CAPCR Submission Form

CAPCR-ID: 18-5241.2

Study Title: Retrospective study to determine the predictors of post liver transplant survival and outcomes in NAFLD

Study Nickname: NAFLD survival

Amendment: extend date collection period

Date Submitted: 10 Jul 2019

PI's Name: Mamatha Bhat
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PI's Location: Toronto General Hospital, Peter Munk Building, 200 Elizabeth St., 11th Floor, Room 11PMB-183, Toronto, Ontario, Canada, M5G 2C4

Study Contacts:
N/A

Prepared by:
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Submission Documents:
Protocol - Protocol
Data Collection/Case Report form --Tracked - DCF_Tracked
Data Collection/Case Report form - Data collection form
Protocol --Tracked - Protocol_Tracked

Reviewed by:
REB (Research Ethics Board)

AMENDMENT PROFILE

1.	**Does this Amendment involve a change to the Principal Investigator (PI)?**	No
2.	**Has this amendment already been implemented to eliminate an apparent immediate hazard to one or more study participants?**	No
3.	**What elements of the study are affected by this Amendment? (Select all that apply.)**	
3.1.	**Study Personnel**	
3.1a.	**Study Personnel (other than PI)**	Yes
3.1b.	**Personnel who may be handling hazardous materials or transporting dangerous goods**	No
3.1c.	**UHN Health Professionals with clinical responsibilities**	No
3.2.	**Study Sites, Sponsors, and Funding**	
3.2a.	**Study sites (either within UHN or external sites)**	No
3.2b.	**Study sponsors or funding sources**	No
3.2c.	**Study budget** ***For example, due to changes in recruitment, sample size, methodology, participant compensation / reimbursement***	No
3.2d.	**Agreement or contract with any party external to UHN**	No
3.2e.	**Transfer of data, materials, human resources, etc. to/from any party outside UHN, or use of third-party software, or transfer of funds to/from UHN**	No
3.3.	**UHN facilities and services**	
3.3a.	**Services or agreements from Princess Margaret Clinical Units or CCRU Research Services**	No
3.3b.	**TRI programs, services, and facilities, including KITE Centre**	No
3.3c.	**Medical Imaging**	No
3.3d.	**Laboratory Medicine Program (LMP)**	No
3.3e.	**Health Professions (e.g. Anesthesia Assistants; Chiropody; Clinical Nutrition; Kinesiology; Lab Medicine Technicians; Nursing; Occupational Therapy; Physiotherapy; Psychology; Respiratory Therapy; Social Work; Speech Language Pathology; Spiritual Care; Therapeutic Recreation)**	No
3.3f.	**Operating Room, Anesthesia, Sterilization and/or Disinfection**	No
3.3g.	**ECG**	No

3.3h. ECHO	No
3.3i. Pulmonary Department	No
3.3j. Apheresis	No
3.4. Study Design	
3.4a. Study Title	No
3.4b. Study start or end date	Yes
3.4c. Study design, including primary outcomes	No
3.4d. Study populations or treatment groups/arms	No
3.4e. Number of study participants	Yes
3.4f. Number of charts to be reviewed	Yes
3.4g. Number of biospecimens to be processed	No
3.4h. Selection, monitoring, or dismissal of study participants	No
3.4i. Evaluation of the clinical efficacy or safety of a study drug, biologic, or natural health product	No
3.5. Investigational Products	
3.5a. Study drug(s)	No
3.5b. Natural health products or biologics	No
3.5c. Use of investigational products, including dose, frequency of dosing, duration of treatment, manufacturing/formulation, placebo use, concommitant medications	No
3.5d. Medical Devices	No
3.5e. Molecular profile required for study inclusion	No
3.6. Study Data	
3.6a. Use, collection, or analysis of retrospective study data	No
3.6b. Source(s) from which retrospective study data will be obtained	No
3.6c. Storage of retrospective data for future use	No
3.6d. Use, collection, or analysis of prospective study data	No
3.6e. Collection or storage of prospective data for future use	No

3.6f. Development, purchasing, or provision of a study-specific website, application, mobile application, database, or e-tool	No
3.6g. Use of electronic tool that collects any personal health information, transmits patient results externally, or requires a patient to enter information	No
3.7. Biospecimens	
3.7a. Addition of laboratory test(s) requiring additional samples from participants	No
3.7b. Use, collection, or analysis of biospecimens	No
3.7c. Source(s) from which biospecimens will be obtained	No
3.7d. Transport or handling of biospecimens	No
3.7e. Genetic research	No
3.7f. Collection or storage of biospecimens for future use	No
3.8. Risks and Safety	
3.8a. Risk to health of a study participant	No
3.8b. Use/handling of radioactive materials, including radioactive drugs	No
3.8c. Handling or transport of hazardous materials	No
3.8d. Use of cannabis at UHN	No
3.9. Research Ethics	
3.9a. Conflict of Interest (actual, apparent, perceived, or potential) for PI or study team member	No
3.9b. Recruitment or consent process (e.g. how or by whom participants will be consented)	No
3.9c. Use of personal health information	No
3.9d. Reimbursement or compensation of study participants	No
3.9e. Monitoring of study, such as DSMB or Steering Committee	No
4. Study participants status (for UHN participants only). Check all that apply.	
4.1. Study does not involve enrollment of participants (retrospective study)	Yes
4.2. No enrollment to date	No
4.3. Currently enrolling participants	No
4.4. Participants have consented but have not yet started intervention/data collection	No

4.5.	**Participants currently receiving study intervention (e.g. study drug, questionnaires, tests, or procedures done for study purposes)**	No
4.6.	**Participants in post-intervention follow-up**	No
4.7.	**Intervention and follow-up complete for all UHN participants** ***Data clarification, analysis, and/or transfer may be ongoing***	No
4.8.	**Study involves non-UHN participants only**	No

AMENDMENT DESCRIPTION

1. **Amendment description**

   extend date collection period

2. **Summarize the changes to the study.**
   Where appropriate, refer to page numbers in the revised Protocol.

   We request to increase our data collection to include patients who were transplanted until the end of 2018. This will increase our anticipated chart review to an estimated number of 3000.

   We also would like to include a secondary analysis to determine how outcomes differ between NASH patients who receive deceased donor liver transplants and those who receive living donor liver transplants.

3. **Provide justification/rationale for the changes to the study.**

   Inclusion of two extra years of liver transplants will allow us to get a more up to date and accurate picture of survival and outcomes.

   Comparison of outcomes of DDLT and LDLTs is important to allow for a better understanding of what complications or outcomes to anticipate after each type of liver transplant.

4. **Has this amendment already been implemented?**

   No

5. **Will the number of participants change as a result of this amendment?**

   Yes

6. **Does this amendment require submission to Health Canada?**

   No

AMENDMENT REVIEW

1. **Are you requesting a "Full Board" REB meeting?**

   No

STUDY BASIC INFORMATION

1. **Full Study Title:**

   Retrospective study to determine the predictors of post liver transplant survival and outcomes in NAFLD

2. **Study Nickname:**

   NAFLD survival

3. **Is there a protocol number or identifier for this study?**

   Yes

If yes, complete the following question:

3a. **Specify the protocol number/identifier.**

18-5241.0

4. **Expected start date of the study at this institution:**

15-Mar-2018

5. **Expected end date of the study at this institution:**

1-Sep-2020

6. **Department/Division/Program Head:**

Atul Humar (atul.humar@uhn.ca)

7. **Site(s) where this study will take place**

TGH

STUDY OVERVIEW

1. **ABSTRACT (Suitable for a public access or lay audience):**

Background:

Due to increasing incidence of diabetes and obesity, NAFLD is expected to become the most common indication for liver transplantation in the next decade. As transplantation does not eliminate risk factors like obesity, diabetes, hypertension and hyperlipidemia, they can have a significant effect on graft and patient survival. Donor factors can also have a significant role in outcomes after transplantation.

Rationale for the study:

Identification of these factors will help improve outcomes in this cohort by modification of risk factors.

Aim:

This study will help identify the predictors of survival post liver transplantation in this cohort. We also aim to compare survival and outcomes in this cohort to patients having liver transplant for all other indications. This would help improve outcomes in this cohort by timely identification and modification of risk factors.

2. **Background of the study: provide a summary of findings from previous studies (pre-clinical and clinical) that lead to the conduct of this study.**

Due to increasing incidence of diabetes and obesity, NAFLD is expected to become the most common indication for liver transplantation in the next decade. As transplantation does not eliminate risk factors like obesity, diabetes, hypertension and hyperlipidemia, they can have a significant effect on graft and patient survival. Donor factors can also have a significant role in outcomes after transplantation.

3. **What is the rationale for this study?**

Identification of these factors will help improve outcomes in this cohort by modification of risk factors.

4. **What are the study hypotheses or research questions?**

1. Predictors of survival in patients transplanted for NAFLD
2. Short and long term outcomes in post-transplant period
3. Donor factors predicting outcomes in this cohort

5. **Describe the primary objectives and briefly describe how they will be measured. Describe the secondary objectives and how they will be measured (if applicable).**

i) To determine the predictors of survival in patients transplanted for NAFLD
1. Donor factors predicting outcomes
2. Graft and patient survival

6. **What is the significance of the study (i.e. the overall anticipated public and/or scientific benefit)?**

   Identification of these factors will help improve outcomes in this cohort by modification of risk factors.

STUDY PERSONNEL - PRINCIPAL INVESTIGATOR

Principal Investigator: Mamatha Bhat

1. **Department/Division**

   N/A

2. **Program**

   MOT

3. **Site/Organization**

   TGH

4. **Does the PI require access to EPR (Electronic Patient Record)?**

   Yes

STUDY PERSONNEL

The following information is to be supplied for each member of the study team, except the PI.

Note: All personnel involved in the conduct of the study at UHN should be listed in this section, including for example, co-investigators, data abstractors and study managers. Omission of study team members from the Study Personnel list may cause a delay in the review of your submission.

1. First and Last Name	Erin Winter	Peregrina Peralta	Ramraj Rajakumar
Email	erin.winter@uhn.ca	peregrina.peralta@uhn.ca	ramraj.rajakumar@uhn.ca
2. Department/Division:	N/A	N/A	N/A
3. Program:	MOT	MOT	MOT
4. Site/Organization:	TGH	TGH	TGH
5. Role(s) in study:	Study Coordinator	Study Coordinator	Research Analyst
6. Appointment expiration date (for time-limited role such as student or research fellow):	N/A	N/A	N/A
7. Does this person require access to EPR (Electronic Patient Record) in order to perform this role?	Yes	Yes	Yes

1. First and Last Name	Sreelakshmi Kotha	Audrey Kim	Ravi Kiran
Email	Sreelakshmi.kotha@uhn.ca	Audrey.Kim@uhn.ca	ravi.kiran@uhn.ca
2. Department/Division:	N/A	N/A	N/A
3. Program:	MOT	MOT	MOT
4. Site/Organization:	TGH	TGH	TGH
5. Role(s) in study:	Research Fellow	Data Abstractor; Study Coordinator; Study Manager; Research Analyst	Research Fellow

6. Appointment expiration date (for time-limited role such as student or research fellow):	N/A	N/A	N/A
7. Does this person require access to EPR (Electronic Patient Record) in order to perform this role?	Yes	Yes	Yes

CONSENT WAIVER REQUEST - SECONDARY USE

1. **Will personal health information be collected, used or disclosed without consent from the individuals to whom the data and/or biospecimens relate?**

   Yes

   If yes, complete the following question

   1a. **Explain why this personal health information is essential to the research.**

   PHI is required to answer the research question, and also to facilitate data collection from multiple sites (EPR,
   OTTR, paper charts).

2. **Explain why the use of health information or biospecimens without the participants' consent is unlikely to adversely affect the welfare of individuals to whom the data and/or biospecimens relate.**

   The study will not affect patient care or management. The result of the study will be reported in aggregate for a peer reviewed journal. Additionally, given the large number of individuals included in this analysis, identification of any particular individual would be extremely difficult therefore this research is unlikely to have any impact on patient confidentiality/privacy

3. **Explain the measures you will take to protect the privacy of individuals, and to safeguard the identifiable information.**

   Information will be collected once per case using MRN as the link between EPR and OTTR records. No other patient identifier will be collected. Once the data collection is complete the file will be anonymized for data management and analyses. The link will be be kept in a Master List and the study data file will contain only the participants study number.

4. **Have any participants previously expressed any preferences about use of their information?**

   No

5. **Explain why it is impossible or impracticable to seek consent from individuals to whom the data and/or biospecimens relate.**

   The analyses includes a significant number of potential candidates that have been transplanted and died or are no longer followed at our institution. Limiting study population by seeking consent might introduce important biases in the study.

6. **Are any other necessary permissions required for the secondary use of information for research purposes?**

   No

DATA COLLECTION AND USE

1. **Detailed description of data gathering processes and procedures**

   Data will be extracted from OTTR, complemented by electronic and/or paper chart review. UHN MRN will be used to populate data from OTTR, EPR and paper charts. Once data collection from electronic and paper sources has been completed, data will be de-identified for analyses.

2. **Describe the methods that will be used to analyze study data. Please provide references to the applicable page(s) of the protocol.**

   Patient characteristics will be described using descriptive statistics. Fisher exact and ?2 tests will be used to compare categorical variables. We will perform univariable and multivariable analysis to determine the risk factors for S. aureus infection post-LT, with specific interest in aspirin and adjusting for diabetes status. All P values less than 0.05 will be considered significant.

3. **Are any interim data analyses planned?**

   No

4. **Indicate how study participants will be identified in study data (e.g. study number, initials).**

   Unique sequential case id number

5. **Will any information collected through this study be linked with any other databases external to UHN? (e.g. other health care institutions, health registries, Statistics Canada)?**

   No

FUNDING

1. **The following information is to be supplied for each funding source:**

1.1. Name of company, granting agency, internal funding source, or other funding source:	MOT
1.2. Type of funding source:	Internal funding
1.3. What is the status of funding from this source?	Obtained

2. **If any requested funding is not received, will you be able to proceed with the study?**

   Not applicable (all necessary funding has been obtained)

3. **If all requested funding is received, will it be sufficient to cover all study costs?**

   Yes

4. **Is this study receiving any Tri Council funding (CIHR, NSERC, SSHRC)?**

   No

   Complete the following questions:

   4a. **If the study has been peer-reviewed, specify the organization or individual that performed the review**

   N/A

5. **Is this study receiving any NCIC funding?**

   No

6. **Is this study receiving any US federal funds?**

   No

7. **Is this research supported by the United States federal government?**

8. **Will the study require a grant account, FC (Functional Centre) or IO (Internal Order), now or in the future?**

   No

PERSONAL HEALTH INFORMATION

1. **Specify all personal health information required to be collected for the conduct of the study, including study recruitment activities**

   UHN Medical Record number

2. **Identify sources of personal health information.**

   Permanent health record/clinical chart

   2a. **Specify where the records required reside (EPR, specific clinics/depts, etc.).**

   EPR/OTTR

3. **Explain why this study cannot reasonably be accomplished without using the PHI outlined in your response above.**

   UHN MRN allows investigators to link data from EPR and OTTR

4. **Will any personal health information will be sent outside of UHN?**

   No

5. **What are the risks if PHI collected for the purposes of this study were released to an unauthorized party?**

   MRN is the only PHI being collected. MRN will be linked to the study id and stored separate from the data being collected. So, if MRN were released, it would only be a number without any other information, so there is only minimal risk for patients.

6. **If PHI were disclosed to an unauthorized party, what specific procedures, methods or controls would be implemented to minimize the potential harms?**

   Yes. All PHI will be stored securely. Study paper files will be stored in a locked cabinet that can be accessed by study team members only. Electronic files will be password protected and stored on a secure UHN server. If there was ever an inadvertent release of PHI, the issue would be investigated immediately. The priorities wouldbe to stop the further release of PHI, to retrieve any info where possible, and to notify the REB and UHN privacy office. Any further action would depend on recommendations from these offices PHI will not be stored alongside study data.

PERSONAL HEALTH INFORMATION - STORAGE

1. **Will the storage of study records conform to the requirements of the 'Storage, Transport & Destruction of Confidential Information' policy?**

   Yes

PERSONAL HEALTH INFORMATION - TRANSPORT

1. **Will the transport of study records conform to the requirements of the 'Storage, Transport & Destruction of Confidential Information' policy?**

   Yes

PERSONAL HEALTH INFORMATION - DESTRUCTION

1. **Will the destruction of study records conform to the requirements of the 'Storage, Transport & Destruction of Confidential Information' policy?**

   Yes

PUBLICATION

1. **How will results be communicated to participants?**

   Publication

2. **How will results be communicated to other stakeholders?**

   Publication

3. **Has the funding agency or sponsoring company placed any restrictions on publication of findings?**

   No

RETROSPECTIVE DATA

1. **Please indicate the types of existing data required for this study**

   For a detailed list of variables, please see the attached data collection document

2. **Justify the existing data required for this study.**

   These variables have been shown to correlate with Renal function outcomes in previous publications. Variables collected allow investigators to compare groups and account for possible confounders that may affect the analysis.

3. **Date range of requested data:**

   Start Date

   1-Jan-1986

   End Date

   30-Jun-2019

4. **Proposed number of UHN patients whose medical and/or research records you wish to access for the purposes of this study:**

   3000

A. STUDY CLASSIFICATION

1.1. Will the study at UHN be using an external ethics review process and/or system (e.g. CTO, OCREB) to obtain REB approval? No

Note: if your study is being reviewed by Veritas, please answer NO

1.2. This submission includes a proposal to: (Check all that apply.)

1.2a.	**Investigate a current research question**	Yes
1.2b.	**Collect and store data and/or biospecimens for future use** ***This includes creation of a data base or biobank.***	No
1.2c.	**Extract and store retrospective data for future use**	No
1.2d.	**Conduct quality assurance and quality improvement studies, program**	No

evaluation activities, and performance reviews, or testing within normal educational requirements when used exclusively for assessment, management or improvement purposes

1.3. Is the focus of the research primarily in the field of health professions education?

2. Does the study involve any interaction with participants? No
Answer YES if you are using any data that does not yet exist. For example: interventional studies; questionnaire/survey/interview; prospective (future) collection of biospecimens. Answer NO if you are using ONLY data or samples that already exist. For example: retrospective chart review; use of previously collected biospecimens.

3. Does the study involve access to or use of data that does not yet exist (prospective data)? No
For example: medical records not yet collected, medical images/reports for scans not yet performed, questionnaires that will be collected as part of the study and databases where the data has not yet been collected.

4. Does the study involve access to or use of data that already exists (retrospective data)? Yes
For example: medical records that have already been collected, medical images/reports for scans that have already been performed, questionnaires that have previously been collected, databases where the data has already been collected.

Does the study involve:

4.1. Use of oncology data? No

4.2. Use of patient information/charts from Health Records? Yes

4.3. Use of information from the Blood Bank, Histotrac, or CoPath systems? No
Anatomic Pathology CoPath; Blood Transfusion (Blood Bank); Histocompatibility (HLA) Histotrac; lab information systems.

4.4. Use of archived medical images/reports? No
'Archived' medical images/reports are images/reports not available through EPR, generated before 2009.

4.5. Use of mPower (formerly known as Montage) search engine? No
mPower is a Google-like search engine for Radiology Information System

4.6. Use of data from GU Biobank? No

4.7. Use of data from Peter Munk Cardiac Centre - Cardiovascular (PMCC-CV) Biobank? No

4.8. Use of data from Leukemia Tissue Bank? No

4.9. Use of previously collected human data from any source not mentioned above? No

5. Does the study involve use of biospecimens or their derivatives that have not yet been collected (prospective biospecimens)? No
For example: tissue, blood, body fluids, DNA, RNA, proteins, etc. that will be collected during the study

6.	**Does the study involve use of biospecimens or their derivatives that have already been collected (retrospective biospecimens)?** ***For example: tissue, blood, body fluids, DNA, RNA, proteins, etc. that have previously been collected.***	No
7.	**Are you seeking consent from any individuals for participation in this study?**	No
8.	**Is anyone at UHN, other than the Principal Investigator, involved in the conduct of this study?** ***Include all personnel involved in the study, for example, staff listed on the protocol; students working for the PI; co-investigators; data abstractor; study manager, etc.***	Yes
8a.	**Is this research primarily conducted by personnel who are on a time-limited work term?** ***For example, students, fellows, residents, visiting collaborators***	No
9.	**Does this study involve research of a seasonal nature?**	No
10.	**Is the focus of the research primarily in the field of rehabilitation?**	No
11.	**Will any research be conducted using any staff, resources, equipment, or facilities, or any administrative, research, or health data, of the Toronto Rehabilitation Institute, including the KITE Centre for Rehabilitation Research?**	No
12.	**Is this study directly related to a previously approved study at this institution (e.g. sub-study, extension, rollover, subsequent to a pilot study)?**	No
13.	**Is the research being conducted *exclusively* in a country other than Canada?**	No
14.	**Is the UHN PI the sponsor of the study (investigator-initiated study)?**	Yes
15.	**Does the PI have an appointment in the UHN Oncology Program?**	Yes

B. RISKS AND SAFETY

1.	**Has this study undergone prior scientific/scholarly review?**	No
2.	**Has this study or a related study undergone review by a Research Ethics Board in Canada?**	No
3.	**Will the study have a Data and Safety Monitoring Board (DSMB)?**	No
4.	**Will the study have a Steering Committee?**	No
5.	**Will the research involve the use of biological agents on UHN premises as outlined in the UHN Research Biosafety Manual?**	No
6.	**Does this study involve radioactive material or radiation treatment devices? (PET scans, Bone scans, HDR, Accelerator, Brachytherapy seeds, Gammaknife)**	No

7.	**Will any member of the immediate study team be handling or potentially exposed to hazardous materials (other than radioactive materials, TDG Class 7)?**	No
8.	**Will any member of the study team be involved in activities with dangerous goods (other than radioactive materials, TDG Class 7) as defined by the Transportation of Dangerous Goods Regulations (TDGR)?** ***Includes packaging, transporting, offering for shipment, receiving dangerous goods such as biohazardous materials, hazardous chemicals, dry ice.***	No
9.	**Does anyone involved in the conduct of this study have a Conflict of Interest (actual, apparent, perceived, or potential)?**	No
10.	**Will the proposed research involve the use of cannabis at UHN?** ***Cannabis means a cannabis plant that belongs to the genus Cannabis and anything referred to in Schedule 1 of the Cannabis Act but does not include anything referred to in Schedule 2 of the Cannabis Act. For more information contact cannabis@uhnresearch.ca .***	
11.	**Will the *storage* of study records require a deviation from the requirements of the Storage, Transport & Destruction of Confidential Information policy?**	No
12.	**Will the *transport* of study records require a deviation from the requirements of the Storage, Transport & Destruction of Confidential Information policy?**	No
13.	**Will the *destruction* of study records require a deviation from the requirements of the Storage, Transport & Destruction of Confidential Information policy?**	No

C. RESOURCES AND SERVICES

1.	**Does the study require any services from the Laboratory Medicine Program (LMP) at UHN?** ***Answer 'Yes' if any of the following is involved in the study: Anatomic Pathology; Cytopathology; Molecular/Genetic; Biochemistry; Hematopathology; Flow Cytometry; Hematology; Blood Transfusion Services (Blood Bank); Histocompatibility (HLA); Specimen Management; Microbiology; Coagulation.***	No
2.	**Does this study involve genetic research?**	No
3.	**Does the study use any medical imaging?**	No
4.	**Does the study impact ECG?**	No
5.	**Does the study impact ECHO?**	No
6.	**Is this a multicentre study (i.e. are non-UHN sites involved)?** ***Answer YES if any research-related activities are occurring at non-UHN sites (such as participant recruitment, enrolment, consenting, data collection, data analysis, etc.)***	No
7.	**Will any party external to UHN be entering into an agreement or contract with UHN in connection with this research?**	No

8.	**Does the study involve any transfer of data, materials, human resources, etc. to/from any party outside UHN, or use of third-party software?** ***"Materials" includes investigational products, biological specimens, etc.***	No
9.	**Is there any transfer of funds to or from UHN for any purpose related to this study?**	No
10.	**Does the study involve any of the Health Professions, as an investigator, study participant, or carrying out study activities?** ***Answer YES if any of the following is involved in the study: Anesthesia Assistants; Chiropody; Clinical Nutrition; Kinesiology; Nursing; Occupational Therapy; Physiotherapy; Psychology; Radiation Therapists; Respiratory Therapy; Social Work; Speech Language Pathology; Spiritual Care; Therapeutic Recreation***	No
11.	**Do you require new space for this study?**	No
12.	**Does the study use any medical devices or equipment?** ***For example, hardware, software, mobile apps, accessories, disposables***	No
13.	**Does the study involve any reusable devices or equipment that require sterilization, high-level disinfection, or reprocessing of equipment or medical devices?**	No
14.	**Does the study involve the use of the Operating Room?**	No
15.	**Will the study impact the provision of anesthesia services, or increase the risk associated with any of these services?** ***Anesthesia services include: general anesthesia, sedation, perioperative pain control***	No
18.	**Does this study require the services of the Cancer Clinical Research Unit (CCRU)?**	
19.	**Does the study require the development, purchasing, or provision of a study specific website, application, mobile application, database, or e-tool (e.g. IOS or Android app, new REDCap project, etc.)?**	
20.	**Does the study require the use of an electronic tool that collects any personal health information; and/or transmits patient results directly to an external site/sponsor, or requires a patient to personally enter information into an electronic system (e.g. electronic survey)?**	
21.	**Does this study require the use of UHN Biospecimen Services?**	