

Office of Human Research Protection Programme (OHRPP) Post-Its:
Bringing you the latest updates on research policies, educational resources and event information

Regulatory Updates

Effective 1 Oct 2021 - New Consent Requirements for HSA Regulated Clinical Trials (CT) Involving Collection of Human Tissue

New CT applications involving collection of human tissue must now provide information on these 3 Specific Consent Elements in the Informed Consent Form:

- (a) that the provision of the tissue is voluntary, and the renunciation of the trial participant's rights to the tissue and any intellectual property rights that may be derived from the tissue;
- (b) whether the trial participant would wish to be re-identified in the case of an incidental finding relating to the collected tissue if the clinical trial expressly provides for such re-identification;
- (c) whether the tissue will be exported or removed from Singapore to a place outside Singapore.

These 3 Elements are in addition to the other consent elements per Regulation 19(1)(a) - (t) of the Health Products (Clinical Trials) Regulations & the Medicines (Clinical Trials) Regulations:

For more information, please refer to the [HSA website for the Guidance document](#).

Effective 1 Oct 2021 - Pharmacists as Principal Investigators of Clinical Trials of Locally Registered Therapeutic Products

From 1 October 2021, registered pharmacists can apply to be Principal Investigators (PIs) of clinical trials. These safeguards and requirements are detailed in the Health Products (Clinical Trials) Regulations & "[Guidance for Pharmacist Principal Investigator](#)".

The guidance will apply to clinical research involving locally registered products of lower risk profiles, including regulated clinical trials. It also states requirements for Pharmacists seeking to be PIs – such as education, training, experience, resources and responsibilities.

Education & Training

Last Call for Registration - Singapore Research Ethics Conference (SREC) 2021

From 23 to 25 November 2021, join the virtual [Singapore Research Ethics Conference](#) and gain knowledge on a wide variety of topics relevant to human subject research and best practices in key areas of research ethics for tomorrow's healthcare.

Featured topics include innovative research, digital health research, medical device research, patient-centric approach in the conduct of research and biobanking, future of clinical research and more!

[Click here](#) to register now!

Upcoming Proper Conduct of Research (PCR) Courses: Want to learn how to conduct your research properly? Online Courses available monthly on eLEARN!

<u>Virtual Workshop Dates</u>	<u>Course Title</u>
Monthly Online Course <i>Register by 15th of the Month</i>	[PCR100] Study Start-Up: Budgeting, Case Report Form Design, Database Design
18 Feb 2022 <i>Registration closes 15 Dec 2021</i>	[PCR200] Study Conduct I: Subject Recruitment & Informed Consent
Monthly Online Course <i>Register by 15th of the Month</i>	(PCR 300) Study Conduct II: Documentation, Safety Reporting & Investigational Products*
7 Jan 2022 <i>Registration closes 15 Nov 2021</i>	(PCR 400) Monitoring, Audits and Inspections*

For course registration and more details, please click [HERE](#).

For enquiries about PCR (Proper Conduct of Research), contact the Research Education team
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