

For Official Use Only:

IRB Log #\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_

Annual Review Form

Human Subjects Research Projects

IRB Log Number: *IRB log number*

|  |  |  |
| --- | --- | --- |
| Principal Investigator/Project Director  Click here to enter text. | Department  Click here to enter text. | Date Submitted  Date |
| Project or Grant Title  Project or grant title | | |

Project Status:

Revision to previously approved project? Yes No Periodic review of continuing project? Yes No

Start and end dates covered by this report: Start date- End Date

IRB approval dates from other institutions, if any. Click here to enter text. Please attach copies.

Federal regulations mandate that all human subject protocols receive continuing review and approval **not less than once per year.** In order to comply with this policy on research involving human subjects, sufficient information must be collected to allow the IRB to conduct a “substantive and meaningful” review. Therefore, in order for the Bellevue College IRB to comply with this and other directives and to grant continuing approval of your protocol, the following information/documents are required: ***a completed continuing review questionnaire and copies of all informed consent documents, surveys and/or questionnaires currently being used.***

I. Briefly summarize the study objectives and procedures (attach additional pages if required).

Enter brief summary

II. Project Implementation Summary

1. Leadership: Have any changes occurred in the leadership, responsibility, or major personnel? If yes, then fully describe in an attachment.

Yes No

1. Objectives: Have any changes in objectives occurred? If yes, then fully describe in an attachment.

Yes No

1. Procedures: Have any changes in procedures occurred? If yes, then fully describe in an attachment.

Yes No

1. Informed Consent Documents: Have any changes been made? If yes, then fully describe in an attachment.

Yes No

1. Research Subjects/Participants
   1. List each group, cohort, etc., if applicable, including control groups, on separate lines. If only one group, descriptions would be “All.”

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **NUMBER OF SUBJECTS**  (at all sites for which you are the PI) | | **AGE RANGE OF SUBJECTS** (at all sites for which you are the PI) | | **GENDER** | |
| Group | This Period | Next Period (anticipated) | This Period | Next Period (anticipated) | % Male | % Female |
|  |  |  |  |  |  |  |
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* 1. Was the subject population (or participating population) representative of the population base from which subjects or participants could be selected with respect to:

**Gender** representation? If no, explain in an attachment.

Yes No

**Minority** representation? If no, explain in an attachment.

Yes No

* 1. Have any subjects withdrawn from the study or project since it began? If yes, explain in an attachment.

Yes No

* 1. Are you aware of any breach in confidentiality? (e.g. unauthorized access to records)

Yes No

1. Unexpected problems:
   1. Have there been any **unexpected** problems? If yes, please summarize these unexpected problems, the number of occurrences, and indicate if they required consent document changes, particularly in the “risks” section. If risks are affected, describe how they are minimized and reasonable in relation to the expected benefits. If available, attach monitoring reports.

Yes  No

1. Proposed Revisions/Amendments/Modifications
   1. Are there any revisions/amendments to the protocol, consent form(s), questionnaires, etc. that are included with this renewal?

Yes  No

* 1. Will the revisions/amendments change the scope or research objectives of the protocol? Following are examples considered to change the scope or research objectives: (1) change in the specific aims approved at the time of funding award; (2) change from the previously approved use of human subjects; (3) shifting the emphasis of the research from one disease to another. If yes, please provide sufficient information/documentation to allow the IRB to review and approve prior to initiation.

Yes  No

* 1. Will the revisions/amendments change risks to subjects? If yes, provide sufficient information/ documentation to allow the IRB to review and approve prior to initiation. In particular, describe how risks are minimized and reasonable in relation to expected benefits.

Yes  No

1. Publications, Presentation, Reports: Provide a listing of all publications, presentations, and reports that have resulted from this work since the last review. If none, indicate not applicable.

As Principal Investigator/Project Director, I acknowledge that I:

* Am responsible for reporting any emergent problems or adverse events;
* Will submit any proposed procedural modifications to the IRB for its review and approval and, except where necessary to eliminate apparent immediate hazards, no such modifications will be put in to effect without prior IRB approval;
* Will renew this application with the IRB no less than annually unless otherwise directed by the IRB Chairperson;
* Will conduct the research project in compliance with the IRB’s understanding and recommendations;
* Will provide the IRB with all information on the research project necessary for its complete review;
* Will not put the research project into effect until final IRB approval is received.

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| --- | --- |
| Signature of Principal Investigator/Project Director | Date |
| Signature of Faculty Advisor (if student project) | Date |

|  |  |  |  |
| --- | --- | --- | --- |
| **FOR COMMITTEE USE ONLY** | | | |
| Signature of IRB Committee Chair | | | Date |
| IRB Chair: Check one box | \_\_\_Approved | \_\_\_Approved with Conditions | \_\_\_Refer to Full Committee Review |

**Routing Instructions**

1) Faculty Advisor (if needed)

2) Institutional Review Board Chair, A242