Cancer Clinical Research Department

Clinical Research Impact Assessment Form

The Impact Assessment and Approval is recommended prior to opening a new study.

The impact assessment process facilitates communication about the potential initiation of new studies. Communication is between the study team, clinical departments and the cancer clinical research department. The purposes of the impact assessment process are:

1. A feasibility analysis to determine the possible impact of a clinical study on hospital resources, and the determination of any accommodations required to conduct the study.
2. Cost recovery agreement between the study team and clinical departments.
3. Service Request for clinical research services provided by applicable departments (e.g., finance, biorepository etc).
4. Collection of performance metrics.

Submitting an Application for Review

Please include own institutional policies and procedures.

Please complete the following sections:

Part 1	General Information. This should be completed for all studies.
Part 2	Indicate which clinical departments and services are to be notified
Part 3	Additional information for departments selected in Part 2
Part 4	Additional information for services selected in Part 2

Part 1: General Information *(must be completed for all studies)*

Section 1: Applicant Information

1. Name of Person completing the Form: 2. Contact:

3. Is this the contact for Impact Questions? Select 3a. If NO, contact name: 3b. Contact:

4. Service Agreements should be directed to:

Note: service agreements are agreements between the research department and department providing services associated with the study.

5. Once OPEN, who is the main contact for this study: 5a. Contact:

6. Principal Investigator:

Section 2: Study Information

1. Protocol Number: 2. REB# (*if known*): 3. REB approved?: Select

4. Protocol Title:

5. Protocol Summary (provide purpose and brief description)

6. Type of Study: Select

6a. For Clinical Trials, indicate what cancer stage the study is targeting (select all that apply):
☐ Prevention ☐ Early Cancer ☐ Advanced Cancer

6b. For Clinical Trials, indicate what treatment line the study is targeting (select all that apply):
☐ Supportive Care ☐ Neoadjuvant ☐ Adjuvant ☐ 1st Line ☐ 2nd line ☐ 3rd line ☐ > 3rd line

7. Approximate date protocol provided to site (by sponsor):

Note: for investigator initiated studies, use the date the protocol was provided to the REB.

8. Target Accrual agreed to: 9. Expected Rate of Accrual (pt/mo):

10.Estimated study duration at site: 11. Estimated Start Date:

12. Indicate how the study is funded: Select

12a. If Industry or Cooperative/Intergroup, indicate sponsor name:

13. If Investigator Initiated, is a CTA required? Select 13a. If YES, date/expected date of No Objection Letter:

14. Study Management Service Provider: Select 14a. If OTHER, please indicate:

Section 3: Sign-Off

Please print Part 1 and have it signed and dated by a personnel authorized to complete/sign off on impact assessment.

Name (Print or Type)

Title

Signature

Date

Part 2: Departments and Services to be Notified *(Must be completed for all studies. Details will be requested for each section.)*

Clinical Departments
Departments providing testing or support.

- ☐ Laboratory Services
  - ☐ Laboratory
  - ☐ Other
- ☐ Pathology
  - ☐ Correlative Studies
  - ☐ Biospecimen Request
  - ☐ Other:
- ☐ Medical Imaging
  - ☐ PET Scan (diagnostic)
  - ☐ LVEF MUGA
  - ☐ Other:
- ☐ Nursing
  - ☐ Ambulatory
  - ☐ Chemo-Suite
  - ☐ Transfusion
  - ☐ Operating Room
  - ☐ Other:
    - ☐ Aphaeresis
    - ☐ Lodge
    - ☐ Inpatient
    - ☐
- ☐ Pharmacy

- ☐ Biomedical Engineering
  - ☐ Equipment
  - ☐ Maintenance Records
  - ☐ Calibration
  - ☐ Other:
- ☐ ECG
- ☐ Cardiac Echo
- ☐ Pharmacist
  - ☐ New IV Agent: approved for RN to administer: Select
  - ☐ Existing IV Agent: Change to approved practice
- ☐ Occupational Health & Safety
- ☐ Pulmonary Department
- ☐ Radiation Safety
- ☐ Radiation Therapy

Other 1

Other 2

Services
☐ N/A

Departments or services that may be outsourced.

- ☐ Biostatistics
- ☐ Correlative Studies/Dedicated Research Lab Support
- ☐ Data Management/Study Coordination
- ☐ Finance Support
- ☐ EDC System
- ☐ DSMB
- ☐ Biorepository

Other 1

Other 2

Part 3: Departmental Specific Information *(must be completed for all departments selected in Part 2 for which additional information is requested)*

Laboratory Services

Back to Part 2

Check off all laboratory services that are impacted (the grey boxes) and complete the appropriate section below each service.

☐ Lab Tests above standard of care

Definition of standard of care:

1. Indicate how tests are to be ordered: Select

NOTES: *(i.e., special requests, contact information, processes and documentation that needs to be submitted)*

2. Complete the table below for ALL **above standard of care** lab tests that will be completed by laboratory services**.**

Test Name	# Times Test is above SOC/patient	Check for paper requisition
		☐
		☐
		☐
		☐
		☐
		☐
		☐
		☐
		☐
		☐
		☐

☐ Specimen Procurement

NOTES: *(i.e., special requests, processes or materials that need to be set up for this service)*

☐ Other

1. Describe additional requests:

Pathology

Back to Part 2

NOTES: *(i.e., special requests, institutional policies or processes that need to be followed)*

1. Has a Pathologist been assigned to this study?: ◯ Yes Name of Pathologist:
◯ Not Yet
◯ Not Applicable

2. Indicate what services are required:
- ☐ Bone Marrow Aspirate Slides. If YES indicate: ☐ May Grunwald Giemsa ☐ Unstained
- ☐ Bone Marrow Biopsy Slides. If YES, indicate: ☐ H& E ☐ Unstained
- ☐ Pathology Slides. If YES indicate: ☐ H& E ☐ Unstained
- ☐ Punch Core Biopsy. If YES indicate: Quantity: Core Size (mm):
- ☐ Pathologist required to complete a study specific form (i.e. CRF)
- ☐ Other

☐ Correlative Studies

1. Select all services requesting the support of the Correlative Studies Support:
- ☐ Ordering Supplies and Kit Development ☐ Correlative CRF Development ☐ Budget Development
- ☐ Archival collection ☐ Sample shipment to an other lab ☐ Processing Invoices
- ☐ Processing Samples

2. Will samples be collected? Select If YES, indicate all sample types requiring Correlative Studies Support:
- ☐ Blood Samples. Indicate:
  - ☐ PK ☐ PBMC ☐ Serum ☐ Plasma ☐ Other, indicate:
- ☐ Fresh biopsy. Indicate collection type:
  - ☐ Frozen ☐ Formalin ☐ RNA Later ☐ TTI Tube ☐ Other, indicate:
- ☐ Other, indicate:

NOTES: *(i.e., special processes and procedures, institutional polices)*

Medical Imaging

Back to Part 2

NOTES: (i.e., special requests, contact information for booking)
1. For medical imaging, above standard of care refers to a change in the frequency of a test, a change in the test protocol or a change to the reporting structure of the results of a test.
2. If a scientific procedure is to be followed, all imaging studies/procedures for research must be booked through: _____ ☐ N/A

1. The following table must be completed for **ALL** imaging tests.

Test Name	Time Point	Check if the Investigator considers this test to be above SOC	Additional Requests/ details (i.e. tumour measurements)
Example: CT Scan	baseline, month 3	☒	RECIST
		☐	
		☐	
		☐	
		☐	
		☐	
		☐	
		☐	
		☐	
		☐	
		☐	
		☐	
		☐	

2. Indicate any additional study specific details:

☐ No additional details
☐ Central reviewing office being used for imaging results. Name of Office:
☐ Dedicated reviewer required
☐ Other. If checked, please describe:

3. Indicate any additional Medical Imaging Services required:

☐ No additional Services
☐ Burn results to CD/DVD
☐ Data-transmittal form to be completed by Medical Imaging staff
☐ Image Guided Biopsy required. If checked, please describe:
☐ Other. If checked, please describe:

Nursing

Back to Part 2

Complete each section related to the Nursing Units impacted, as indicated in Part 2.

NOTES: *(i.e., special requests, processes or related institutional policies)*

All Nursing Units

1. Does this study require coordination of care with another impacted area (i.e. Radiation)? Select

NOTES: If YES, ensure to complete the Coordination of Care section in this form.

Ambulatory Nursing Units

1. For the patient population being treated in this study protocol, compare and contrast the standard of care and the research protocol based on the Areas of Impact:

AREAS OF IMPACT	Standard of Care	Research Protocol
Frequency of Clinic Visits		
Duration of Visit		
Treatment Administered		
Patient Monitoring		
Additional Requirements of the clinical nurses		

2. Comments/ pertinent information:

Chemo-Suite and In Patient Nursing Units

Study Visit Information

1. For the patient population being treated in this study protocol, compare and contrast the standard of care and the research protocol based on the Areas of Impact:

AREAS OF IMPACT	Standard of Care	Research Protocol
Patient Volume		Select
Treatment Protocol		
Visit Frequency		
Nursing area involved	☐ Chemo-Suite Time Required ☐ In-patient overnight stay required ☐ Same Day Discharge	☐ Chemo-Suite Time Required ☐ In-patient overnight stay required ☐ Same Day Discharge
Describe, if necessary		
Infusion Time		
Infusion Administration		Select

2. Indicate any Monitoring or Extra Requirements of Nursing for the study protocol

Monitoring or Extra Requirment	Frequency	Responsible Party
☐ Blood Pressure		Select
☐ Heart Rate		Select
☐ Respiration Rate		Select
☐ Temperature		Select
☐ Oxygen Saturation		Select
☐ ECG Monitoring		Select
☐ Antidote kit for extravasations available		
☐ Anaphylactic kit at bedside		

Continued on the next page

Nursing *continued*

3. Is the study drug on the Institution's approved drug list for administration by RN**?** Select

NOTES: *(i.e., special requests, processes or related institutional policies)*

4. Describe the treatments to be administered:

4a. Name of Agent 1 | Method of Administration: Select

Responsible Party for Administration: Select

Dose: | Schedule:

Potential Acute Reactions (indicate Incidence):

4b. Name of Agent 2 | Method of Administration: Select

Responsible Party for Administration: Select

Dose: | Schedule:

Potential Acute Reactions (indicate Incidence):

4c. Name of Agent 3 | Method of Administration: Select

Responsible Party for Administration: Select

Dose: | Schedule:

Potential Acute Reactions (indicate Incidence):

4d. Name of Agent 4 | Method of Administration: Select

Responsible Party for Administration: Select

Dose: | Schedule:

Potential Acute Reactions (indicate Incidence):

5. Indicate any additional request or comments:

Staff Education

6. Indicate who will be responsible for staff education:

Name: | Contact Info:

Continued on the next page

Nursing *continued*

Operating Room

1. Identify important timing requirements for surgery:

2. Will research biopsies be collected during surgery?: Select

If YES, describe:

Aphaeresis

1. Describe the impact:

Lodge

1. Describe the impact:

Inpatient

1. Describe the impact:

Other

1. Describe the impact:

Pharmacy

Back to Part 2

1. Complete the table below for **ALL** Treatment drugs used in the study

Drug Name	Is this Standard of Care?	How is the drug supplied/funded?
	Select	Select
	Select	Select
	Select	Select
	Select	Select
	Select	Select
	Select	Select

NOTES: *(i.e., special requests if drugs is not SOC or funded by sponsor, institutional policies or contact information if required)*

Biomedical Engineering

Back to Part 2

Equipment

1. Describe the impact:

Maintenance Records

1. Describe the impact:

Calibration

1. Describe the impact:

Other

1. Describe the impact:

ECG

Back to Part 2

1. Indicate the # of ECGs that are required above standard of care per patient:

2. Indicate where will the ECG be conducted: ☐ At the ECG department ☐ Clinic ☐ Inpatient ☐ Chemo-suite ☐ Other location:

3. Is a single cardiologist required for confirmation of the ECG: Select If YES, do you require a CV: Select

4. Are the ECG results to be loaded into EPR: Select If NO, complete the following questions:

4a. The results require confirmation by a cardiologist: Select 4b. Identify the ECG by: Select

4c. How many copies of the report are required: 4d. Reports should be sent to:

NOTES: *(i.e., booking procedures including contact information)*

Cardiac Echo

Back to Part 2

1. Indicate the number of tests above standard of care per patient:

1a.Time points of tests:

2. Does the imaging protocol differ from the standard protocol: Select

If YES, explain:

3. Are quantitative measurements required: Select

If YES, explain:

Continued on the next page

Echo *continued*

4. Do scans need to be copied to CD: Select

If YES, explain:

5. Does a data-transmittal form need to be completed: Select

If YES, explain:

Pharmacist

Back to Part 2

NOTES: *(i.e., process to approve study drug internally, additional documentation or contact information)*

Occupational Health and Safety

Back to Part 2

Any study that would require special treatment post exposure or could require the involvement of infection control should be reviewed by the Occupational Health and Safety Committee, as per institutional policies.

Pulmonary Department

Back to Part 2

1. Describe above standard of care requirements (i.e.test, frequency)

Radiation Safety

Back to Part 2

Complete this section for any tests or procedures that involve radiation or radioactive materials.

Note: for radiation therapy, complete the Radiation Therapy section in this form.

1.Indicate the isotope being used in this study:

2. Indicate the amounts for administration:

3. Indicate where the administration will occur:

4. Does this study require approval by Health Canada? Select If YES, when is approval expected:

5. Indicate who will be responsible for staff education:

Name: Contact Info:

**Placeholder for physics and credentials

NOTES: *(i.e., institutional policy or procedures regarding safety radiation devices)*

Radiation Therapy

Back to Part 2

1.Would this patient population typically receive radiation therapy if not on study protocol? Select

2. Are there additional requirements for RT planning? Select

If YES, describe:

3. Are there additional requirements for RT treatments (i.e. timing)? Select

If YES, describe:

4. Machine Energy Required:

5. Describe any additional equipment needed or quality control measures (e.g., credentialing, validation):

6. Does this study require coordination of care with an other impacted area (i.e. Radiation)? Select

NOTES: If YES, ensure to complete the Coordination of Care section in this form.

7. Indicate any additional request or comments:

Coordination of Care

Back to Part 2

1. Describe the critical timings that must occur between different clinical department's treatments and tests:

Other

Back to Part 2

Describe the impact on the departments listed in 'Other':

Other 1:

Other 2:

Part 4: Service Request Information *(must be completed for all outsourced services selected in Part 2 for which additional information is requested)*

Correlative Studies

Back to Part 2

1. Select all services requesting the support of the Correlative Studies Support:

- ☐ Ordering Supplies and Kit Development
- ☐ Correlative CRF Development
- ☐ Budget Development
- ☐ Archival collection
- ☐ Sample shipment to an other lab
- ☐ Processing Invoices
- ☐ Processing Samples

2. Will samples be collected? Select If YES, indicate all sample types requiring Correlative Studies Support:

- ☐ Blood Samples. Indicate:
  - ☐ PK ☐ PBMC ☐ Serum ☐ Plasma ☐ Other, indicate:
- ☐ Fresh biopsy. Indicate collection type:
  - ☐ Frozen ☐ Formalin ☐ RNA Later ☐ TTI Tube ☐ Other, indicate:
- ☐ Other, indicate:

NOTES: *(i.e., special processes and procedures, institutional polices)*

Dedicated Research Lab ☐

Back to Part 2

NOTES: *(i.e., institutional policies, biosafety certificate requirements)*

Biostatistics ☐

Back to Part 2

NOTES: *(i.e., process to request biostatistical support including contact information)*

Data Management/Study Coordination

Back to Part 2

1. Indicate the services that will be required:

- ☐ CTA to Health Canada
- ☐ Monitor Visit Support
- ☐ Query resolution
- ☐ Budget/Contract Management
- ☐ Study File Maintenance
- ☐ REB Submission. Indicate type: Select
- ☐ CRF Design and data entry
- ☐ CRF Completion
- ☐ Monitoring (in-house)
- ☐ Database entry (not eCRF)
- ☐ Other. Indicate:

Finance Support

Back to Part 2

1. Indicate the services that will be required:

- ☐ Clinical Trial Financial Feasibility Review
- ☐ Administrative Billing, Accounts Receivable and Cash Receipt Transactions
- ☐ Administrative Accounts Payable and Cash Disbursements Transactions
- ☐ Financial Reconcilliation
- ☐ Financial Reporting
- ☐ Other

EDC System

Back to Part 2

1. Does the study require Electronic Data Capture System? Select

2. Indicate which additional roles research support is being requested to perform:

- ☐ Monitor Role
- ☐ Data Entry
- ☐ None of the above. The sponsor investigator will perform both roles.
- ☐ Other

NOTES: *(i.e., clarification on roles, institutional policies)*

DSMB

Back to Part 2

1. Is the study only running at a single center? Select

If multi-center, indicate anticipated number of centers:

NOTES:

Biorepository

Back to Part 2

NOTES:

1. Indicate what services are required:

☐ Tissue collect during surgery. If yes select processing method:
- ☐ Fresh
- ☐ Frozen
- ☐ Paraffin Embeded

Other

Back to Part 2

Describe the impact on the services listed in 'Other':

Other 1:

Other 2:

Comments: