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

**Project Annual Report Form**

*For ongoing projects, this form must be submitted to* [*pharmacy.ethics@tcd.ie*](mailto:pharmacy.ethics@tcd.ie) *annually no later than the anniversary of the project approval date (i.e. if project was approved on 1st June, report is due by 1st June annually)*

**Part A – Details of project**

|  |  |  |
| --- | --- | --- |
| Application reference number |  | |
| Date of original submission |  | |
| Date of original ethical approval |  | |
| Date(s) of approval for any previous amendments |  | |
| Applicant\* name  \*Person to whom ethical approval was granted |  | |
| Applicant email |  | |
| Applicant ID Number (TCD applicants) | TCD staff ID: | TCD student ID: |
| Title of research project |  | |
| Project conclusion date (*i.e.* last data collection timepoint) |  | |  |  |  |  | | --- | --- | --- | --- | |  | Anticipated |  | Actual | |

**Part B – Project report**

|  |  |
| --- | --- |
| **Date(s) of PREVIOUS annual report(s), if any:** |  |

|  |
| --- |
| **Brief summary of progress to date (since previous annual report, if any).** This should include the number of participants who have been recruited and the number who have completed the study. (Maximum 500 words.) |
|  |

|  | **YES** | **NO** |
| --- | --- | --- |
| **Is the study continuing?**  If so, please provide the *anticipated* conclusion date in Part A above. Otherwise, please specify the *actual* conclusion date in Part A above. |  |  |
| **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.\***  \* 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, OR participant information leaflets. |  |  |
| *Details of modifications (if any) in past year* |
| **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.†**  † 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 pharmacy.ethics@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. |  |  |
| *Details of all adverse outcomes and events (if any) in past year, whether serious or not* |
| **In the past year, have there been any complaints associated with the conduct of the research, *e.g.* regarding data protection? If so, please provide details in the space below.** |  |  |
| *Details of complaints (if any) in past year* |
| **Is all data being stored in accordance with the approved study protocol, Trinity’s Data Protection policy, Trinity’s Good Research Practice Policy and the requirements of all relevant data protection legislation? If not, please provide details and explain below.** |  |  |
| *Details and explanation of deviation from data storage policy/procedures (if any)* |
| **Will all data be kept for 7 years from the study’s conclusion in accordance with good practice recommendations? If not, please provide details and explain below.** |  |  |
| *Details and explanation of deviation from data retention guidelines (if any)* |

**Part C –Signature(s)**

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| --- | --- | --- | --- | --- |
| **Applicant to whom ethical approval was granted** (all studies) | |  | **Supervisor** (only where applicant to whom ethical approval was granted is a student) | |
| *Name* |  |  | *Name* |  |
| *Signature* |  |  | *Signature* |  |
| *Date* |  |  | *Date* |  |