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 Services:_____

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