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| **OHTN Cohort Study Research Proposal Form**1. **Principal Investigator Information**
 |
| **Principal Investigator(s)** |
| Name |  | Phone number |  |
| Position |  | Email |  |
| Organization  |  |
| Mailing Address |  |
| Academic Appointment  | [ ]  Yes [ ]  No | If yes, specify University and department: |
| Student Project  | [ ]  Yes [ ]  No  | If yes, specify please specify program:[ ]  Masters [ ]  Doctorate [ ]  Medical School [ ]  Post Doctorate   |
| Project Related Responsibilities  |  |
| Prior experience with the OCS, including committee membership or OCS research projects.  |  |
| Education, knowledge, skills & experience related to role in the study.  |  |
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| Education, knowledge, skills & experience related to role in the study.  |  |
| 1. **Co-Investigators Information**
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| **Co-Investigator(s)** |
| Name |  | Phone number |  |
| Position |  | Email |  |
| Organization  |  |
| Mailing Address |  |
| Academic Appointment  | [ ]  Yes [ ]  No | If yes, specify University and department: |
| Student Project  | [ ]  Yes[ ]  No  | If yes, specify please specify program:[ ]  Masters [ ]  Doctorate [ ]  Medical School [ ]  Post Doctorate   |
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| Mailing Address |  |
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| Student Project  | [ ]  Yes[ ]  No  | If yes, specify please specify program:[ ]  Masters [ ]  Doctorate [ ]  Medical School [ ]  Post Doctorate   |
| Project Related Responsibilities  |  |
| Prior experience with the OCS, including committee membership or OCS research projects.  |  |
| Education, knowledge, skills & experience related to role in the study.  |  |
| 1. **Other Member(s) of the Research Team**
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| Name | Organization | Position | Role in Project | Relevant Skills and Knowledge |
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| 1. **Project Title**
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| 1. **Duration of Project**
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| Anticipated Start Date |  |
| Anticipated End Date |  |
| 1. **Plain Language Statement**
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| **Plain Language Statement** *(maximum 500 words)*Summarize the proposed project in language that will be intelligible to a lay reader. Include what you hope to learn from this study.  |
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| 1. **Research Objectives and Rationale**
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| **Research Objectives and Rationale** List the proposed research objectives/questions and/or hypothesis(es), if applicable. Include a rationale for the study based on clinical experience, relevant scientific literature, etc. Indicate if this research is novel, or a replication of a study in a different setting or with a different population.  |
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| 1. **Relevance and Impact**
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| **Relevance and Impact**What do you hope to learn from the study? Describe how the successful completion of the project will improve services or prevention interventions for those infected and/or at risk of HIV? How will it benefit the priority population(s)? Does it have the potential to shift current research, clinical practice or service paradigms? If yes how? |
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| 1. **Community Engagement and Knowledge Translation and Exchange**

Community involvement in OCS research projects is a critical component of OCS principles and values, and is recommended in all stages of research. Provide a plan for community engagement and results dissemination to scientific, community based, and stakeholder audiences. |
| **Community Engagement** Summarize how community was involved in the development of the research idea and/or how they will be involved across the project. Describe how you intend to get input from diverse members of the community, in particular members of priority populations and/or subpopulations most affected by the issue of the study.  |
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| **Knowledge Translation and Exchange**List the evidence-sharing activities, methods and approaches to be used and how they are likely to support the intended impacts? How will you put research evidence into the hands of people who will use it? |
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| 1. **Inclusion of participants of all genders, ages and ethno-racial backgrounds**

The OCS is committed to the inclusion of participants from groups that have historically been under-represented, such as racialized people, women, transgender people, and young people.  |
| **Inclusion**Please indicate how you intend to ensure inclusivity in this research project. Please justify any exclusions in your study based on race, gender, age, etc.  |
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| 1. **Data Elements and Analysis Plan**
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| **Data Requested** |
| Will this project be with OCS- ICES linked data?  | [ ]  Yes[ ]  No |
| Are you requesting the analysis be carried out by the OCS research team? | [ ]  Yes[ ]  No |
| List the specific OCS data elements requested. Justify requests for any High-Risk Data Elements (listed in *OCS Data Release Policy*). You may attach the list in a separate document. If the study requires OCS/ICES linked data, please separately list the ICES data elements required.  |
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| **Methods**What are the inclusion/exclusion criteria? Describe your data analysis plan. What associations will you test? What are the outcomes associated with your research objectives/questions? Are there particular statistical methods that will be used? If appropriate, what do you plan to include as co-variates in a multi-variable regression? |
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| 1. **Benefits and Harms**
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| **Benefits and Harms**Indicate any issues relating to: 1) vulnerability of participants, 2) potential risks to participants, 3) adequacy of protection against risks, 4) potential benefits to the participants and others, and 5) importance of the knowledge to be gained. |
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| 1. **Ethical Review Requirements**
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| **Ethical Review Requirements**Describe the requirements and/or plan for ethical review of the proposed research. Indicate if the research proposal qualifies for implicit REB approval under the OCS multi-site study approval with the University of Toronto REB. If the study qualifies for implicit approval, what are the particular study objectives in the OCS Scientific protocol that apply.  |
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| 1. **Data Management and Security**
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| **Data Management and Security**List the names of all Researchers who will have access to the OCS research data set (must also be listed as co-investigators). All Researchers must adhere to theOCS Data Security Requirements for Researchers. If this is not possible, describe and justify an alternative Data Management and Security Plan. |
| Person with Access | Affiliation | TCPS2 Completion | Why Access is Required? |
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1. **Study Documents**.

The following Study documents should be included for review:

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| **External Scientific Reviews (if applicable)** *For Researchers who have undergone external scientific review as part of an application for funding, attach copies of the scientific reviews.* | [ ]  Attached[ ]  Not Applicable  |
| **Curriculum Vitae***Include copies of CVs for the Principal and any Co-Principal Investigators.* | [ ]  Attached |
| **Research Ethics Board Approval Letter***If applicable, include a copy of the REB letter of approval for the Research Proposal. They are required prior to OCS data release.*  | [ ]  Attached[ ]  Not Applicable |
| **Letter from Academic Supervisor (*if applicable*)***Student PIs are asked to include a letter of support from their academic supervisor.*  | [ ]  Attached[ ]  Not Applicable |