**PROSPECTIVE RESEARCH STUDY (NON-INTERVENTIONAL)**

Date form completed:

**Study Title:**

1. **STUDY ARMS OR GROUPS**
2. Will study participants be assigned to arms or groups?

[ ]  Yes [ ]  No

1. If yes, please complete the table below with information about each study arm:

| Arm/group name/number | Arm Type | # of THP participants enrolled | Arm assignment (e.g. randomized) | Length of participation |
| --- | --- | --- | --- | --- |
|       | Other (please specify): |  |       |       |
|       | Choose an item. |  |       |       |
|       | Choose an item. |  |       |       |
|       | Choose an item. |  |       |       |

1. If Arm Type is selected as ‘Other’, please specify:
2. Provide a brief description of the time commitment required for study participants (e.g. participants will be seen weekly for a 1 hour appointment for two months and then seen for a 1 hour appointment yearly for 10 years afterwards):
3. **STUDY PROCEDURES**
4. Will any study specific procedures and activities occur with study participants?

[ ]  Yes [ ]  No

1. If yes, indicate which types of procedures and activities are being done in this study for research purposes only (check all that apply):

| [ ]  Participant visits | [ ]  Imaging | [ ]  Biological Samples |
| --- | --- | --- |
| [ ]  Instruments/Questionnaires | [ ]  Interviews | [ ]  Education |
| [ ]  Observation | [ ]  Focus Groups  | [ ]  Other (please specify):       |

*Include only those* ***procedures which are added on to standard of care and not considered part of the diagnostic/therapeutic "routine" care*** *of patients including all participant contact (e.g. telephone surveys), number of additional blood samplings, increased volumes of blood, additional test on a routine sample, etc.*

* 1. **PARTICIPANT VISITS**
1. **Type of visit (Check all that apply):** **☐ N/A**

| [ ]  Extension of a regular visit | [ ]  Extra hospital/clinic visit |
| --- | --- |
| [ ]  Participant visit to an external site | [ ]  Study visit to participant’s home |
| [ ]  Virtual visits | [ ]  Other (please specify):       |

1. Frequency of each type of visit:
2. Number of each type of visit:
3. Describe what will happen at each participant visit (*provide protocol page reference*):
4. Duration of each study visit (please provide in minutes):
5. Protocol page reference for rationale for the visits:
6. **Virtual Visits:**
7. Which virtual platform(s) will be used to facilitate virtual research visits?

|  |  |  |
| --- | --- | --- |
| [ ]  Skype | [ ]  Zoom | [ ]  Teams |
| [ ]  WebEx | [ ]  Other(please specify):       |  |

1. What measures are in place to maximize safety when engaging virtually?

|  |
| --- |
| [ ]  Participant to confirm they have a confidential space |
| [ ]  Suggest personal/identifiable items are removed from view |
| [ ]  Safety plan for participants requiring urgent follow up |
| [ ]  Offer alternative secure method (e.g. phone) |
| [ ]  Other (explain):       |

1. Do virtual visits exclude any populations based on socio-economic status or raise other ethical issues related to fairness and equity?

[ ]  Yes [ ]  No

* 1. **IMAGING**

1. **Type of imaging (check all that apply)**  [ ]  **N/A**

| [ ]  MRI | [ ]  X-ray | [ ]  MUGA | [ ]  Ultrasound |
| --- | --- | --- | --- |
| [ ]  PET/CT | [ ]  Mammogram | [ ]  Angiogram | [ ]  Resting SYMA Scan |
| [ ]  CT | [ ]  Fluoroscopy | [ ]  Bone Scan | [ ]  Submaximal Stress Test |

| 1. Will sedation or anesthesia be required for any of the imaging being done in this study? [ ]  Yes [ ]  No
2. If yes, what is the length of time of sedation or anaesthesia:

i. Total time for clinical purposes:       ii. Additional time for research purposes:        1. Who will be administering the sedation or anaesthesia?
 |
| --- |
| 1. Is a contrast agent being used for any of the imaging being done in this study?

[ ]  Yes [ ]  No |
| 1. Frequency of each type of imaging:
 |
| 1. Length of time of each type of imaging *(Indicate whether this is an extension of time to imaging that the participant is undergoing for clinical purposes):*
 |
| 1. Who will be responsible for medical oversight of the participant, during and following the imaging procedure?
 |
| 1. Protocol page references for rationale for imaging:
 |

* 1. **BIOLOGICAL SAMPLES** [ ]  **N/A**
1. **Type of samples being collected (check all that apply**)

| [ ]  Blood  | [ ]  Urine  |
| --- | --- |
| [ ]  Tissue  | [ ]  Saliva  |
| [ ]  Bone marrow  | [ ]  Other (please specify):       |

1. The sample will be taken:

|  |  |  |
| --- | --- | --- |
| [ ]  by separate sample collection | [ ]  with routine sample collection | [ ]  both |

1. If samples are taken by a separate sample collection, describe the process for collection of samples, including who is obtaining these samples:
2. Indicate the location where the samples will be collected:

1. Will there be genetic testing on any of the samples collected in this study?

[ ]  Yes [ ]  No  **If yes, please also fill out Appendix D**

1. Is there a pain management plan for sample collection? [ ]  Yes [ ]  No

* 1. If yes, describe the pain management plan (e.g. will a topical anesthetic be used?):
1. Will any of the samples be retained for future use? [ ]  Yes [ ]  No

1. If yes, describe where the samples will be kept, the length of time they will be stored, and the process for disposal:

*Please note that a separate consent statement for retention of samples needs to be included in your consent form.*

1. Describe when and how the samples will be discarded or destroyed:
2. Describe the plan for handling any incidental findings that may arise from the use of the samples:
3. Will the samples be de-identified: [ ]  Yes [ ]  No

1. If yes, how will the samples be de-identified?

1. If no, what measures will be used to maintain patient confidentiality?
2. Will samples and/or the results of the analysis of the samples be linked to other information about a participants? [ ]  Yes [ ]  No
3. If yes, please describe what information will be linked and provide the rationale/justification for this linkage:
4. Samples being collected (please complete the table using the following information):
5. **Quantity** - Provide quantity of sample taken for research purposes (please specify the quantity taken each time a sample is collected for research purposes).
6. **Frequency** - Describe the frequency of sample collection.
7. **Protocol page** - Provide protocol page reference for rationale for collection and use of this biological sample(s).
8. **Type of sample** – Indicate the type of sample(s) being taken for research purposes (this section is only relevant for “tissue” and “other”).

| **Samples** | **Quantity** | **Frequency** | **Protocol page**  | **Type of sample** |  |
| --- | --- | --- | --- | --- | --- |
| Blood |       |       |       |  | [ ]  N/A |
| Urine |       |       |       |  | [ ]  N/A |
| Tissue |       |       |       |       | [ ]  N/A |
| Saliva  |       |       |       |  | [ ]  N/A |
| Bone Marrow |       |       |       |  | [ ]  N/A |
| Other (please specify):       |       |       |       |       | [ ]  N/A |

* 1. **INSTRUMENTS: QUESTIONNAIRES/SURVEYS, INTERVIEW SCRIPTS/FOCUS GROUPS GUIDES** [ ]  **N/A**
1. Please indicate which of the following will be used in this study (select all that apply):

| [ ]  Questionnaires/Surveys[ ]  Interview Script/Focus Group Guide |
| --- |
| 1. Will an online data collection platform be used (e.g. Survey Monkey)?

 [ ]  Yes [ ]  No   |
| 1. If yes, provide the name of and location of the server for the online data collection platform:
 |
| 1. Will validated instruments and/or questionnaires be used in this study?

[ ]  Yes [ ]  No   |
| 1. If yes, please list the validated questionnaires/surveys:
2. Have/will any modifications been made to the validated questionnaires/surveys for use in this study?
3. Has/will the instruments/questionnaires been piloted? [ ]  Yes [ ]  No

*All instruments/ questionnaires and interview scripts that will be used in this study with copyright dates should been included with the REB submission package.* |
| 1. **Recordings** [ ]  **N/A**
2. What type of recording will be used to record the interview or focus group (e.g. Audio, video or both)?
3. Will the recording be de-identified? [ ]  Yes [ ]  No

 1. If yes, how will they be de-identified?
2. Describe where you will be storing the recordings:
3. How will recordings be securely destroyed at the end of the data retention period?

*\* If recording is optional, a consent statement should be included on the consent form.* |
| 1. Who will be administering/conducting the survey, questionnaire, interview or focus group?
2. Please indicate the method of instrument administration:

 [ ]  In Person [ ]  By Telephone [ ]  Other, please specify:      1. Provide the frequency of the questionnaires, interview, or focus group(s) sessions:
2. Provide the length of time for questionnaire completion, interview sessions or focus group(s):
 |
| 1. Will the data collected from the questionnaires, interviews, or focus groups be:

[ ]  De-identified [ ]  Anonymized [ ]  Anonymous  |

1. **WITHDRAWAL**
2. Do study participants have the option to withdraw from continued participation in the study?

[ ]  Yes [ ]  No

1. If no, provide justification:
2. If yes, what procedures will be followed for study participants who wish to withdraw at any point during or after the study (e.g., how does the participant withdraw, what will happen with data collected up to the time of withdrawal)?
3. Please provide protocol page reference for the description of the withdrawal process, and ensure the process for withdrawal has been documented in the consent form:
4. **RESEARCH PARTICIPANfsT REIMBURSEMENT AND RECOGNITION**

*(Any reimbursements, recognitions or incentives to the participants need to be addressed in the consent process)*

1. Will there be any financial expenses incurred by study participants tied to their participation in this study? [ ]  Yes [ ]  No
2. If yes, please describe the expenses:
3. Have specific funds been provided in the budget for reimbursements or gifts to participants, e.g. travel, parking, time spent, etc.? [ ]  Yes [ ]  No

1. How will study participants be recognized or compensated for their participation in this study?

[ ]  **N/A**

| [ ]  Thank you letter | [ ]  Certificate |
| --- | --- |
| [ ]  Community service hours | [ ]  Financial compensation for participation |
| [ ]  Gift/Gift Cards | [ ]  Other (please specify):       |

1. Please state the value of the selected item(s) and provide justification:
2. How is this cost being covered?