UOW ADMINISTRATION

CLINICAL TRIAL INSURANCE REQUIREMENTS

What Constitutes a Clinical Trial for Insurance Purposes?

Please forward this form to Insurance Officer in Financial Services Building 36, to ensure your trial is covered by the Clinical Trial Insurance.

Researcher: _____________________________________ Ethics Number: __________________________
Project Title: ______________________________________________________________________________
______________________________________________________________________________

Section A

Does my study or research involve humans to test any of the following?

- a drug
- a surgical procedure or device
- a therapeutic procedure or device
- a preventative procedure or device
- a diagnostic procedure or device

Does the nature of my study or research require the investigator or an assistant to be a registered medical practitioner or other registered qualified health service provider?

Does the study or research require any of the following?

- penetration of the skin (other than taking of blood samples)
- biopsy or any taking of or extraction of tissue samples
- penetration of the bodily orifices (other than ears and mouth)
- insertion of diagnostic or other device within the bodily orifices (other than ears and mouth)
- be undertaken by a registered medical practitioner or other registered qualified health service provider?

Does the study or research involve?

- a pregnant subject
- the study being conducted in the USA or Canada
If the answer is “Yes” to any of the above questions, the study or research is likely to be a Clinical Trial for the purpose of insurance protection. Please complete Section B and Section C and return this form to Financial Services, a copy of the completed form should be attached to your ethics application.

Section B

Does the study or research involve:

- evaluating outcomes of established health care management or treatment relating to the condition or illness from which the participants are suffering?  
  □YES □NO
- participant involvement only through the completion of questionnaires or interviews?  
  □YES □NO

Section C

- Name of Principal Investigator and university status
- School/Department
- Trial title and brief description
- Name of sponsor (if applicable)
- Is indemnity provided by the sponsor
- Granting body for non-sponsored trials
- Target participant numbers for the full trial period
- Number of sites
- Invasive nature of the trial
- Starting date of the trial
- Estimate period of the trial
- Name of drug (if applicable)
- Dosage of drug (if applicable)
- Are you aware of any claims from previous phases  
  □YES □NO