**Logo, company name

Description automatically generated**

|  |  |
| --- | --- |
| **Box No.** | **Document Type** |
|  | Signed protocol and any amendments |
|  | Participant information materials, including brochures, questionnaires, surveys, measuring instruments |
|  | Advertising materials used to recruit study participants |
|  | Correspondence with the REB, including submissions, reports and approvals |
|  | Health Canada authorization of the protocol and any amendments |
|  | Signed study agreements and contracts |
|  | Evidence of qualifications and licensure for investigators |
|  | Sponsor’s study initiation report and other evidence of study training for team members |
|  | Correspondence with the sponsor / CRO (e.g., letters, emails, meeting notes) |
|  | Signed informed consent forms and addendums |
|  | Source documents including visit notes, participant questionnaires, surveys, diaries |
|  | Copies of completed case report forms |
|  | Documentation of corrections to case report forms |
|  | Participant identification code list |
|  | Participant screening and enrollment log(s) |
|  | Delegation and signature log / list |
|  | Decoding procedures for blinded trials |
|  | Serious adverse events reported by the investigator to the sponsor, REB and/or Health Canada, as applicable |
|  | Safety information provided by the sponsor to the investigator |
|  | Product information (e.g., product licenses, product monographs, investigator’s brochures, device manuals) |
|  | Instructions for handling investigational product and study-related materials |
|  | Shipping records for investigational product and study-related materials |
|  | Records of investigational product accountability at the site |
|  | Documentation of investigational product destruction / return |
|  | Reference ranges for study-specified medical / lab / technical procedures / tests |
|  | Certification / accreditation / quality control assessments / validations for study-specified medical / lab / technical procedures / tests |
|  | Records of specimen processing / shipment |
|  | Records of any retained body fluids / tissue samples |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |

**Storage Box Content List**

*In the left column, record the number of the box containing the documents identified on the right (as applicable). Keep this form to help you easily identify the location of specific documents. (Note: It is not necessary to keep copies of original documents retained by others. For more information, refer to Health Canada’s Guidance for Records Related to Clinical Trials and ICH E6: Good Clinical Practice Guidelines.)*

***ROMEO/REB File No.:*** ***Date of Transfer to Research and Innovation:***