BIOIVT
ELEVATING SCIENCE™

KEY POINTS TO HUMAN BIOSPECIMEN USE FOR RESEARCH

RESPECT FOR PERSONS, BENEFICENCE, AND JUSTICE.

TYPE OF COLLECTION	REGULATORY REQUIREMENTS	DATA	KEEP IN MIND
PROSPECTIVE	REQUIRES INFORMED CONSENT / IRB REVIEW	CAN BE TAILORED TO NEED / EXTENSIVE	VARIABLE ACCRUAL TIMELINES
RETROSPECTIVE	RECOMMENDED IRB REVIEW THAT SAMPLES DO NOT COUNT AS HUMAN RESEARCH SUBJECTS	LIMITED TO AVAILABILITY / CONNECTION TO MEDICAL RECORDS	NOT COLLECTED TO SPECIFIC STANDARDS
POST-MORTEM	REQUIREMENTS GOVERENED BY FEDERAL OR STATE LAWS, INCLUDING NEXT-OF-KIN; AUTHORIZATION OR EU/UK GOVERNMENTAL LICENSING	DEPENDENT ON NEXT-OF-KIN / CONNECTION TO MEDICAL RECORDS	VIABILITY OF SAMPLES

THE RELIABILITY OF DATA DERIVED FROM HUMAN SPECIMENS IS DEPENDENT ON THE QUALITY AND CONSISTENCY OF THE ANALYZED SAMPLE.

THE ABCs OF QUALITY

HUH?

ETHICS

HIPAA (United States)
The Health Insurance Portability and Accountability Act (HIPAA) requires that covered entities obtain authorization or waiver of authorization for the use and disclosure of PHI (45 CFR 164.508).

HTA (United Kingdom)
The Human Tissue Authority (HTA) was created by Parliment as a non-departmental public body (otherwise known as an "arms-length body") of the Department of Health, and are overseen by an Authority of lay and professional members appointed by the Government.

IEC (Non-United States)
International Ethics Committees (IECs) are committees formally designated to review and approve the initiation of a clinical research study involving human participants and to provide continuing review of the research study.

IRB (United States)
Institutional Review Boards (IRBs) are responsible for the regulatory oversight of research involving human research subjects. IRBs are governed by Office of Human Research Protection (OHRP) 45 CFR Part 46 regulations.

PHI (United States)
Protected Health Information (PHI) is a vital component of informed consent. It balances the subjects rights of privacy while allowing researchers to access the type of data collected and how the information will be used, including in the future.

GOVERNMENT REGULATORY

CDSCO (India)
The Central Drugs Standard Control Organization (CDSCO) is the national regulatory body for Indian pharmaceuticals and medical devices. Within the CDSCO, the Drug Controller General of India (DCGI) regulates pharmaceutical and medical devices, under the gamut of Ministry of Health and Family Welfare.

CFDA (China)
The China Food and Drug Administration is responsible for drafting laws, regulations and rules, and policy plans on the administration and supervision of food safety, drugs, medical devices and cosmetics.

EMA (European Union)
The European Medicines Agency (EMA) protects public and animal health in 28 EU Member States, as well as the countries of the European Economic Area, by ensuring that all medicines available on the EU market are safe, effective, and high quality.

EUTCD (European Union)
The European Union Tissue and Cell Directives (EUTCD) established a harmonized approach to the regulation of tissue and cell across Europe. The Directives set benchmark standards that must be met for activity involving tissues and cells for patient treatment.

FDA (United States)
The Federal Drug Administration (FDA) is responsible for protecting the public health in the US by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation.

PMDA (Japan)
The Pharmaceuticals and Medical Devices Agency is an independent agency that is responsible for reviewing drug and medical device applications and works in conjunction with Japan's Ministry of Health, Labor and Welfare (MHLW) to assess new product safety, develop comprehensive regulations and monitor post-market safety.

QUALITY

GCP (World-wide)
The principles of Good Clinical Practice (GCP) help assure the safety, integrity, and quality of research by addressing components related to the design, conduct, and reporting of clinical research such as investigator and sponsor requirements, monitoring plans, records and reports, etc.

INFORMED CONSENT?

Informed consent is the understanding and written acceptance of the research, its risks, benefits and use of specimens and data gathered as a result of the research. Participants must be provided adequate information to make an 'informed' decision. This information should include the purpose of the study, study procedures, risks and discomforts, benefits of participation, compensation for participation, use of health information and information regarding voluntary withdrawal.

COMMERCIAL USE?

It is important that participants are informed of the commercial use of samples and data. This entails informing the participant that specimens provided may result in new products, tests, or discoveries and that these developments may have commercial value and that there is no intention to share the monetary benefits from these products tests or discoveries. This also entails informing the participant regarding the potential publishing of study results in journals, academic papers, etc., and an assurance that identifying data will not be published. Participants must be informed of the storage and future use of samples and data.

GENETIC TESTING?

An important portion of the consent document is to include language for genetic testing. Potential subjects must be informed if their samples will undergo genetic testing, if genetic testing is optional (in rare cases) and if a link is made between the samples and the donor, that there is an assurance from the researchers to not identify the donor.

CAP BIOREPOSITORY ACCREDITATION

Designed to improve the quality and consistency of facilities that collect, process, store, and distribute biospecimens for research.

ISO 9001 CERTIFICATION

This standard is based on a number of quality management principles including a strong customer focus, the motivation and implication of top management, the process approach and continual improvement.

45 CFR 46.102(F)

Defines human subject as, a living individual about whom an investigator conducting research obtains, 1) data through intervention or interaction with the individual, or, 2) identifiable private information.

FOR MORE INFORMATION ON STANDARDS

ISBER - International Society for Biological and Environmental Repositories
NCI Best Practices - National Cancer Institute
BBMRI - Biobanking and Biomolecular Resources Research Infrastructure
ESBB - European, Middle Eastern and African Society for Biopreservation and Biobanking

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