Western Research

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Guidance Document	Clinical Trials Registration Requirement
Effective Review	Delegated & Full Board
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1. PURPOSE

The purpose of this document is to provide the rationale as to why the Office of Human Research Ethics (OHRE) requires that a Clinical Trial* be registered prior to the release of the Ethics Approval notice.

2. BACKGROUND

The REB is governed by regulatory policies and guidelines. The purpose of these Policies/guidelines is to establish principles to guide the design, ethical conduct and ethics review process of research involving humans. The Declaration of Helsinski-Ethical Principles for Medical Research Involving Human Subjects (WMA 2013), the Tri-council Policy Statement: Ethical Conduct for Research Involving Humans (Chapter 11), WHO, ICMJE Policy requires ALL Clinical Trials to be registered. Clinical trial registries allow access to information about ongoing clinical trials so that anyone may have information about trials and their results.

Purpose of registering clinical trials:

- Fulfill ethical obligations to participants and the research community
- Provide information to potential participants and referring clinicians
- Reduce publication bias
- Help editors and others understand the context of study results
- Help REBs determine the appropriateness of a research study
- Promote more efficient allocation of research funds
- Provide a public record of basic study results in a standardized format
- Promote the fulfillment of ethical obligations to participants and the overall contribution of research results to medical knowledge
- Facilitate systematic reviews and other analyses of the research literature

3. RESPONSIBILITY

It is the responsibility of the REB to ensure that a clinical trial is registered before recruitment of the first trial participant. In order to ensure that no participants are enrolled in a study prior to the registration of the trial the REB requires that the site provide the name of the registry and the clinical trials registration number before the initial approval notice is issued.

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4. **PRACTICE**

The REB will review a study that has not been registered but will require that the study be registered as part of the recommendations from the REB. Responses to recommendations from the REB can be submitted and will be processed without the registration number but the approval notice will be held until the registration number is received.

REFERENCES

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*Definition of a Clinical Trial: Any investigation involving participants that evaluates the effects of one or more health-related interventions on health outcomes.