Clinical Trials of Natural Health Products and Functional Foods

Are you considering a clinical trial for your natural health product or functional food?

The Human Nutraceutical Research Unit (HNRU) at the University of Guelph is your best choice for a clinical trial to assess the health-related outcomes of a natural health product or functional food. Utilize the knowledge and expertise of nutrition professors and scientists in designing and conducting your clinical trial.

What is the HNRU?

Randomized, double-blind, placebo-controlled clinical trials with human subjects are the gold standard in proving the efficacy of nutraceuticals and functional foods in order to support marketing strategies. The HNRU is a business and educational unit within the Department of Human Health and Nutritional Sciences at the University of Guelph. The HNRU conducts clinical trials to assess the efficacy of functional foods and natural health products and has a special interest in research directed towards value-added foods that offer health promotion as well as disease prevention. The HNRU is available to the natural health products and food industry to evaluate products in controlled human studies for potential health claims.
Clinical Trial Methodology

1. Background literature research & customized protocol development
2. Human research ethics board approval
3. Clinical trial application to NHPD
4. Recruitment of subjects
5. Baseline assessment and blood & tissue collection
6. Post-intervention blood & tissue collection
7. Blood & tissue analysis, data input
8. Statistical analysis
9. Preparation of full report
10. Publication-ready manuscript for possible publication

How human trials can be used for marketing natural health products and functional foods

- Respected journal publication of your study results can enhance market credibility, result in popular press reporting and improve product sales.
- Completion of clinical trials can support product-specific health claims and product licensing applications for Natural Health Products Directorate (NHPD) of Health Canada.

How the HNRU can work for you

- Consultation to determine feasibility of a human trial
- Expertise in navigating NHPD regulations to ensure accurate and efficient preparation of applications for clinical trial approval.
- Double-blind, placebo-controlled human trials, from study design to journal publication.
- Exercise testing to determine the ability of your product to enhance athletic performance and fitness ability.
- Specific blood tests, including cardiovascular, immunological and hormonal indices in accredited labs.

External resources that enhance HNRU expertise

- University of Guelph – Laboratory Services Division for analytical testing.
- Guelph Food Technology Centre for design of value-added foods.
- Other universities and medical schools as needed.
- Enhanced networking and linkages through MaRS Landing.