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**RESEARCH ETHICS BOARD – ANNUAL PROGRESS REPORT**

**INFORMATION & INSTRUCTION SHEET**

**BACKGROUND – WHY IS AN ANNUAL PROGRESS REPORT REQUIRED?**

* As per TCPS2 6.14, research is subject to continuing research ethics review from the date of initial REB approval throughout the life of the project;
* At a minimum, research must be reviewed annually;
* As with initial REB applications, renewals may be reviewed by the Full Board or in a delegated fashion, depending on the risk associated with the protocol under review;
* Following initial review, the REB will continue to ensure that all stages of the research study are compliant with TCPS2 and remain ethically acceptable

**WHAT HAPPENS IF I DON’T SUBMIT AN ANNUAL PROGRESS REPORT?**

When a project/study is reviewed and approved by the REB, the approval is in effect for a period of one year (unless otherwise determined by the REB). The study has an expiry date which is clearly indicated in the approval letter that was sent by the REB. If a study is not renewed prior to that date, your REB approval has expired and permission to carry out the study is no longer granted. Studies that have expired will be put on hold until approval has been reinstated. ***This means that no study related activities (i.e. recruitment) may continue until re-approval has been obtained and cost-centres will be paused until approval has been re-instated***.

**HOW CAN I AVOID STUDY SUSPENSION?**

* Carefully review each approval letter you receive. The expiration date will be clearly noted.
* Track expiry dates in your calendar(s). To be compliant with the applicable clinical research regulations (TCPS2, ICH-GCP and the approved N2 SOPs), **it is the responsibility of the Principal Investigator to ensure their studies do not expire.**
* Accurately complete the annual progress report form and submit it to the REB ***4 weeks*** ***prior to the expiration date*** of your study.
* The “Summary of Activity” section of the report must be completed when you submit the renewal form. Without this information, the form will be returned to you for completion.

**IMPORTANT REMINDER!**

Researchers are required to report to their REB any changes to the current approved protocol and/or ICF. These changes may include, but are not limited to: changes in the treatment or intervention, changes to the protocol, eligibility criteria, follow-up assessments etc. Changes must not be implemented without REB review and approval. Depending on the significance of the change, review may be done in a delegated fashion unless Full Board review is required per TCPS2 and GCP guidelines. **Please see the amendment form for further information**.

***Please delete this page once you have completed the form. Do not submit this page with the form.***

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**RESEARCH ETHICS BOARD – ANNUAL PROGRESS REPORT**

Please complete the following information. *Annual progress reports must be submitted 4 weeks prior to expiration of the last approval*. Studies that have expired will be placed on hold until appropriate review has been completed and approval is re-instated.

|  |  |
| --- | --- |
| **REB NUMBER:** Click here to enter text.  **PRINCIPAL INVESTIGATOR:** Click here to enter text.  **PROTOCOL TITLE:** Click here to enter text. | **DATE:** Click here to enter a date.  **DATE OF LAST APPROVAL:** Click here to enter a date. |

1. **Study Type:**

Clinical Trial (drug, device or NHP) – **REGULATED** by Health Canada

Clinical Trial (Other Interventional) – **NOT REGULATED** by Health Canada

Surveys/Interviews

Observational

Chart Review

1. **Expected date of study completion as previously approved:** Click here to enter a date.
2. **Is the study expected to be complete by the date noted above?**

Yes

No, but we are planning to terminate the study before the completion date

No, we will require the REB to approve an extension to the study timeline.

We are requesting an extension of the study with an expected completion date of:

Click here to enter text.

1. **Is there sufficient funding in place for project completion?**

There is sufficient funding in place to extend the completion date as indicated

We are seeking additional funding to support the extension of the study

We do not have sufficient funding to extend the study

1. **Ongoing Research Recruitment**

***The Royal’s REB is required to provide ongoing research recruitment metrics to The Royal’s leadership team. Investigators/research teams are responsible for providing accurate recruitment numbers on the annual reports submitted to the REB for quality and strategic planning reporting. The following numbers are required.***

**For Definition purposes:**

1. **Clients of The Royal:** Clients are defined as patients/clients of The Royal who have a hospital ID number (MRN) and attend inpatient and/or outpatient visits.
2. **Family Members of Clients of The Royal:** Family members are defined as mother, father, grandparents, aunts, uncles, cousins, siblings, step-parents, spouse/common-law/partner, and/or children of clients of The Royal.

**\****When reporting, please specify if other care providers (e.g. close friends) who participate in research have been reported as non-patients or family members.*

1. **Research Registry at The Royal:** Research participants that are recruited directly from a research registry at The Royal.
2. **Community:** Research participants that are recruited from outside of The Royal, but still within the Ottawa/Brockville communities. (e.g. community centres, universities, doctors offices, etc.)
3. **Online Anonymous:** Research participants that are recruited online, and their identifying information remains completely anonymous to the researcher.
4. **Other:** All other research participants that do not fit into the above-mentioned categories.

**Annual Report Summary**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Information Required** | **Clients of The Royal** | **Family Members of Clients of The Royal** | **Community** | **Online Anonymous** | **Other** |
| **Enrollment Target:** The total number of participants expected to be enrolled at this site, as indicated in the protocol and approved by the REB during the initial approval OR following a sample size amendment approval. |  |  |  |  |  |
| **Total Enrollment to Date:** The total number of participants who have consented to participate ***since the study opened to recruitment***. |  |  |  |  |  |
| **Total Enrollment Since Last Approval:** This is the total number of participants that have been enrolled ***since the date of the last REB approval***. |  |  |  |  |  |
| **Total Withdrawals to Date –** The total number of participants who have ***withdrawn since the start of the study***. |  |  |  |  |  |
| **Total Withdrawals Since Last Approval:** The Total number of participants who have ***withdrawn from the study since the last REB approval***.  **Reason for Withdrawals:** List the reasons participants have withdrawn from the study (Eg. 2 patients moved, 1 patient died, 3 non-compliant with study)  Click here to enter text. |  |  |  |  |  |

*Note: For* ***chart review/database*** *type research activities in which participant consent is not obtained, recruitment numbers are* ***not applicable.*** *Please proceed to the summary of research activity section below.*

**Have you recruited, or are you actively recruiting, participants from The Royal Research Registry?**

☐ Yes ☐ No

**SUMMARY OF RESEARCH ACTIVITY SINCE LAST APPROVAL**

*Please provide a* ***brief*** *description of the study activity that has occurred since the last REB approval. This may include information about recruitment challenges, DSMB review, adverse events, interim analyses etc.*

***Important:*** *This section is mandatory. If left incomplete, the form will be returned to the investigator for completion and annual approval will not be issued.*

Click here to enter text.

1. **Current protocol/Informed Consent Form status:**

|  |  |
| --- | --- |
|  | There have been no changes made to the protocol or the ICF since the last annual renewal (or initial approval if this is the first annual report for this study); |
|  | Changes have been made to the protocol and/or ICF since the last annual renewal and these have been submitted to the REB for review. Approval has been obtained or approval is currently pending REB review; |
|  | Changes have been made to the protocol and/or ICF since the last annual renewal and the amendment forms and documents are included with this submission for review by the REB |

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*I confirm to the best of my knowledge that the information provided above is accurate and true.*

*I agree to conduct this trial as per the Tri-Council Policy Statement (TCPS-2), the ICH Good Clinical Practice Guidelines (GCP), and all other regulatory guidance that may be applicable to this study including the Health Canada Division 5 Food & Drug regulations, Natural Health Product regulations, Division 3 Radiopharmaceutical regulations and the Health Canada Medical Device regulations, as well as all institution specific policies and procedures.*

**Qualified/Principal Investigator Name (typed):** Click here to enter text.

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**Qualified/Principal Investigator Signature** **Date of Signature:** Click here to enter a date.

***You must keep a copy of this completed form for your study file***