**School of Pharmacy & Pharmaceutical Sciences**

**Level 1 Research Ethics Committee**

**REPORTING**

***Annual project report from investigators***

Ongoing research will be subject to continuing ethics review. An annual report to the School of Pharmacy and Pharmaceutical Sciences Research Ethics Committee (SoPPS REC) will be required from investigators, including a brief synopsis of progress during the past year, an indication of compliance with the approved proposal/details of amendments to the proposal, and confirmation of appropriate data management. A report template is included at the end of this document.

This report will include information on project amendments and adverse events. However, it is important to note that:

* **Any significant alteration to a previously approved proposal must receive approval from the SoPPS REC before implementation.** Significant alterations include changes to personnel, study design/methodology (including recruitment methods and informed consent procedures), duration, patient information leaflets.
* **Any serious or unexpected adverse events on participants, or unforeseen events that might affect the benefits/risks ratio of the proposal, must be reported to the SoPPS REC immediately, in writing, by email to** [**sryder@tcd.ie**](mailto:sryder@tcd.ie)**.** These will in turn be reported immediately by the SoPPS REC to the University’s Research Ethics Policy Committee (REPC). A serious adverse event is defined as any untoward medical occurrence that results in death, is life threatening, requires in-patient hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability/incapacity, or results in a congenital anomaly/birth defect. An unexpected adverse event is an adverse reaction, the nature and severity of which is not consistent with the applicable product information. Such adverse/unforeseen events should also be included in the annual project reports submitted by investigators. However, the annual reports will also contain details of any other adverse events/outcomes associated with conduct of the research. Such other adverse events/outcomes will be notified by the SoPPS REC to the REPC on an annual basis.

***Notification of project termination***

The SoPPS REC must be notified of the date when a project concludes, within 90 days of the conclusion date. The conclusion date is defined as the last data collection timepoint. If the project is terminated prematurely, the SoPPS REC must be informed of the reason(s) for premature termination.

***End of project report***

An end of project report must be submitted by the investigators to the SoPPS REC within one year of the project’s conclusion. This report will include a brief synopsis of the main project outcomes, an indication of compliance with the approved proposal/details of amendments to the proposal (including information on premature termination if applicable), and confirmation of appropriate data management. A report template is included at the end of this document.

Annual and end of project reports should be submitted to Chair, School of Pharmacy & Pharmaceutical Sciences Research Ethics Committee, Panoz Building, East End 4-5, Trinity College, Dublin 2; [sryder@tcd.ie](mailto:sryder@tcd.ie).

**School of Pharmacy & Pharmaceutical Sciences Research Ethics Committee**

**Project Annual Report Form**

Name of investigator (print): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Title of project: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date of previous annual report (if any): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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| --- | --- | --- |
| **Questions:** | **YES** | **NO** |
| Is the study continuing? If so, please provide the *anticipated* conclusion date in the space below. Otherwise, please specify the *actual* conclusion date. | □ | □ |
| In the past year, have there been any modifications to the procedures for which approval was granted? If so, please provide details in the space below.\* | □ | □ |
| In the past year, have there been any adverse outcomes or events associated with the conduct of the research? If so, please provide details in the space below.† | □ | □ |
| Is all data being stored in accordance with Trinity’s data storage policy, in adherence to the Freedom of Information Act, and in compliance with the requirements of the Data Protection Commissioner? If not, please explain below. | □ | □ |
| Will all data be kept for 5 years in accordance with Trinity’s data storage policy? If not, please explain below. | □ | □ |

Conclusion date (*i.e.* last data collection timepoint) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ □ Anticipated □ Actual

Brief summary of progress to date (since previous annual report, if any; maximum 300 words)

Modifications in the past year, if any, to the procedures for which approval was granted\*:

All adverse outcomes/events in the past year, if any, associated with the conduct of the research†:

Explanation of any deviation from data storage policy/duration:

\* Note that any significant alteration to a previously approved proposal must receive **prior approval** from the SoPPS REC before implementation. Significant alterations include changes to personnel, study design/methodology (including recruitment methods and informed consent procedures), duration, patient information leaflets.

† Note that any serious or unexpected adverse events on participants, or unforeseen events that might affect the benefits/risks ratio of the proposal, must also be reported to the SoPPS REC **immediately, in writing, to sryder@tcd.ie**. A serious adverse event is defined as any untoward medical occurrence that results in death, is life threatening, requires in-patient hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability/incapacity, or results in a congenital anomaly/birth defect. An unexpected adverse event is an adverse reaction, the nature and severity of which is not consistent with the applicable product information.

**School of Pharmacy & Pharmaceutical Sciences Research Ethics Committee**

**End of Project Report Form**

Name of applicant (print): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Title of project: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date of study conclusion (*i.e.* last data collection timepoint): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

|  |  |  |
| --- | --- | --- |
| **Questions:** | **YES** | **NO** |
| Is a summary of the main outcomes of the project provided in the space below? If not, please provide an explanation below. | □ | □ |
| Were there any modifications to the procedures for which approval was granted? If so, please provide details in the space below. | □ | □ |
| Were there any adverse outcomes associated with the conduct of the research? If so, please provide details in the space below. | □ | □ |
| Was the project terminated prematurely? If so, please provide details in the space below. | □ | □ |
| Is all data being stored in accordance with Trinity’s data storage policy, in adherence to the Freedom of Information Act, and in compliance with the requirements of the Data Protection Commissioner? If not, please explain below. | □ | □ |
| Will all data be kept for 5 years in accordance with Trinity’s data storage policy? If not, please explain below. | □ | □ |

Summary of the main outcomes of the project (maximum 500 words), or explanation of why summary has not been provided.

Modifications, if any, during the full course of the project to the procedures for which approval was granted:

All adverse outcomes, if any, during the full course of the project associated with the conduct of the research:

Reason(s) for premature termination of study, if applicable:

Explanation of any deviation from data storage policy/duration: