**BRUYÈRE HEALTH RESEARCH ETHICS BOARD (BREB) SUBMISSION FORM – CHART/DATABASE REVIEW & SECONDARY USE**

**Please direct all questions regarding the completion of this form to the REB office:** [**REB@bruyere.org**](mailto:REB@bruyere.org)

**Visit the REB Website:** [**https://www.bruyere.org/en/researchethicsboard**](https://www.bruyere.org/en/researchethicsboard)

**DEFINITIONS**

**Chart Review:** A retrospective review of previously recorded clinical patient data. An example would be EMR records at Bruyère Health.

**Database Review:** A review of single or multiple clinical, government or other outside databases that contain a repository of previously collected information. An example would be ICES.

**Secondary Use:** A review of research data (including biological samples or images) collected from past or present research studies that is available for further and future research purposes. This may involve a repository or a single research study. An example would be the Canadian Longitudinal Study on Aging.

**INSTRUCTIONS AND USE OF THIS FORM:**

This form is to be used for studies involving retrospective chart and database reviews, and the proposed secondary use of data, biological samples, or stored medical images, where consent is sought to be waived.

Please note that if your research relies exclusively on secondary use of ***anonymous*** information or biological samples, then REB review is not required unless the data or samples might reasonably be re-identified. Information or samples are “anonymous” if they never had identifiers associated with them (e.g. an anonymous survey), and the risk of identification of individuals is low or very low.

If identifiable data or samples are to be used, consent of the original donor is required unless **ALL** **OF** the following conditions are met:

* It is essential to the research that data or samples be identifiable.
* You will comply with any known preferences previously expressed by individuals about the use of their information or samples, including in the original consent.
* It is impossible or impracticable to seek consent from individuals to whom the information relates.

1. The REB Checklist **must** accompany this submission to be considered for REB review.
2. TCPS 2 Certificates issued with the last **5 years** for all research personnel **must** accompany this submission to be considered for REB review.
3. **Unless specifically indicated, do not refer to, or attach other documents to complete a section of the REB application.**
4. A complete application and supporting documents (e.g. original study protocol if applicable) must be submitted to the REB for review. It is the responsibility of the applicant to contact the Bruyère Health REB office for instructions regarding the preparation of forms and other documents, review requirements, etc.
5. For studies that will incorporate any components other than chart/database reviews, or secondary use of information, please use the **BREB – GENERAL** form.

***\*Once your application is completed, please send the application, all appendices and the Research Study Summary to your Research Services Manager for review and to obtain the Section 20 signature. When this is completed, please send your application and all appendices to the REB office for review:*** [***REB@bruyere.org***](mailto:REB@bruyere.org)

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| 1. **VERSION DATE** *(Please enter a new version date every time this form is re-submitted with changes)* | |
|  | |
| 1. **FULL STUDY TITLE** *(Ensure title is consistent on all submitted documents/materials)* | |
|  | |
| 1. **STUDY DURATION** | |
| Expected Start Date:  Expected Completion Date: | |
| 1. **STUDY ORIGIN AND FUNDING** | |
| 1. **Please check one:**   **Investigator Driven**  **Industry/External Sponsor Driven**  *(Please note that any contract or agreement with the Sponsor/Funder must be submitted to your Research Services*  *Manager)* | |
| 1. **Has this research been funded**?  Yes  No | |
| **If yes, provide the following:**  Name of the Agency/Sponsor/Grant/Award:    Name of the Contact Person for the Agency/Sponsor:    Agency/Sponsor Reference number (if applicable):    Amount of funding received: | **If no, has funding been applied for?**  Yes  No  If yes, provide the name of agency/Sponsor/Grant/Award:    Amount of funding applied for:    Date submitted: |
| 1. A detailed budget is attached as an appendix.   Yes  No  If no, explain: | |
| 1. If there is no funding or insufficient funding for this project, how will the costs of the study be met? *(Please do not leave this section blank)* | |
| 1. **TEAM OF INVESTIGATORS** | |
| 1. **Principal Investigator** *(This individual has the overall responsibility for the project at all research sites. If the Principal Investigator is a student or trainee, the Bruyère Health Student/Trainee Supervisor must be affiliated with Bruyère Health and be the PI’s supervisor)* | |
| **Last Name:** | **First Name:** |
| **Title/Position:** | **Phone Number:** |
| **Department/Unit:** | **Email Address:** |
| **Division/Portfolio** | **Signature:**  **Date:** |
| **Check if applicable:** *(Please note that for multi-site research that also involves Bruyère Health, the Bruyère Health investigator may be listed in the co-investigator section.)*  **Bruyère Health Student/Trainee Supervisor:** If the Principal Investigator is a student/trainee or has no affiliation  with Bruyère Health, identify the Bruyère Health Researcher who will serve as the study’s contact person for the \  Bruyère Health REB. | |
| **Last Name:** | **First Name:** |
| **Title/Position:** | **Phone Number:** |
| **Department/Unit:** | **Email Address:** |
| **Division/Portfolio:** | **Signature:**  **Date:** |
| Principal Investigator Agreement – By signing above, I assume full responsibility for the scientific and ethical conduct of the study as described in this REB application and supporting documentation (e.g. protocol), and agree to conduct this study in compliance with the Tri-Council Policy Statement 2: Ethical Conduct for Research Involving Humans; the provisions of the Personal Health Information Protection Act 2004, and any other relevant laws, regulations or guidelines endorsed by Bruyère Health, and the Bruyère Health Research Institute. I certify that all researchers and other personnel involved in this project at this institution are appropriately qualified and experienced or will undergo appropriate training and supervision to fulfill their role in this study. | |
| 1. **Co-Investigators** (duplicate this section as necessary) | |
| **Name:**  **Title/Position:**  **Department/Institution:**  **Email Address/Phone #:** | **Name:**  **Title/Position:**  **Department/Institution:**  **Email Address/Phone #:** |
| **Name:**  **Title/Position:**  **Department/Institution:**  **Email Address/Phone #:** | **Name:**  **Title/Position:**  **Department/Institution:**  **Email Address/Phone #:** |
| **Study Staff who will have access to the study data (include name, role in study (e.g. Research Assistant, Master’s student, Pharmacists, etc.), email address and office phone number, if applicable.)** | |
| 1. **STUDY TYPE (choose one)** | |
| Chart Review (of confidential Bruyère Health medical charts/records)  Database Review (review of data from outside sources)  Secondary Use of clinical data, including biological samples or images | |
| 1. **STUDY DESCRIPTION** | |
| Describe the purpose, research question(s), and objective(s) of the study (max 150 words). | |
| 1. **TYPE OF DATA** (medical files, blood, tissue, survey or other quantitative or qualitative data, etc.) | |
| Briefly describe the charts/data/samples/images to be used and how they will contribute to the study objectives. | |
| 1. **PARTICIPANT POPULATION** | |
| Specify the population to which the charts/data/samples/images relate (include, as relevant, age, demographics, diagnosis, etc.). | |
| 1. **NUMBER OF CHARTS, RECORDS & SAMPLES** | |
| What is the expected number of charts/data/samples/images expected to be accessed/retrieved? | |
| 1. **DATES OF ACCESS** | |
| Specify the time period from which the charts/data/samples/images will be accessed/retrieved (e.g. Sept 2010 – Sept 2013).  **From:**  **To:** | |
| 1. **DATA SOURCE** | |
| Identify the hospital, institution, data repository or commercial vendor from which you will be accessing/acquiring the charts/data/samples/images. Include original protocol approval letter if available.  **Name:**  **Address:**  **Contact name and contact details:**  **Describe the processes and conditions for approving the release of the charts/data/samples/images:** | |
| 1. **DATA COLLECTION** | |
| 1. **To what extent will the data from participant’s information be identifiable:**   Directly identifying information (individual may be readily identified from data)  Indirectly identifying information (individual may reasonably be identified through a combination of indirect  identifiers)  Coded information (there is a code linking study data with personal identifiers and stored apart from the data;  information is not otherwise identifiable)  Anonymized information (identifying information has been effectively removed and individuals may not be  identified or re-identified from data)  Anonymous information (no identifiers were ever collected from data or sample donors)  Explain if needed. | |
| 1. Include a Data Capture Sheet as an attachment to this Form, that includes all data to be extracted about participants, including any identifiers. | |
| 1. **ACCESS TO CHARTS, RECORDS & SAMPLES** | |
| If accessing patient charts/databases at Bruyère Health, or at an outside institution, please indicate the application/approval status:  Privacy/Institutional Access has been granted by the Bruyère Health Privacy Office, or equivalent at an outside  institution. (approval is attached to this form).  Privacy/Institutional Access approval as described above is pending  (approval will be provided upon receipt).  For outside institutions, access is pending Bruyère Health REB  approval.  *Please note that for Bruyère Health charts/records,* ***you must obtain*** *approval from the Bruyère Health Privacy Office prior to accessing patient charts/health records. Contact the Privacy Office:* [*chartaccess@bruyere.org*](mailto:chartaccess@bruyere.org) | |
| 1. **CONSENT PROCESS** | |
| 1. Please explain the consent process used in the original collection of the data, biological samples or images that will be used for the current research study. In addition, please attach the consent form and any other explanatory documentation relating to the original data or sample collection. | |
| 1. For charts and databases, explain if consent will be sought, and if not, why this is impractical and/or impossible: | |
| 1. **RISKS** | |
| Identify if use of the data may lead to any potential harm to data donors, whether physical, psychological, social, legal, or other, to the data or sample donors. | |
| 1. **PRIVACY & CONFIDENTIALITY – DATA COLLECTION, STORAGE AND SHARING** | |
| 1. Explain how charts/data/samples/images will be accessed (include the method of transfer, where the data will be stored (e.g. secure Bruyère Health server, locked lab only accessible to authorized research staff, etc.). | |
| 1. Explain how you will protect the privacy and confidentiality of the individuals whose data is being accessed/acquired (e.g. assigning a code) as well as data safeguard measures such as password protection or encryption of data: | |
| 1. **CONTRACTS AND AGREEMENTS  Not applicable** | |
| Have all study contracts been approved by the relevant departments at the research site? These contracts/agreements may include, but are not limited to, data sharing agreements, service agreements, material transfer agreements involving human material and licencing agreements for the use of copyrighted materials.  Yes  No  If no, explain:  *\*(Please contact your Research Services Manager for assistance)* | |
| 1. **CONFLICT OF INTEREST**  **Not applicable** | |
| Will the Principal Investigator, Student/Trainee supervisor, or any Co-Investigators or other research staff involved in this research study, or any member of their immediate family:   1. Function as an advisor, employee, officer, director or consultant for the study sponsor?   Yes  No   1. Have direct or indirect financial interest in the sponsoring corporation (e.g. stocks)?   Yes  No   1. Receive an honorarium or other financial benefits from the sponsor (apart from fee for service or regular   salary)?  Yes  No  **If the answer is yes to any of the above questions, please complete the Conflict of Interest Declaration.** | |
| 1. **DIVISION/DEPARTMENT/PROGRAM APPROVAL** | |
| This should not be completed by an administrator who is listed as the study’s Principal Investigator, Student/Trainee Supervisor, Co-Investigator, or anyone else listed on this application. *(If this section is signed by anyone listed on the application form, the application will be returned)*  All applications being submitted to the Bruyère Health REB must be reviewed and approved by the Bruyère Health Research Institute **prior to REB submission**. To facilitate this review, please contact your Research Services Manager. All research that involves recruiting participants from within Bruyère Health requires the approval from the appropriate Bruyère Health Director and Medical Chief. To obtain this approval, the **Research Study Summary** must be provided to the Director and Medical Chief, and the applicable unit manager(s) must verify that their unit(s) are in agreement with this project and has the resources to support it as outlined in the Bruyère Health REB application. Include as many copies of this form as are needed – one per signature. | |
| **I have reviewed this application and by signing below, I certify that:**   1. The study is consistent with hospital/faculty policies and mission.   Yes  No  Not applicable   1. The study resources (budget, space and support staff) and/or the resources of my division, department or program are adequate to support the study.   Yes  No  Not applicable  ***Note:*** *In the case where a study will affect more than one financial cost centre within a facility, separate copies of Section 25 should be completed for each cost centre. Contact the REB to identify the appropriate administrators.* | |
| **Name:**  **Title/Position:**  **Dept/Unit & Location:**  **Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Date:** | **Name:**  **Title/Position:**  **Dept/Unit & Location:**  **Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Date:** |
| 1. **IMPROVING THE CLARITY AND USABILITY OF THIS FORM** | |
| If you have any suggestions to make this form clearer, easier to use, or to ensure that it captures all ethically relevant information, please email the REB office at: [REB@bruyere.org](mailto:REB@bruyere.org) | |
| **Notice with Respect to the Collection of Personal Information** | |
| The personal information requested on this form is collected in accordance with ***“Freedom of Information and Protection of Privacy Act”*** (FIPPA). The information provided will not be used for any purposes other than those stated upon this form unless you provide consent. Should you have any questions concerning your personal information, please email the REB office at: [REB@bruyere.org](mailto:REB@bruyere.org) | |