



# Research Ethics Board Committee Review Sheet

<b>Principal Investigator</b>			
<b>Date</b>		<b>Department</b>	
<b>Project Title</b>			
<b>Meeting Date</b>			

- Category 1: Approved
- Category 2: Some concerns must be addressed (detail below)
- Category 3: Decision deferred. More information/revisions required (detail below)
  - I wish to see revisions
  - Needs external review
- Category 4: Not Approved

<b>Comments</b>			
<b>Signature</b>		<b>Date</b>	

1. **RESEARCH PROPOSAL:**

a) **Data Collection/Confidentiality:**

Will study records be maintained in a confidential fashion?

Yes  No  N/A

b) **Aim or Hypothesis:**

Is adequate evidence presented to justify the proposal on scientific grounds?

Yes  No

Is the use of human participants justified?

Yes  No

Comments

c) **Study Design:**

Is the design appropriate to test the hypothesis?

Yes  No

Describe any concerns re: design

d) **Participants:**

Are there concerns regarding:

	Yes	No
- source of participants	<input type="checkbox"/>	<input type="checkbox"/>
- unjustified use of special populations ( <i>eg. minors</i> )	<input type="checkbox"/>	<input type="checkbox"/>
- undue pressure for participants to consent	<input type="checkbox"/>	<input type="checkbox"/>
- procedures to obtain consent	<input type="checkbox"/>	<input type="checkbox"/>
- deception of participants about aspects of the study	<input type="checkbox"/>	<input type="checkbox"/>
- availability of adequate numbers of participants	<input type="checkbox"/>	<input type="checkbox"/>

<b>Describe any concerns</b>

e) **Radioisotopes?**      Yes          No   

f) **Compensation:**  
If there is any, is it used in such a way or is the amount such that it can be construed as an improper inducement of participants?  
Yes          No          N/A   

g) **Potential benefits and risks to individual participants:**  
Is the described balance of benefit/risk justified?  
Yes          No          N/A   

<b>Describe any concerns</b>

h) **If this is a therapeutic trial, is there standard therapy for the illness?**  
Yes       No       N/A

If yes, is the experimental therapy adequately justified?  
Yes       No

<b>Any Concerns:</b>

## 2. INFORMATION LETTER:

Informed consent normally requires two components: the information to potential participants and the consent form both of which must be in lay language.

The following elements should be described in the information to potential participants (check if item is present):

- aims of the study
- the fact that it is a research project
- special research techniques to be employed, e.g. randomization
- the procedures/therapy involved
- alternative therapies (if a therapeutic trial)
- potential benefit
- potential risks (beyond minimal risk)
- anticipated time duration
- rules for the participant to stop their participation in the study at any time
- voluntary nature of the study
- statement that the participant may withdraw without prejudice
- statement regarding confidentiality of records
- statement of any limitations of confidentiality
- statement of who will have access to the data
- details of any financial compensation
- the participant may consult with the investigator or Department Head at any time

### **3. CONSENT FORM:**

Where applicable, the following elements must appear in the consent form (check each item if present):

- I have read and understand the material in the information letter
- I understand my participation is voluntary
- I have the freedom to withdraw at any time
- I have the freedom not to answer any question
- I understand that the information will be confidential within the limits of the law
- I understand I can keep a copy of the signed and dated consent form
- I understand that I can contact the UPEI Research Ethics Board at (902) 620-5104, or by e-mail at lynmacdonald@upei.ca if I have any concerns about the ethical conduct of this study.

<b>Signature</b>		<b>Date</b>	
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