PRINCIPAL INVESTIGATOR REVIEW OF ONGOING RESEARCH REPORT

1. PI/SITE ADMINISTRATIVE INFORMATION

Name of Principal Investigator:			
Site / Clinic / Company Name:			
Site Contact Person for IRB Issues:			
Contact's Phone	( ) -	Contact's Fax	( ) -
Contact's Email Address:			
Street:			
City:		Province / State:	
Country:		Postal / Zip Code:	

2. STUDY IDENTIFICATION

Sponsor of the Research:		
Protocol Number:		(If there is no Protocol Number check here: ☐)
Protocol Title:		

3. STUDY ENROLMENT

☐ Study not yet initiated:
- ☐ Funding issues
- ☐ Other: _____

☐ Study is dormant:
- ☐ Funding issues
- ☐ Accrual problems (see recruitment difficulties below)
- ☐ Other: _____

☐ Enrolment open and is at: _____ percent of projected enrolment.

☐ Enrolment closed – experimental procedures continue.
Date last Participant enrolled: _____/_____/_____
DD MM YYYY

☐ Enrolment closed – follow-up only. No further experimental procedures.
Date last Participant enrolled: _____/_____/_____
DD MM YYYY

First Participant In: _____/_____/_____ DD MM YYYY	Projected Date of Study Enrolment Completion: _____/_____/_____ DD MM YYYY

Total number of Participants enrolled in this Study at this Site:		Total number of Participants withdrawn in this Study at this Site:	

If any, please provide reasons for Participant withdrawal:

- ☐ Lack of Efficacy
- ☐ Adverse Event(s)
- ☐ Lost to Follow-Up (unable to contact Participant)
- ☐ Withdrew consent (Specify if any reason given):_____
- ☐ Other (Specify):_____

Were there any difficulties recruiting or retaining Participants in this Study? ☐ Yes ☐ No

If yes, please explain:

4. STUDY PROTOCOL

What is the date of the Study Protocol currently in use, including any Amendments?

Study Protocol: _____/_____/_____ (DD MM YYYY) Last Amendment: _____/_____/_____ (DD MM YYYY)

5. INFORMED CONSENT DOCUMENTATION

Date of the Informed Consent Documentation currently in use: _____/_____/_____ (DD MM YYYY)

Was the Informed Consent Document duly signed by the Study Participant and the Investigator or his delegate prior to any Study related procedures?	☐ Yes ☐ No
Were copies of the Informed Consent Document provided to each Study Participant?	☐ Yes ☐ No
Were any problems encountered while communicating the Study to the Study Participants?	☐ Yes ☐ No

If yes, please list problem categories:

- ☐ Informed Consent Document is too technical
- ☐ Informed Consent Document is too long
- ☐ Same questions are constantly asked by Study Participants
- ☐ Other (please explain): _____

6. RECRUITMENT MATERIALS

Are there any Recruitment Materials used in this Study? ☐ Yes ☐ No

If yes, what is the date of the following Recruitment Materials currently in use?

- ☐ Poster _____/_____/_____ (DD MM YYYY)
- ☐ Flyer _____/_____/_____ (DD MM YYYY)
- ☐ Newspaper ad _____/_____/_____ (DD MM YYYY)
- ☐ Radio ad _____/_____/_____ (DD MM YYYY)
- ☐ Television ad _____/_____/_____ (DD MM YYYY)
- ☐ Other: _____

7. INVESTIGATORS

Are there any changes in the duties of the Investigators participating in the Study at this Site?	☐ Yes ☐ No
If yes, please provide details:	
Does the Principal Investigator have any new conflicting interests since the last approval of the Study at his/her Site?	☐ Yes ☐ No
If yes, please provide details:	
Has the Principal Investigator been audited for any study by Health Canada, the FDA or OHRP since the last approval of the Study at this Site?	☐ Yes ☐ No
If yes, please provide details and/or a copy of the Audit Report as soon as possible:	
Are there any current investigations or charges involving the Principal or Sub-Investigator(s)?	☐ Yes ☐ No
If yes, please provide details:	
Are all Investigators participating in the Study at this Site approved by the IRB? *If no, please provide their Curriculum Vitae and Medical License for review and approval.*	☐ Yes ☐ No

☐ I have provided an updated copy of Current Medical Licenses of all Investigators participating in the Study at this Site for the upcoming year.

8. SAFETY AND COMPLAINTS

Since the last IRB review, have there been any Unanticipated Problems (including Adverse Events) involving risks to Participants or others that have not yet been reported to the IRB? *If yes, attach a summary describing the Unanticipated Problems involving risks to Participants or others.*	☐ Yes ☐ No
Since the last IRB review, have there been any significant Protocol Deviations that have not yet been reported to the IRB? *If yes, attach a summary describing the nature of the significant Protocol Deviations.*	☐ Yes ☐ No
Have there been any Protocol Deviations that do not require reporting to the IRB but are repeating or are of similar nature? *If yes, attach a summary describing the nature of the Protocol Deviations.*	☐ Yes ☐ No
Since the last IRB review, have any Participants or others complained to the Site about the research? *If yes, attach a summary describing the number and nature of the complaints.*	☐ Yes ☐ No
How many unexpected and related Serious Adverse Events were experienced in this Study at this Site in total?	
How many unexpected and related Serious Adverse Events were experienced in this Study at this Site since last approval?	

9. STUDY MONITORING

Since the last IRB review, did the Sponsor monitor the Study?	☐ Yes ☐ No
If yes, what is the number of monitoring visits to this Site?	
In the opinion of the Principal Investigator, have the risks or potential benefits of this research changed? *If yes, attach a summary description of those changes.*	☐ Yes ☐ No

I certify that I have submitted all the required documentation and that the above information is accurate and truthful to the best of my knowledge.

Print Name

Signature of the Principal Investigator

_____ / _____ / _____
DD MM YYYY