**CONTINUING REVIEW APPLICATION**

Please complete this form in its entirety. Please DO NOT copy and paste information from your initial application OR a previous continuing review.

1. **PARTICIPANT ENROLLMENT:**

**The number of participants currently approved for this protocol can be found in Section 2 of your Initial Application or Amendment or Continuing Review if an increase in enrollment was requested. Address over-enrollment in the Section 5 below.**

1. **IRB Approved, Number of Participants:** Click here to enter text.

**Please provide the total number of participants enrolled during the last approval period in the table below. Please add gender categories based on the data collected in the approved protocol. You may include additional gender categories, if needed, by adding new columns to the chart.**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **TOTAL PARTICIPANTS ENROLLED IN LAST APPROVAL PERIOD** | | | | | | |
| **Adults** | | | **Minors** | | | **TOTAL:** |
| Click or tap here to enter text. | Click or tap here to enter text. | **Gender Not Collected** | Click or tap here to enter text. | Click or tap here to enter text. | **Gender Not Collected** |
| 0 | 0 | 0 | 0 | 0 | 0 | 0 |

**Please provide the total number of participants enrolled to date in the table below. Please add gender categories based on the data collected in the approved protocol. You may include additional gender categories, if needed, by adding new columns to the chart.**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **TOTAL NUMBER OF PARTICIPANTS ENROLLED TO DATE** | | | | | | |
| **Adults** | | | **Minors** | | | **TOTAL:** |
| Click or tap here to enter text. | Click or tap here to enter text. | **Gender Not Collected** | Click or tap here to enter text. | Click or tap here to enter text. | **Gender Not Collected** |
| 0 | 0 | 0 | 0 | 0 | 0 | 0 |

\*To have the chart calculate your total automatically, please complete each column; highlight the “0” located in the TOTAL column; right click, and choose the option “Update Field.” This should calculate your total automatically.

1. **Will the protocol remain open to participant enrollment? If enrollment will remain open, a copy of the CONSENT FORM(S) must be included with your application.**

**Yes  No**

**If the protocol will NOT remain open to enrollment, please state why.**

Click here to enter text.

1. **Were there any participant withdrawals?**

**Yes  No**

**If YES, please explain.**

Click here to enter text.

1. **PROJECT SUMMARY:**

**Provide a summary of the study progress to date. This should include any interim findings (positive/negative), problems encountered, goals for upcoming approval period and a projected completion date (i.e. March 2016). Please indicate if any additional risks have been identified.**

Click here to enter text.

1. **PROBLEM HISTORY**
2. **Have any adverse events and/or unanticipated problems involving risks to participants or others occurred during the last review period?**

**Yes  No**

**If YES, please explain.**

Click here to enter text.

1. **Have you experienced any participant complaints?**

**Yes  No**

**If YES, please describe participant complaints and discuss how these problems were handled.**

Click here to enter text.

1. **DEVIATIONS**

**Were there any deviations to the currently approved IRB protocol? A deviation is any difference in study conduct from the criteria or activities prescribed in the IRB approved protocol, which may or may not affect the participants’ rights, safety, welfare and/or the integrity of the study.**

**Yes  No**

**If YES, please explain why these occurred.**

Click here to enter text.

**If YES, please state how you plan to prevent this deviation from occurring in the future (An attached “Corrective Action Plan” is required).**

Click here to enter text.

1. **REQUEST FOR APPROVAL OF NEW CHANGES**

**If MINOR CHANGES are being made during this Continuing Review Application, a copy of the updated documents (project, surveys, advertisements, etc.) must be included with the application. Please clearly describe the requested changes in the space below AND state what impact the change will have on risks to participants. Substantial changes to the application WILL NOT be permitted during this transaction.**

Click here to enter text.

1. **CONSENT FORMS**

**If the project will remain open to participant enrollment, please upload a copy of the consent form(s) with your Continuing Review application. If more than one consent form (Parent Consent, Assent, Group A, Group B, etc.) will be used for this protocol please list them below. Or, if this project was previously approved for a waiver of consent, please indicate this below.**

Click here to enter text.

1. **DATA AND SAFETY MONITORING:**

**Required for protocols presenting GREATER THAN MINIMAL RISK. State if project was monitored during the previous approval period and provide a summary of the reviews findings, if any. If the project was not greater than minimal risk, data and safety monitoring may not be required, and is not applicable.**

Click here to enter text.

1. **CONFLICT OF INTEREST**

**Indicate if any Conflict of Interest (COI) issues exist that were not previously reported to the IRB Office. If there is a new COI issue, describe the potential COI, including a plan to mitigate the conflict and how the conflict may affect the level of risk to study participants. UMCP policy on COI:** [**Conflict of Interest**](https://research.umd.edu/coi)**.**

Click here to enter text.

1. **FUNDING SOURCES/RESEARCH SUPPORT**

**Provide the names of any organization, including Federal agencies, providing funding/support for the research protocol.**

Click here to enter text.

**NOTE: The consent forms in your approved IRBNet PACKAGE must be used. When creating or editing your consent form, please provide the most recent IRBNet package number at the bottom, right corner of the consent form. This ensures you are using the most “up-to-date” version of the form.**

**To find your IRBNet package number, go to the MY PROJECTS tab and click on the title of your project. In the PROJECT OVERVIEW page, your IRBNet package number will be listed at the top, next to your project title.**

**REQUIRED SIGNATURES:**

**The Principal Investigator, Co-Investigator, and/or Student Investigator, in electronically signing this Continuing Review Application on IRBNet, certify that they have conducted research in accordance with the IRB-approved protocol and that any consent forms used in connection with the project have been retained by the Principal Investigator unless otherwise indicated in this Continuing Review Application.**