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| **Date Last reviewed** |  |
| **Date Last revised** | 2015-07-13 |

Please review the information below. If you have any questions, please contact Risk Management & Insurance at riskmgmt@ucalgary.ca or 403-220-5847.

 **PROCESS APPROVAL SHEET**

**INTERNATIONAL INVESTIGATOR-INITIATED CLINICAL TRIALS**

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| **PROJECT INFORMATION**  |  |

Project Code: Ethics ID:

Protocol #:

(if applicable)

Protocol Title:

Principal Investigator Name:

Sponsor Name:

Countries with Sites:

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| **Checklist** |
| **Study is a comparison of two existing standards of care in all countries included in the study.**  | [ ]  |
| **Study introduces a new device** | [ ]  |
| **Study introduces a new medication** | [ ]  |
| **Study conducted with an approved existing device or medication that is being used for a different indication (i.e. a heart medication that is being tested for use with stroke patients).** | [ ]  |
| **Reviewed Items** | **Yes** | **No** | **Comments** |
| 1. Discussion has taken place between the PI and Risk Management & Insurance. This Clinical Trial has been determined to **NOT REQUIRE** separate Clinical Trial insurance.
 | [ ]  |  |  |
| **IF STEP 1 IS YES, NO CLINICIAL TRIAL INSURANCE REQUIRED. LEGAL SERVICES CAN PROCEED TO NEGOTIATE CONTRACT WITH SITES.**  |
| **NAME: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ TITLE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_****SIGNATURE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_****DATE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |
| 1. Discussion has taken place between the PI and Risk Management & Insurance. This Clinical Trial has been determined to **REQUIRE** separate Clinical Trial insurance.
 | [ ]  |  |  |
| 1. The Placement of Clinical Trial Insurance Form has been received by Risk Management & Insurance.
 | [ ]  | [ ]  |  |
| **Reviewed Items** | **Yes** | **No** | **Comments** |
| 1. The Protocol has been received by Risk Management & Insurance.
 | [ ]  | [ ]  |  |
| 1. The Informed Consent (both in English and the language of each participating country) has been received by Risk Management & Insurance.
 | [ ]  | [ ]  |  |
| 1. The draft agreement has been received by Risk Management & Insurance.
 | [ ]  | [ ]  |  |
| 1. The Ethics Approval Letter and a copy of the Certification of Institutional Ethics Review for the protocol has been received by Risk Management & Insurance.
 | [ ]  | [ ]  |  |
| 1. Risk Management & Insurance has sent documentation to broker to get a formal quote.
 | [ ]  | [ ]  |  |
| **IF STEPS 2-8 ARE COMPLETE, LEGAL SERVICES CAN PROCEED TO NEGOTIATE CONTRACT WITH SITES, HOWEVER, CONTRACT CANNOT BE SIGNED UNTIL INSURANCE IS PURCHASED.** |
| **NAME: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ TITLE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_****SIGNATURE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_****DATE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |
| Insurance has been purchased: Country \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Beginning Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_End Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | [ ]  | [ ]  | Per Occurrence: $Annual Aggregate: $ |
| Insurance has been purchased: Country \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Beginning Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_End Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | [ ]  | [ ]  | Per Occurrence: $Annual Aggregate: $ |
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| **IF INSURANCE HAS BEEN PURCHASED FOR THAT COUNTRY, LEGAL SERVICES CAN PROCEED TO HAVE CONTRACTS SIGNED WITH THE SITES IN THAT COUNTRY.** |
| **NAME: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ TITLE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_****SIGNATURE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_****DATE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |