**STOHN PBRN Study Concept Template**

(use Calibri 11-point font and do not exceed seven pages)

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| **Protocol Title** | <Insert protocol title> |
| **Principal Investigator/Study Team****Institution** | <Insert name of Principal Investigator. Insert names of Study Team members/investigators to date.><Insert PI’s institution/affiliation.> |
| **Background and Scientific****Rationale** | <Describe the research problem and provide compelling scientific rationale for the research.><Summarize prior studies that may provide background to this research. Summarize experience and/or history relevant to the research.><Briefly discuss any literature that may provide background and rationale for this study.> |
| **Specific Aims** | <List specific aims of the study> |
| **Expected Risks/Benefits** | < Include expected risks and benefits to subjects and/or society.> |
| **Eligibility** | <Identify the subject/donor population being evaluated by the protocol.><List inclusion and exclusion criteria.><Indicate the source of subjects/donors.><Describe specifically and state the justification for any vulnerable population or any excluded populations, for example: minors.> |
| **Subject Enrollment** | <Describe participant identification and screening.><Describe the primary strategy for participant recruitment and enrollment.> |
| **Study Design and Procedures** **Study Model** | <Describe the study design and study groups or cohorts.> |
|  **Intervention** | <Describe intervention if there is an intervention> |
|  **Biospecimens Collected** | <List any biospecimen types to be collected and purpose for each sample type. Will biospecimens be retained for future research? If so, is DNA extraction and analysis possible from retained specimens?> |
|  **Other Data Collected** | <Specify other types of data that will be collected, e.g., photographic or radiographic images, periodontal measurements, questionnaire responses, etc. For survey studies, describe the development or selection of the questionnaire> |
|  **Outcome Measures** | <Specify primary and/or secondary outcome measurement(s) or observation(s) used to assess the effect of an intervention or to describe the patterns of disease, traits or associations with exposures or risk factors which are the focus of the study. If appropriate to study design, you may wish to include independent and dependent study variables.> |
|  **Time Perspective** | <What is the temporal relationship between the observation period and time of participant enrollment? Is the study prospective, retrospective, cross‐sectional or other (explain)?> |
|  **Enrollment** | <What is the participant target enrollment ‐ per site and study total?> |
|  **Retention** | <Describe the primary strategy for participant retention, if applicable.> |
|  **Study Sites** |  <List any other sites that would be involved> |
|  **Planned Accrual Period** |  <Insert time (months, years, etc.)> |
|  **Planned Study Duration** |  <Insert time from first participant‐first visit to last participant‐last visit(months, years, etc.)> |
|  **Duration of Subject Participation** | <How many study visits are required for each participant? What is the expected duration of subject participation?> |
| **Justification for why the STOHN PBRN is the best setting for the study as compared to an academic health center or similar setting** |  |
| **Feasibility to conduct high quality****study and recruitment potential** |  |
| **Potential to change clinical practice** |  |
| **Impact on the oral health of the****public** |  |