SingHealth CIRB: Illuminaté

"To Énlighten... Ethics, above all"

Adapted version for researchers, investigator and study coordinators

SingHealth
Defining Tomorrow's Medicine

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In this issue >>>

Clinical Research/ Trial & Regulations:

1. Types of Clinical Research >>>

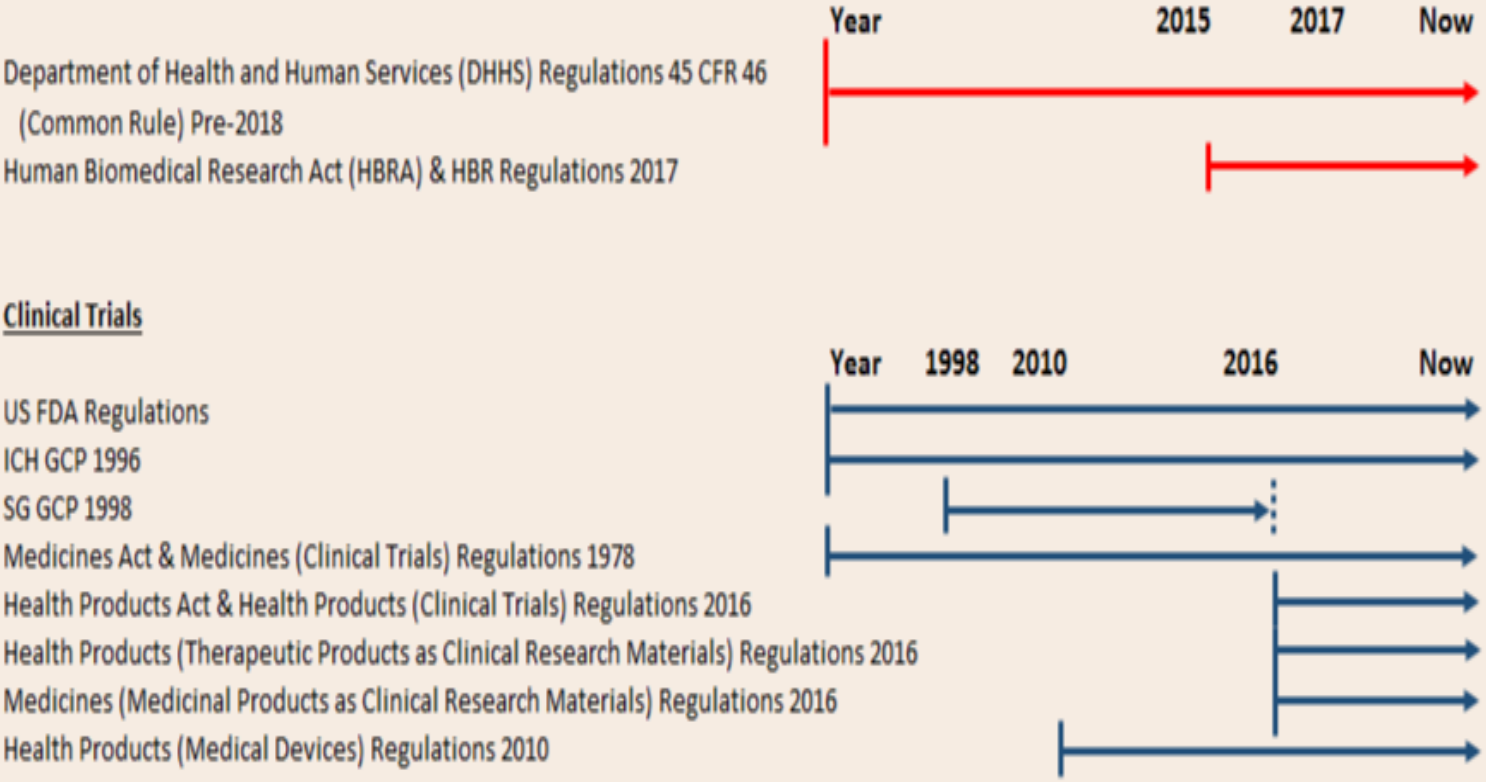
- **Treatment Research** generally involves an intervention or new approaches.
- **Prevention Research** looks for better ways to prevent disorders from developing or returning. Different kinds of preventive research may study medicines, vitamins, vaccines, minerals, or lifestyle changes.
- **Diagnostic Research** refers to the practice of looking for better ways to identify a particular disorder or condition.
- **Screening Research** aims to find the best ways to detect certain disorders or health conditions.
- **Quality of Life Research** explores ways to improve comfort and the quality of life for individuals with a chronic illness.
- **Genetic studies** aim to improve the prediction of disorders by identifying and understand how genes and illnesses may be related. Research in this area may explore ways in which a person's genes make him or her more or less likely to develop a disorder. This may lead to development of tailor-made treatments based on a patient's genetic make-up.
- **Epidemiological studies** seek to identify the patterns, causes, and control of disorders in groups of people.
- **Observational studies** observe people in normal settings where they do not involve testing medications and a person's regular medications may not need to be changed. Researchers gather information, group volunteers according to broad characteristics, and compare changes over time. For example, researchers may collect data through medical exams, tests, or questionnaires about a group of older adults over time to learn more about the effects of different lifestyles on cognitive health. These studies may help identify new possibilities for clinical trials. Examples of other kinds of research include:
  - A long-term study that involves psychological tests or brain scans
  - A genetic study that involves blood tests but no changes in medication
  - A study of family history that involves talking to family members to learn about people's medical needs and history

2. Types of Clinical Trial >>>

Clinical trial is a research study conducted to investigate new treatments, such as a new drug compound or an existing therapy, in human volunteers or research participants. Each clinical trial is designed to learn about a potential treatment and its effect on humans. Clinical trial is often conducted in four phases. Each phase has a different purpose to help researchers answer different questions.

Phase I trials	Phase II trials	Phase III trials	Phase IV trials
• Testing an experimental drug or treatment in a small group of people for the first time. • Researchers will evaluate the treatment's safety, determine a safe dosage range, and identify side effects.	• The experimental drug or treatment is given to a larger group of people to see if it is effective and to further evaluate its safety.	• The experimental study drug or treatment is given to large groups of people. • Researchers confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow experimental drug or treatment to be used safely.	• Conducted to gather additional information about a drug's safety, efficacy, and optimal use. • Sometimes also known as post-marketing studies.

3. Regulations >>>



Regulations of Clinical Research & Others >>

DHHS Regulations 45 CFR 46

The regulations apply to all research involving human subjects conducted, supported or otherwise subject to regulation by any federal department or agency which takes appropriate administrative action to make the policy applicable to such research.

HBRA 2015/ HBR Regulations 2017

Research will fall within scope of the HBRA if it satisfies at least one **Purposive** element and one **Methodological** element or where it involves **Sensitive** research.

Others

For studies that meet the Exemption Categories (Pre-2018), they will fall out of scope of the HBRA & DHHS Regulations 45 CFR 46.

In Singapore:

HBRA is applicable to all Clinical Research, unless it falls out of scope.

Non-HBR studies are those that fall out of scope of the HBRA. For these studies, DHHS Regulations 45 CFR 46 (Pre-2018) or the exemption categories will apply.

ICH E6 (R2) GCP has been adopted for all research.

Clinical Trial Regulations >>

All clinical trials of **therapeutic products** and **medicinal products** (e.g. Chinese Proprietary Medicines, health supplements that are being investigated for the treatment or prevention of disease), are regulated by Health Sciences Authority (HSA) except for observational clinical trials.

The conduct of **medical device** clinical trial is not regulated by HSA. However, **Clinical Research Materials (CRM)** notification may be required for medical device used in the trial.

CRM refer to therapeutic products, medicinal products, medical devices or placebos that are manufactured, imported or supplied for use on subjects in Singapore in accordance with the research protocol. This is regardless of the products' registration status in Singapore.

Regardless of whether HSA regulates the clinical trial, the manufacture, import and supply of therapeutic products, medicinal products or medical devices used as a CRM in Singapore must comply with the regulatory controls for clinical research materials.

Observational clinical trials and medical device trials are required to **comply with** the requirements of the **HBRA**.

Guideline for Good Clinical Practice >>

Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects.

Compliance with this standard provides public assurance that the rights, safety and well-being of trial subjects are protected, consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data are credible.

The objective of this ICH GCP Guideline is to provide a unified standard for the European Union (EU), Japan and the United States, as well as those of Australia, Canada, the Nordic countries and the World Health Organization (WHO), to facilitate the mutual acceptance of clinical data by the regulatory authorities in these jurisdictions.

Prior to 1 Nov 2016, the GCP compliance standards used by HSA was based on the Singapore Guideline for Good Clinical Practice Guidelines (SGGCP).

From 1 Nov 2016, it has been based on the ICH E6 (R2) Good Clinical Practice Guidelines (ICH E6 (R2) GCP).

Type	Key Regulations (Clinical Trials)	Key Regulations for CRM
Therapeutic Products	Health Products Act and Health Products (Clinical Trials) Regulations	Health Products (Therapeutic Products as Clinical Research Materials) Regulations
Medicinal Products	Medicines Act and Medicines (Clinical Trials) Regulations	Medicines (Medicinal Products as Clinical Research Materials) Regulations
Medical Devices	-	Health Products (Medical Devices) Regulations

Takeaway message...

Most research conducted in Singapore have to comply with the HBRA Regulations, unless the research (i) is regulated by HSA, (ii) falls out of scope of the HBRA or (iii) is funded by NHS, and/ or regulated by the DHHS or US FDA.

All research activities are to be conducted according to the ICH E6 (R2) GCP standards.

If you have any questions, please contact CIRB at irb@singhealth.com.sg