecimens management

Countries	Applicable law/regulation/guidelines	Provisions for storage	Provisions for transfer	Requirements for genetic tests	Measures for handling paediatric and vulnerable populations	Measures for samples destruction (consent withdraw)
Angola	NA	yes	yes	yes	yes	yes
Argentina	NATIONAL LAW 25326 10/30/2000	yes	yes	yes	yes	yes
Azerbaijan	None	no	no	yes	yes	yes
Bangladesh	None	no	yes	yes	no	yes
Belgium	Belgian Law amending the law of 19 December 2008 on the acquisition and use of human body material with a view to medical application to humans or scientific research, and the applicable royal decrees	yes	yes	yes	no	yes
Brazil	Ministério da Saúde – Portaria n. 2.201, de 14 de setembro de 2011	yes	yes	no	no	yes
Brunei	Details not available	no	no	no	no	no
Canada	NA	NA	NA	NA	yes	NA
Côte d'Ivoire	NA	NA	NA	yes	NA	NA
Cyprus	Standards for quality and safety Human tissues, cells and related products. Law 187(I) of 2007; Cyprus National Bioethics Committee. Opinion on the Establishment and Use of Biobanks and Registries of Human Biological Samples for Research Purposes	yes	yes	NA	NA	yes
Democratic Republic of the Congo	NA	NA	yes	NA	yes	NA
Denmark	Details not available	yes	yes	NA	NA	yes
Germany	Details not available	yes	yes	yes	yes	yes
Greece	NA	NA	NA	NA	NA	NA
India	Indian Council of Medical Research. National ethical guidelines for biomedical and health research involving human participants, 2017	yes	yes	yes	yes	yes
Israel	Details not available	yes	yes	yes	yes	yes
Italy	ISO/DIS 20387(en); Autorizzazione n. 8/2016; Autorizzazione n. 9/2016;	yes	yes	yes	yes	yes

	CNBBSV. Raccolta di campioni biologici a fini di ricerca: consenso informato, 2009; ISBER Best Practices: Recommendations for Repositories Fourth Edition; OECD Guidelines on Human Biobanks and Genetic Research Databases, 2009; D. Lgs. n. 191 2007; D. Lgs. n. 16 2010; D. Lgs. n. 85, 2012					
Kenya	Details not available	yes	yes	NA	yes	NA
Malaysia	Ministry of Health. Malaysian Guidelines on the use of Human Biological Samples for Research, 2015. Standard Operating Procedure for Transport of Biological Specimens, 2012 Biosafety Act of Malaysia, 2007	yes	yes	yes	yes	NA
Malta	None	no	no	yes	yes	yes
Nigeria	National Health Research Ethics Committee, 2007	yes	yes	no	NA	yes
Pakistan	NA	NA	yes	no	NA	NA
Philippines	Section 15 of Executive Order No. 247, 1995; Administrative Order No. 96-20	yes	yes	yes	yes	yes
Portugal	Diário da República n.º 166/2014, Série I de 2014-08-29	NA	no	no	NA	no
South Africa	National Health Act, 2003; National Health Research Ethics Guidelines, 2015	yes	yes	no	NA	no
Spain	Details not available	yes	yes	NA	NA	NA
Sri Lanka	Transplantation of Human Tissues Act, 1987	no	yes			no
Switzerland	NA	NA	NA	NA	NA	NA
Tanzania	NA	NA	NA	yes	yes	yes
United Kingdom	Human Tissue Act, 2004	yes	yes	yes	yes	yes
United States of America	Coded Private Information or Biospecimens Used in Research Guidance, 2018; Coded Private Information or Specimens Use in Research Guidance, 2008; Fetal Tissue Transplantation Research Guidance, 2003; Human Embryonic Stem Cells, Germ Cells, and Cell-Derived Test Articles: OHRP Guidance, 2002 Issues to Consider in the Research Use of Stored Data or Tissues, 1997	yes	yes	NA	yes	yes

	Statute on Fetal Tissue Transplantation Research, 1993; Guidelines for Human Biospecimen Storage, Tracking, Sharing, and Disposal within the NIH Intramural Research Program, 2021; Withdrawal of Subjects from Research Guidance, 2010; DF/HCC Guidance - Maximum Blood Draw for Research Purposes, 2021; Boston Children's Hospital. Institutional Review Board (IRB) Policies & Procedures, 2020; Guidance on Important Considerations for When Participation of Human Subjects in Research is Discontinued, 2008 (draft)					
Zambia	National Health Research Act, 2013	NA	yes	NA	NA	NA

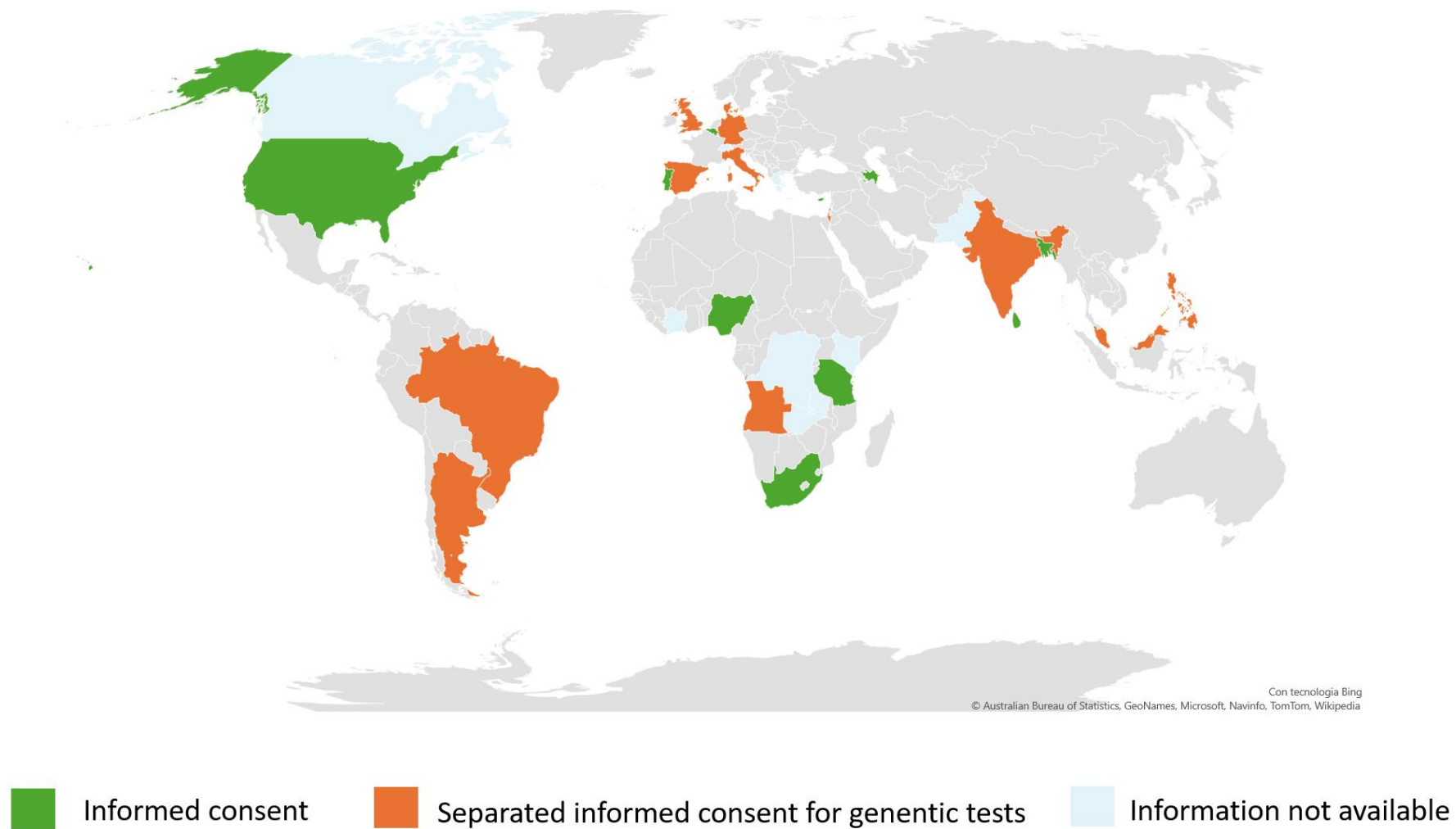


Figure S2. Requirement for informed consent and separate informed consent for genetic tests, geographical distribution.