

Clinical investigation of medical devices for human subjects — Good clinical practice (ISO14155)

We are pleased to announce that the University of Calgary now has access to the ISO14155 standard for medical device research. You can access this standard using your UCalgary credentials on the [Training & Education](#) section of the CCCR Quality Assurance website.

Due to the copyright protection, these standards *may not* be shared with parties external to our institution.

What is the ISO14155 standard about?

The International Organization for Standardization (ISO) has developed this standard to address the good clinical practice for clinical investigations carried out to assess the effectiveness or safety of medical devices in human participants.

Who needs to train on this standard?

In addition to following the Principles of the Declaration of Helsinki and the Tri-Council Policy Statement, it is also expected that medical device research, regulated by Health Canada Medical Device Regulations, should follow the good clinical practice that is set out by ISO14155. It is mandatory for research teams who are conducting research under an Investigation Testing Authorization (ITA), complete and document training on this standard.

It is highly recommended that any teams that conduct medical device research not regulated by Health Canada, should be familiar with ISO14155 as well.

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