**Clinical Research Services Department Application**

**The Clinical Research Services Department (CRSD) requires the following information in supplement to the TBRHSC REB application to ensure all organizational impact has been approved by the institution. Submit the TBRHSC REB Application, CRSD Application and all study documents to** **researchprogram@tbh.net** **and** **TBR\_REO@tbh.net****.**

**For Office Use Only:**

RP Number:

Submission Date:

Review Date:

Authorization Date:

|  |  |
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| **Study Title:** |       |
| **Section A: Description of Research Team** |
| **List everyone who will be involved in developing/implementing the study at TBRHSC and the activities they will perform related to this project. Please select research team members who have completed TCPS2/CITI certification and ensure their certificate has been submitted to the CRSD.** |
| **STUDY TEAM ROSTER - VERSION 1.0** |
| **TCPS2/CITI****Certificate** | **NAME** | **AFFILIATION TO TBRHSC** | **ACTIVITIES****(Enter codes from Figure1)** |
| [ ]  |       | Choose an item. |       |
| [ ]  |       | Choose an item. |       |
| [ ]  |       | Choose an item. |       |
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| [ ]  |       | Choose an item. |       |
| [ ]  |       | Choose an item. |       |
| **PRINCIPAL INVESTIGATOR:** | **C.V.** | Choose an item. |
| **I attest that the roster above lists the complete study team and the study activities they have been delegated. Additional duties may be identified during review, in which case an amended team roster may be requested.** |
|       |  |  |
| **Name** | **Signature** | **Date (dd/mmm/yyyy)** |
| **FIGURE 1****List of codes to use when delegating study activities to team members on****SECTION A) Study Team Roster.** |
| **STUDY IMPLEMENTATION DUTIES** |
| 1. Obtaining informed consent
2. Identification / Recruitment
3. Confirmation of eligibility criteria
4. Screening of participants
5. Randomization procedure
6. Conducting study visits
7. Recording of medical history
8. Physical assessments
9. Data Collection / data entry
10. Data query resolution
11. Case report forms sign-off
12. Adverse event reporting
13. Dispensing of study medication
14. Maintain screening / activity logs
 | 1. Study drug administration
2. Blood / sample collection
3. Processing / transport of samples
4. Review of lab and other results
5. Maintenance of site file
6. REB communication (ongoing)
7. Annual / final REB reporting
8. Drug storage, destruction and accountability records
9. Access the electronic medical record
10. Review paper medical chart
11. Access PACs
12. Working on a study that involves MRI
13. Specify:
 |
| **STUDY DOCUMENT DUTIES** |
| 1. Write / review protocol
2. Create / review consenting material
3. Create / review recruitment material
4. Create database
5. Create case report forms
6. Specify:
 | 1. Perform data analysis
2. Interpret data
3. Read incidental findings
4. Specify:
 | 1. Write / review publication
2. Present at a conference
3. Present to TBRHSC
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| **Section A: Description of Research Team - Continued** |
| **Will external researchers require access to the TBRHSC site?** | **[ ]  YES** | **[ ]  NO** |
| **List external researchers that will require access to TBRHSC/TBRRI** |
| **Name** | **Access to Patient Area** | **TBRHSC Area Accessed** |
|       | **[ ]** YES | **[ ]** NO |       |
|       | **[ ]** YES | **[ ]** NO |       |
|       | **[ ]** YES | **[ ]** NO |       |
|       | **[ ]** YES | **[ ]** NO |       |
|       | **[ ]** YES | **[ ]** NO |       |
| **External researchers who will require access to TBRHSC are required to complete TBRHSC Safety Orientation and submit proof of WSIB to obtain an identification badge. If the researcher requires access to patient areas proof of immunization is required. Once the CRSD receives this list, we will forward the requirements to the project best contact.** |

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| **Section E: Local Implementation** |
| **RESOURCES REQUIRED** | **[ ]  N/A** |
| **Select or enter all TBRHSC departments / services that will be impacted or utilized during the implementation of this project.** |
|  | **Department / Service** | **Description of Impact / Resources** |
| **[ ]**  | **Clinical Research – Support Services** |       |
| **[ ]**  | **Clinical Trials** |       |
| **[ ]**  | **Diagnostic Imaging** |       |
| **[ ]**  | **PACS** |       |
| **[ ]**  | **Clinical Laboratory** |       |
| **[ ]**  | **Pharmacy** |       |
| **[ ]**  | **Cardiac Catheterization Lab** |       |
| **[ ]**  | **Regional Stroke Program** |       |
| **[ ]**  | **Chemotherapy** |       |
| **[ ]**  | **Cardio-respiratory** |       |
| **[ ]**  | **Operating Room** |       |
| **[ ]**  | **Surgical Day Care** |       |
| **[ ]**  | **Rehabilitation** |       |
| **[ ]**  | **Fracture Clinic** |       |
| **[ ]**  | **Pre-admissions** |       |
| **[ ]**  | **Emergency** |       |
| **[ ]**  | **Inpatient Units:** |       |
| **[ ]**  | **Specify:**       |       |
| **[ ]**  | **Specify:**       |       |

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| **Section F: Recruitment of Participants Involved in the Research** |  **[ ]  N/A** |
| **Ensure the “SECTION A) Study Team Roster” lists all research team members who will be identifying/recruiting participants.** |
| **A TBRHSC space/room will be used to recruit/identify participants** | **[ ]  YES** | **[ ]  NO** |
| **List space(s) required to recruit/identify:** |
|       |
| **Participants will be recruited via INformed - internal electronic communications** | **[ ]  YES** | **[ ]  NO** |

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| **Section G: Informed Consent** |  **[ ]  N/A** |
| **Ensure the “SECTION A) Study Team Roster” lists all research team members who will be obtaining informed consent from participants.** |
| **A TBRHSC space/room will be used to consent participants?** | **[ ]  YES** | **[ ]  NO** |
| **List space(s) required to consent:** |
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| **Section K: Personal Health Information** |
| **Ensure the “SECTION A) Study Team Roster” lists all research team members who will be accessing paper medical charts, electronic medical records (EMR) or PACS. All researchers accessing paper charts, EMR or PACS for research purposes are required to have a signed TBRHSC Confidentiality Agreement on file with the CRSD. Contact** **researchprogram@tbh.net** **for information.** |
| **PAPER HEALTH RECORDS** | **[ ]  N/A** |
| **Location of Charts** | Choose a Department |
| **Report Generation Required:** | **[ ]  YES** | **[ ]  NO** |
| **If YES; Report Generated by:** |       |
| **Patient Chart Population being accessed:** |
|       |
| **Range of Dates of Included Charts:** |
|       |
| **Approximate Number of Charts:** |       |
| **INFORMATION SYSTEMS** | **[ ]  Meditech** | **[ ]  PACS** | **[ ]  N/A** |
| **Report Generation Required from Information Systems** | **[ ]  YES** | **[ ]  NO** |
| **Patient Chart Population being accessed:**  | **[ ]  Same as for paper charts** |
|       |
| **Range of Dates of Included Charts:**  | **[ ]  Same as for paper charts** |
|       |
| **List all study team members who will be accessing Meditech for study-related purposes. Include both study team members who require an account to be created and those who have an existing account.**  |
| **Has an existing account** | **Name** |
| **[ ]**  |       |
| **[ ]**  |       |
| **[ ]**  |       |
| **[ ]**  |       |
| **[ ]**  |       |
| **[ ]**  |       |
| **[ ]**  |       |
| **List all study team members who will be accessing PACS for study-related purposes. Include both study team members who require an account to be created and those who have an existing account.**  |
| **Has an existing account** | **Name** |
| **[ ]**  |       |
| **[ ]**  |       |
| **Description of Images to be reviewed via PACS:** |
|       |

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| **Section M: Funding Sources** | **N/A [ ]**  |
| **FINANCIAL ADMINISTRATION** |
| **Funds are being administered by:** | Choose an item. |
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| **Funds will be administered to the following:** | **Description / Payee** |
| **[ ]**  | **TBRRI** |       |
| **[ ]**  | **TBRHSC Resource Owner(s)** |       |
| **[ ]**  | **CRSD – Support Services** |       |
| **[ ]**  | **Clinical Trials** |       |
| **[ ]**  | **TBRHSC Physician** |       |
| **[ ]**  | **TBRHSC Employee** |       |
| **[ ]**  | **Specify:**       |       |

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| **Section M: Funding Sources – Continued** |
| C**ONTRACTS / RESEARCH AGREEMENTS** |
| **Attach the contract(s) / research agreement(s) with this submission for organizational review.** |
| **[ ]**  | **A contract is required** |
| **[ ]**  | **No contract is required** |
| **[ ]**  | **I need help determining if this is required** |
| **Parties to the contract include:** | **1.**      **2.**      **3.**       |

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| **Section M: Funding Sources – Continued** |
| **TBRRI Hiring Process** |
| **List all researchers who will be hired through TBRRI to conduct paid/volunteer services for this study. Researchers being hired through TBRRI will complete TBRRI and TBRHSC orientation.** |
| **[ ]**  | **Require TBRRI to hire a paid/volunteer researcher** |
| **[ ]**  | **TBRRI Hiring is not required** |
| **[ ]**  | **I need help determining if this is required** |
| **Name** | **Job Description** | **TBRRI Orientation** | **TBRHSC Orientation** |
|       | Choose an item. | Choose an item. | Choose an item. |
|       | Choose an item. | Choose an item. | Choose an item. |
|       | Choose an item. | Choose an item. | Choose an item. |