**OxTREC APPLICATION FORM: For NIH Funded Studies Only**

Please note that as a condition of the grant funding, completion of the following sections is compulsory for any study funded by the US National Institutes of Health (NIH).

**45. Data and Safety Monitoring**

*Please provide a copy of the Data and Safety Monitoring Plan*.

NB: The Principal Investigator has the ultimate responsibility for the conduct of this research study. The study-specific scientific protocol should include detailed information about tests and procedures employed to safeguard the health and safety of the subjects. Additionally, the PI must prepare a specific data and safety monitoring plan taking into account national guidelines and the study’s complexity, risk, and size. The plan should include the administrative processes for recording and evaluating the data quality and integrity. The plan should also specify the responsibilities of research team members and the schedules for reviewing and reporting study progress and adverse events.

Further information and guidance may be found on the [NIH website](https://humansubjects.nih.gov/data_safety).

**46. Subject Participation**

Please complete the NIH Targeted/Planned Enrolment Table, summarizing enrolment for all
sites where University of Oxford-related activities are to be conducted, over all of the years of the study. The Ethnic Category Total of all Subjects and the Racial Category Total of all Subjects must be equal.

|  |  |  |  |
| --- | --- | --- | --- |
| **Ethnic Category** | Females | Males | Total |
| Hispanic or Latino |  |  |  |
| Non Hispanic and Non Latino |  |  |  |
| Total of all subjects |  |  |  |
|   |   |   |   |
| **Racial Category** | Females | Males | Total |
| American Indian / Alaska Native |  |  |  |
| Asia |  |  |  |
| Native Hawaiian or other Pacific Islander |  |  |  |
| Black or African American |  |  |  |
| White |  |  |  |
| Total of all subjects |  |  |  |

**47. Inclusion Across the Lifespan**

*Please provide a copy of the Inclusion Plan for Individuals Across the Lifespan. If there is exclusion based on age, please provide the rationale and justification for this.*

NB: NIH policy requires that investigators include individuals of all ages when conducting clinical research, unless there is a strong justification for their exclusion.
Exclusion based on age must be due to **ethical** or **scientific** reasons.

Further information and guidance, including acceptable justifications for exclusion, may be found on the [NIH website](https://grants.nih.gov/grants/funding/lifespan/lifespan.htm).

**48. Genomic Data Sharing**

*If applicable, please provide a copy of the Genomic Data Sharing Plan.*

NB: The [NIH Genomic Data Sharing Policy](https://osp.od.nih.gov/wp-content/uploads/NIH_GDS_Policy.pdf) expects all investigators seeking NIH funding to develop a genomic data sharing plan if they are proposing research that will generate large-scale human or non-human genomic data.

Further information and guidance on the type of information that should be included in a genomic data sharing plan, when the plan should be submitted, and examples of genomic data sharing plans may be found on the [NIH website](https://osp.od.nih.gov/wp-content/uploads/NIH_Guidance_Developing-GDS_Plans.pdf).

**Additional Requirement for Clinical Trials**

*Investigators should note that, for all NIH-funded clinical trials, the NIH require that an IRB-approved (i.e. ethics committee-approved) version of the informed consent form for the trial be posted on a public federal website. This must be done after enrollment ends and within 60 days of the last study visit. Further details can be found on the* [*NIH website*](https://nexus.od.nih.gov/all/2019/06/04/where-to-post-informed-consent-forms-for-nih-funded-clinical-trials/)*.*