**NSU Researcher Information**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Principal Investigator | |  | | | | | |
| Select One: | Faculty | | Staff | | | | Student |
| School/Unit | |  | | | Department/ Center |  | |
| Phone # | |  | | Email | |  | |
| Campus Address | |  | | | | | |
|  | | | | | | | |
| **Project Information** | | | | | | | |
| Title | |  | | | | | |
| Brief Description | |  | | | | | |
| Financial Sponsor | |  | | | | | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Report Period |  | |  |  |
| *(up to 1 year)* | Month/Year | to | | Month/Year |

|  |  |  |
| --- | --- | --- |
| Is this research project ongoing at this site? | Yes | No |

Termination date:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Do you wish to continue this research? | Yes | Post the current consent form to this project in IRBNet. | | |
|  | No | This will be considered the closeout report for the project (not for closure to patient entry). | | |
|  |  | | | |
| Did you actively enroll subjects or collect data during the report period? | | | Yes | No |

**Please provide the following information for this site:**

|  |  |
| --- | --- |
| **Required Information** | **Totals for the  Report Period** |
| Number of Subjects Enrolled |  |
| Number of Subjects Enrolled by Category (federal government reporting requirement) | |
| Males |  |
| Females |  |
| Black, Non-Hispanic |  |
| American Indian/Alaskan Native |  |
| Asian/Pacific Islander |  |
| Hispanic |  |
| White, Non-Hispanic |  |
| Other or Unknown |  |
| Number of Subjects Withdrawn from the Study |  |

|  |  |
| --- | --- |
| **Required Information** | **Totals** |
| Total Number of Subjects Enrolled Since the Initiation of This Project |  |
| Number of Subjects Engaged in the Study at the Present Time |  |
| Number of Subjects Withdrawn from the Study Since Initiation |  |

|  |  |
| --- | --- |
| Total Number of Subjects Enrolled Across All Sites to Date |  |

|  |  |  |
| --- | --- | --- |
| Is the study closed to subject entry? | Yes | No |

|  |  |
| --- | --- |
| If yes, date of closure (day/month/year): |  |

|  |  |  |
| --- | --- | --- |
| Is closure permanent? | Yes | No |

|  |  |
| --- | --- |
| Please describe any medical, legal or practical difficulties that were encountered during the reporting period of the study aside from adverse events. Difficulties may include complaints of subjects, logistic problems of performance, or any difficulties that may pertain to the rights of these subjects. |  |

|  |  |
| --- | --- |
| **Number of local adverse events:** | **Number of non-local adverse events:** |

|  |  |
| --- | --- |
| Please provide a brief description of trends in adverse events. Adverse events must be reported to the NSU IRB within five days of the investigator being notified. If there are events that have not been reported to the IRB, submit notification with a brief explanation via IRBNet. |  |

|  |  |  |
| --- | --- | --- |
| **Prompt** | **Response** | |
| *Yes* | *No* |
| Has the protocol or consent form changed in any way since the last approval? If yes, use IRBNet to submit to a copy of any amendment(s) not previously submitted. |  |  |
| Has any new information become available during the course of the research that may affect the subject's willingness to continue participation in the study? |  |  |

|  |  |
| --- | --- |
| If yes, explain: |  |

|  |  |  |
| --- | --- | --- |
| **Prompt** | **Response** | |
| *Yes* | *No* |
| Was new information provided to subjects? If yes, use IRBNet to submit documentation. |  |  |
| Is there recent information, especially regarding risks associated with the research, that the IRB should be aware of when conducting the continuing review? If yes, use IRBNet to submit the pertinent information. |  |  |

Please use IRBNet to submit a brief overview of research results/observations obtained to date. If applicable, include local and multisite information and one copy of any publications that have resulted from this research.

|  |  |  |  |
| --- | --- | --- | --- |
| NSU Principal Investigator |  | Date |  |
| NSU Faculty Mentor/Advisor  (if applicable) |  | Date |  |
| NSU Department Head/Dean |  | Date |  |