Catholic Health Initiatives
Institute for Research and Innovation (CIRI)
Initial IRB Application

Last edited by: Elizabeth Bright
Last edited on: April 1, 2019
PI Name: David Pruitt, MD

☐ Exemption ☐ Expedited ☑ Full Board
☐ Treatment Use ☐ Emergency Use ☐ Not Research
☐ Ceding

[Jump to Instructions]

[1146402-2] SMAP-AV: Saving Mucosa with Prophylactic Aloe Vera Therapy

I. Principal Investigator or Treating Physician

Name: David Pruitt
Degree(s)/ Title: MD
Phone: [redacted]
Email: DEPruitt@[redacted]
Dept: Cancer Center
CHI Facility: CHI-St. Vincent Hospital - Cancer Center - Hot Springs
Mailing Address: [redacted]

Is the PI a student/trainee/resident/fellow? ☐ Yes ☑ No
Primary Contact? ☐ Yes ☑ No
CIRI-employed Clinical Project Manager submitting to CHIRB? ☐ Yes ☑ No
CIRI-Employed Name:
Financial Conflict of Interest? ☐ Yes ☑ No

II. Project Mentor N/A ☑

Name:
Degree(s)/ Title:
Phone:
Email:
Dept:
CHI Facility:
Mailing Address:
Financial Conflict of Interest? ☐ Yes ☐ No

III. Primary Contact N/A ☐

Name: Candis Oliver
Degree(s)/ Title: RN, OCN, MA
Phone: [redacted]
Email: COliver2[redacted]
Dept: CHI-St. Vincent Cancer Center- Hot Springs, AR
CHI Facility: CHI St. Vincent Hospital - Hot Springs, AR
Mailing Address: [redacted]

Financial Conflict of Interest? ☐ Yes ☑ No

IV. Additional Personnel N/A ☐

Please complete this section for each Additional Personnel.

Name: Elizabeth Bright **Degree(s)/ Title:** RN, OCN

Phone: [redacted] **Email:** ebright@[redacted]

Dept: Cancer Center **CHI Facility:** CHI-St. Vincent Hospital - Hot Springs, AR

Role: Co/Sub Investigator

Mailing Address: [redacted]

Will this person conduct the informed consent process? ☑ Yes ☐ No

Will this person have a financial conflict of interest? ☐ Yes ☑ No

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Name: Vicky Sanders **Degree(s)/ Title:** MSN,BSRN,CNML

Phone: [redacted] **Email:** vickysanders@[redacted]

Dept: Administration **CHI Facility:** CHI-St. Vincent Hospital - Hot Springs, AR

Role: Administrator

Mailing Address: [redacted]

Will this person conduct the informed consent process? ☐ Yes ☑ No

Will this person have a financial conflict of interest? ☐ Yes ☑ No

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V. Location Information

Affiliated Locations:

- ☐ CHI National Office
- ☐ CIRI Cooperative Group Network
- ☐ Centura
- ☐ Arkansas (Little Rock) - St. Vincent Infirmary Medical Center
- ☐ Iowa (Des Moines) - Mercy Medical Center
- ☐ Iowa - Wheaton Franciscan Healthcare
- ☐ Kentucky - Flaget Healthcare
- ☐ Kentucky (Louisville) - Jewish Hospital and St. Mary's Healthcare
- ☐ Kentucky (Lexington) - Saint Joseph Health System
- ☐ Nebraska (Grand Island) - St. Francis Medical Center

- ☐ Nebraska (Omaha) - Alegent Creighton Health
- ☐ Nebraska (Lincoln) - Nebraska Heart Institute
- ☐ Nebraska (Lincoln) - St. Elizabeth's
- ☐ Nebraska (Kearney) - Good Samaritan
- ☐ North Dakota - St. Alexius Health
- ☐ Oregon (Roseburg) - Mercy Medical Center
- ☐ Pennsylvania (Reading) - St. Joseph Regional Health Network
- ☐ Tennessee (Chattanooga) - Memorial Health Care System
- ☐ Texas (Bryan) - St. Joseph Health Care System
- ☐ Texas (Lufkin) - Memorial Health System
- ☐ Texas (Houston) - St. Luke's Health
- ☐ Texas (Houston) - Texas Heart Institute
- ☐ Washington (Tacoma) - Franciscan Health System
- ☑ Other

If "Centura" or "Other" was selected:

Other/Centura Performance Site: CHI-St. Vincent Hospital - Hot Springs, AR

VI. Data Security Risk Assessment and Mitigation:

Disclosed Information:

Disclosures will be made on a need to know basis only. Only the minimal necessary patient information to complete the study will be disclosed - this will include the age, sex smoking status, cancer type and stage, P16 status and chemotherapy regimen if applicable. The research team will have access to the patient's EMR and will access only the information that is needed to collect the above listed data for the purpose of the research project.

The participant will be identified by the first and last initial of their name.The participants will be chosen based on the biopsy proven diagnoses of head and/or neck cancer.

How will you obtain the protected health information that will be used at any point in the study?

PHI will be obtained through accessing medical records (for diagnosis verification) and directly from the research participant.

Which identifiers will you have possession of at any point in the study?

- ☑ Name of individaul or family members
- ☐ Address
- ☐ All elements (except years) of dates related to an individual
- ☐ Telephone numbers
- ☐ Fax number
- ☐ Email address
- ☐ Social Security Number
- ☐ Medical record number

- ☐ Health plan beneficiary number
- ☐ Certificate or license number
- ☐ Web URL
- ☐ Finger or voice print
- ☐ Any other characteristic that could uniquely identify the individual
- ☐ Account number
- ☐ Any vehicle or other device serial number
- ☐ Internet Protocol (IP) Address
- ☐ Photographic image
- ☐ None

If you selected "Social Security Number", please provide justification to include, use or disclose the social secruity number.

How will you maintain the data/PHI?

Paper records will be stored in a locked file cabinet in a secure area - in the navigators office. EMR will be stored in accordance with CHI- St. Vincent Hospital - Hot Springs guidelines and rules on a HIPPA compliant server.

Data collected will be maintained on CHI issued computers only. No laptops or personal computers will be used. CHI meets industry standards for data security. CHI issued computers are already encrypted, as per CHI privacy and security policies that state encryption is mandatory on all devices handling CHI data.

There will be no sharing of information via email.

The only access to the research data will be by those individual identified as research stff and will only be accessible in the research area(radiation center).

All computer access must have secure user name/password per HI policy per standard or security.

How will you transfer, transmit, transport data/PHI?

There should be no transfer, transmitting or transport of data/PHI. The research records will be contained in the CHI- St. Vincent Cancer Center - Hot Springs with access limited to research staff.

How will you remove the HIPAA identifiers?

The files will be maintained for 5 years -post close of study-att he CHI- St. Vincent Cancer Center, Hot Springs, AR and will be destroyed after that.

Only research staff or staff with a need to know will have access to the list of patients - which will be kept locked and secured in an office.

Who will see the PHI at the research site?

The PI and research staff are team members who will see and have access to the PHI

Who will see the PHI other than the research site?

- ☑ Institutional Review Boards
- ☑ Federal and state regulators

- [x] Institutional research oversight/quality assurance/compliance personnel
- [ ] Researchers at other institutions who are collaborating on the study
- [ ] Sponsor of the research and sponsor's representatives (Laboratory, CRO, specimen repository)
- [ ] Sponsor monitors or auditors
- [ ] Regulatory agencies from other countries
- [ ] Data Safety Monitoring Board
- [ ] Student's mentor at their school/college/ university
- [ ] NIH, NCI
- [ ] Other:

How will you store or destroy the dataset and any identifying information after the study is complete?

The data will be destroyed 5 years post study completion.

Are there additional details related to data security for your study that have not been captured in an earlier question?

None

VII. Type of Review Requested:

- [ ] Determination of Not Human Subject Research
- [ ] Determination of Exemption
- [ ] Expedited and Limited IRB Review
- [x] Full Board
- [ ] CHIRB to cede to another IRB OR another IRB to cede to CHIRB
- [ ] Treatment Use including Single Patient Use
- [ ] Emergency Use

VIII. Project Summary

Project Summary:

The purpose of this study is to prevent drastic weight loss, less than 10%, in patients receiving external beam radiation therapy specifically for those patients with a biopsy confirming diagnoses of head and/or neck cancer with the prophylactic use of Aloe Vera Juice (manufactured by Fruit of the Earth).

IX. Ceding - CHIRB N/A ☑

Please complete this section for each non CHI-affiliated institution/site.

Name of Institution/ Site:

OHRP IRB Registration Number:

IRB's FWA#:

Investigator's Name:

IRB Contact Person:

Investigator's Phone:

Investigator's Email:

Research Activities Performed:

- ☐ Recruiting Subjects
- ☐ Consenting Subjects
- ☐ Performing research interventions with subjects
- ☐ Analysis of identifiable data
- ☐ Analysis of only de-identified data
- ☐ Other

If "Other" was selected:

Flow PHI:

PHI Protection:

X. Ceding - Other IRB N/A ☑

Name of Other IRB:

OHRP IRB Registration Number:

IRB's FWA#:

IRB Contact Person Information:

Contact Name:

Contact Title:

Contact Phone:

Contact Email:

Contact Mailing Address:

Why would it be appropriate for CHIRB to cede to an outside IRB for this study?

What research activities will take place at CHI facilities?

What research activities will the CHI investigative team perform?

- ☐ Recruiting Subjects
- ☐ Consenting Subjects
- ☐ Performing research interventions with subjects
- ☐ Analysis of identifiable data

☐ Analysis of only de-identified data ☐ Other

If "Other" was selected:

Other Research Activity Performed:

Risks Associated with Research:

Flow PHI:

PHI Protection:

CHI Investigator Responsibility: ☐ Yes ☐ No

XI. Treatment Use N/A ☑

Investigational Agent (FDA Approved)? ☐ Yes ☐ No

Treatment Use Apparatuses ☐ Drug ☐ Device

XII. Treatment Use - Drug N/A ☑

Name:

Manufacturer Name:

IND Number

Person for IND:

Number of Patients:

Serious Diagnosis of Patient(s):

Explanation for Satisfactory Drug/Therapy:

Safety for Patient(s)/Population:

XIII. Treatment Use - Device N/A ☑

Name:

Manufacturer Name:

IND Number:

Population Size: ☐ Single Patient ☐ More than one patient

If more than one patient, what is this estimated number of patients?

Significant Risk: ☐ Yes ☐ No

FDA Approved: ☐ Amended IDE ☐ New IDE

Serious Diagnosis of Patient(s):

Explanation for Satisfactory Drug/Therapy:

Safety for Patient(s)/Population:

XIV. Determination of Exemption N/A ☑

Category:

- ☐ Category 1
- ☐ Category 2
- ☐ Category 3
- ☐ Category 4
- ☐ Category 5
- ☐ Category 6
- ☐ Category 7
- ☐ Category 8

Exemption Category 1 Explanation:

Exemption Category 2 and 3 Criteria:

- ☐ The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
- ☐ Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation
- ☐ The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects.

Exemption Category 2 or 3 - Proposed Details :

Exemption Category 2 - Children :

Children Involved in Research? ☐ Yes ☐ No

Children as Research Subjects? ☐ Yes ☐ No

Exemption Category 2 - Procedures for Privacy:

Exemption Category 3 Criteria:

Benign Behavioral Interventions:

Deception? ☐ Yes ☐ No

Exlusion of Children? ☐ Yes ☐ No

This response is optional:
Authorized Deception of Subjects:

Exemption Category 4 Criteria:

- ☐ The identifiable private information or identifiable biospecimens are publicly available
- ☐ Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects and the investigator may not contact or re-identify the subjects.
- ☐ The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under HIPAA.
- ☐ The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities.

Exemption Category 5 Criteria:

Federal Website:

Exemption Category 7 Criteria - Broad Consent:

- ☐ Obtain Broad Consent

Broad Consent Description:

- ☐ Obtain Waiver for Broad Consent
  - ☐ The only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality.
  - ☐ The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context.
  - ☐ If the subjects or legally authorized representatives are member of a distinct cultural group or community in which signing forms is not the norm, and there is an appropriate alternative mechanism for documenting that informed consent was obtained.

Tracking Declined Consent:

Alternative for Documenting Broad Consent:

Exemption Category 8 Criteria - Broad Consent:

- ☐ Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained. (Please upload a copy of the broad consent form to your submission).
- ☐ There are adequate provisions for protecting the privacy of subjects and to maintain the confidentiality of data.
- ☐ The research to be conducted is within the scope of the original broad consent used to collect the data and/or tissue.
- ☐ The investigator does not plan to return individual research results to subjects.

Provisions for Protecting Privacy:

Does the research involve the following:

Prisoners? ☐ Yes ☐ No

Diminished Autonomy? ☐ Yes ☐ No

If you your research involves diminished autonomy, please describe what additional protections will be put in place for protecting individuals with diminished autonomy.

Deception? ☐ Yes ☐ No

If deception will occur:

Reason for Deceiving Participants:

Authorized Deception? ☐ Yes ☐ No

Opportunity to Authorize Deception:

Procedures that Ensure Participants Are Debriefed:

XV. Expedited Review N/A ☑

Expedited Review Category:

- ☐ Category 1
- ☐ Category 2
- ☐ Category 3
- ☐ Category 4
- ☐ Category 5
- ☐ Category 6
- ☐ Category 7
- ☐ Category 8
- ☐ Category 9

XVI. Sponsor Sources N/A ☐

- ☑ None/Internal funding
- ☐ Federal
- ☐ Private (Industry, Foundations, Other)

Individuals Authorizing Use of Internal Funds:

IRB Fees:

We are requesting a waiver of IRB fees for this study. Though we have some funds allocated for this study, staff and the PI will receive no additional pay for participating with this project. The project benefits not only the patients, but our organizantion and the communities we serve. The purpose of the project is to prevent weight loss in our head and/or neck patients; therefore decreasing the need for hospitalizations due to the insertion of feeding tubes or malnutrition. Doing this saves valuable medical dollars and improves patient outcomes.

Federal Funding:

Funding/Sponsor Source:	PI of Contract/Grant:	Contract/Grant #:	Contract/Grant Title:

Private (Industry, Foundations, Other):

Name:	PI of Title:	Company or Organization:	Mailing Address:	Email:	Phone:	Insufficent Funding:

XVII. Participant Information N/A ☐

If applicable:

How will this project differ from the routine (standard of) care and normal clinic operations?

This project will actually be the same as the standard of care treatment for people diagnosed with head and/or neck cancer. However, the data of those not participating will not be included in the study.

Anticipated Number of Subjects: 30

Vulnerable Populations

- ☐ Pregnant Women, Fetuses, or Non-Viable Neonates
- ☐ Children
- ☐ Individuals with Decisional/Cognitive Impairment
- ☐ Employees
- ☑ None
- ☐ Neonates
- ☐ Prisoners
- ☐ Wards of the state
- ☐ Economically disadvantaged
- ☐ Other:

Inclusion Criteria:

Inclusion Criteria:

- Patient will have a biopsy confirmed diagnosis of head and/or neck cancer
- Patient will be receiving external beam radiation therapy at CHI- St. Vincent Cancer Center - Hot Springs + or - chemotherapy with curative intent
- P16+ or P16- (negative)
- Smoker or non-smoker
- Male or Female
- Age 20+
- Patients with head and/or neck cancer receiving external beam radiation therapy at CHI-St. Vincent Cancer Center- Hot Springs, AR
- ECOG performance status of 0, 1 or 2
- Patients with Stage I, II,III or IV head and/or neck cancers

Exclusion Criteria:

Exclusion Criteria:

Vulnerable population as defined as:

- Adults unable ot consent; and/or cognitively impaired
- Individuals who are not yet adults (infants, children, teenagers)
- Pregnant women
- Prisoners

ECOG performance status of 3 or 4

Patients with recurrent head and neck cancer

Plan for Recruitment:

Potential participants will be patients with a biopsy confirmed diagnosis of head and/or neck cancer who will be receiving external beam radiation therapy at CHI-St. Vincent Cancer Center - Hot Springs. The PI or research staff will screen all head and/or neck cancer patients to ensure they meet inclusion/ exclusion criteria and ensure the patient is not part of a vulnerable population as defined in the protocol. All patients recruited for the study will be a patient at CHI- St. Vincent Cancer Center - Hot Springs, AR receiving external beam radiation therapy treatment.

Potential Participants:

Potential participants will be identified when they are referred to CHI-St. Vincent Cancer Center - Hot Springs for consultation regarding treatment for a diagnosis of head and/or neck cancer.

Participants Recruitment:

- ☑ Research personnel to speak directly with patient during an office visit
- ☐ Patient gave permission for future research or future contact through a previous consent form
- ☐ Advertisement
- ☐ Recruitment letters or flyers
- ☐ Telephone recruitment calls
- ☐ Not applicable
- ☐ Other

If "Other" was selected:

Additional Information on Recruitment:

non applicable

XVIII. Project Information N/A ☐

Is this a clinical trial that meets the FDA's definition of "Applicable Clinical Trial" that is required by U.S. law to be registered on ClinicalTrials.gov?

- ☐ Yes
- ☑ No

Will drugs or biologics to be administered as a research procedure in the protocol?

- ☑ Yes
- ☐ No

Will you be collecting biological specimens to analyze as part of this protocol?

- ☐ Yes

☑ No

Will you be banking biological specimens for unspecified future research use?

☐ Yes

☑ No

Will you be banking data for unspecified future research use?

☐ Yes

☑ No

Which of the following informed consent/assent options apply to this study?

☑ Consent will be obtained from and documented (signed by) each subject

☐ Consenting non-English speaking subjects using fully translated consent forms.

☑ Consenting non-English speaking subjects using a short-form.

☐ Requesting a waiver or alteration of consent

☐ Requesting a waiver of documentation of consent

Participant Identification, Screening, Recruiting and Determining Eligibility:

☐ The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative

☑ The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens

☐ Not Applicable

Description for Oral/Written Consent:

The consent process will take place at CHI-St. Vincent Ca Cancer Center - Hot Springs, AR .

The informed consent document will be reviewed will be reviewed with the patient by the PI/research staff on the date of their CT simulation. Adequate time will allotted for questions and answers with the review of the informed consent document. The patient will be allowed to take the informed consent document home to discuss with family/significant other.

the PI/research staff will meet with the patient prior to the patients first external beam radiation therapy to discuss questions/concerns of research study. If patient agrees to participate, the patient will sing the informed consent document in the presence of the PI/research staff.

Patient will be given a copy of the singed informed consent document

XIX. Waiver of Documentation of Consent N/A ☑

Conditions for Waiver of Documentation of Consent:

☐ The only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality

☐ The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context

☐ The subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than

minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained

Explanation for Minimal Risk of Subjects:

Alternative Mechanism for Informed Consent:

To what portion(s) of this study does this waiver of documentation pertain?

XX. Waiver or Alteration of Consent N/A ☑

To what portion(s) of this study does this waiver or alteration pertain?

Explain why this research involves no more than minimal risk to the subjects:

Explain why the waiver or alteration will not adversely affect the rights and welfare of the subjects:

Explain why the research could not practicably be carried out without the waiver or alteration:

Provide rationale why the identifiers are required to conduct the research:

XXI. HIPAA Authorization N/A ☐

Which method will you use to conform to HIPAA regulations?

- ☐ A signed HIPAA authorization (or combined consent and HIPAA authorization form)
- ☐ Requesting a waiver or alteration of HIPAA authorization
- ☑ Both a HIPAA waiver (e.g. for screening medical records) AND a combined consent and HIPAA authorization for prospective research

XXII. Off-Label/Investigational Drugs/Biologics N/A ☐

Please complete this section for each off-label or investigational drug or biologic.

Trade Name:	Fruit of the Earth - Aloe Vera Juice	**Generic Name:**	Aloe Vera Juice
IND/BB-IND#:	142369	**IND Holder:**	CHI- St. Vincent Hospital - Cancer Center - Hot Springs, AR

Status: ☐ FDA approved (Off-Label)

☑ IND

☐ Other:

If this is an FDA approved drug/biologic not being used in accordance with its approved indication, how does the use of this drug/biologic differ from the approved indication?

The proposed mechanism of the Aloe Vera Juice (manufactured by Fruit of the Earth) is to coat the mucosa. Coating the mucosa will decrease irritation to the lining in the throat and esophagus; thereby allowing the patients to eat and/or drink with less discomfort. Better nutrition will enable the patient to maintain caloric intake to prevent weight loss.

XXIII. FDA Approved Drugs/Biologics

N/A ☑

Please complete this section for each FDA approved drug or biologic.

Trade Name: **Generic Name:**

XXIV. Medical Devices

N/A ☑

Please complete this section for each medical device.

Device Name: **IDE Holder:**

IDE Number:

FDA Approved? ☐ Yes ☐ No

Off-Label Use? ☐ Yes ☐ No ☐ Not FDA Approved

FDA Designation? ☐ A ☐ B ☐ N/A

Local Approval ☐ Yes ☐ No ☐ N/A

Approved by:

Device Risk?

☐ Significant Risk
☐ Non-Significant Risk
☐ Not yet determined
☐ N/A

XXV. HIPAA Waiver Request

N/A ☐

Portion of Study: ☐ Entire study ☑ Identification and Recruitment ☐ Other:

☐ Telephone Consent

Covered Entities: CHI-St. Vincent Cancer Center Hot Springs-AR

Brief Description of PHI Used:

The information will include the paitent's initials, age sex, smoking status, cancer type and stage, P16 status and chemotherapy regimen, if applicable.

Data collected will be maintained on CHI issued computers, no laptops will be used. CHI meets industry standards for data security. CHI issued computers are already encrypted, as per CHI privacy and security policies that state encryption is madatory on all devices handling CHI data.

There will be no sharing via email. The only access to the research data will be by those individuals identified as research staff and will only be accessible in the research area (radiation center). All computer access must have secure username/password per CHI policy for standard for security.

Brief Description of PHI Disclosed:

The PHI will not be disclosed outside of this study unless information is requested by a federal agency.

List of PHI Sources:

PHI sources will be the EMR and the patient interviews

Access to Identifiers:

Only the PI and research staff will have access to the patient identifiers. Information will be provided if/ when requested by outside entities - i.e., FDA , OHRP, etc.

Plan to Protect Identifiers:

Only the minimal necessary patient information will be disclosed during the study. The information will include the paitent's initials, age sex, smoking status, cancer type and stage, P16 status and chemotherapy regimen , if applicable . The research team will have access to the patients electronic medical record and will access only the information that is needed to collect the above listed data which is needed to conduct the study.

CHI-St. Vincent-Hot Springs will follow the policy for encryption of data per CHI Policy and Standards to protect the CHI confidential information.

Identifiers Destroyed:

The research information will be stored in a secure, locked area for 5 years post study completion, at which time the records will be destroyed (shredded).

Waiver Justification:

It is important to collect all appropriate clinical cases to ensure a representative and unbiased sample of the study population as appropriate for the study.

PHI Justification:

Access to the data is necessary as it is the premise of the study - collecting and monitoring patients weight during extenal beam radiation therapy treatment.

PHI as Minimum Information:

PHI is limited to those involved in the research and must be accessed in order to retrieve the necessary information (monitoring weight for loss/neutrality/gain during radiation treatment) for the study.

Number of Records Accessed: ☐ Less than or equal to 50 ☑ Greater than 50

Principal Investigator/Treating Physician Attestation

Please note that the PI must sign this package. If the PI is a student, resident, trainee, or fellow, this package must also be signed by the mentor.
This application must be sent to the CHIRB by the Principal Investigator only after the Principal Investigator has reviewed and determined that all information is accurate. The Principal Investigator assumes responsibility for ensuring that (please check all):

- I certify that the information provided in this application, and the accompanying materials, is complete and correct. All required materials have been uploaded as part of this submission.
- I certify that all known unanticipated problems (including those that are SAEs, involve potential or real loss of privacy/ confidentiality) have been reported to the CHI.
- I certify that all personnel engaged in research activities on this project are listed on this application and that all personnel have been informed of the requirement to complete Financial Conflict of Interest (FCOI) disclosures (your application will not move forward until this is completed).
- I certify that any change in investigator or study staff's Conflict of Interest status are accurately reported as required by CHI's Governance Policy No.1 and to the IRB.
- I certify that all personnel engaged in research activities are in compliance with the current CIRI Research Education Plan.
- I understand that as Principal Investigator, I have ultimate responsibility for the conduct of the study, the ethical performance of the project, and the protection of the rights and welfare of human subjects.
- I certify that the study will be conducted The Principal Investigator and study staff will conduct the study only as described in the application and accompanying protocol.
- Any changes to the protocol or research personnel will be submitted to the IRB for prospective approval, except when necessary to eliminate apparent immediate hazards to the subject(s).
- I agree to comply with all CHIRB policies and procedures, including the CHI Research Data Security requirements as well as with all applicable federal, State, and local laws regarding the protection of human subjects in research.
- I will ensure that this study is performed by qualified personnel adhering to the study protocol, and will retain auditable records for all research activities including personnel trainings.
- I will only Access, Use, and Disclose PHI as described in this application.
- If changes in obtaining, storing, transmitting, transporting, destroying of PHI are needed, an amendment/modification form must be submitted for review and approval prior to implementation of the change.
- If the data is lost, stolen, or improperly used, accessed or disclosed in any way other than outlined in the study, I will notify the Privacy Officer immediately. This includes loss or theft of hardcopy,

computer or mobile device containing PHI, faxing to wrong number, etc. I will also notify the IRB, as applicable, as this may constitute an Adverse Event per the Common Rule.

- I understand that if I do not abide by CHI Data Security requirements that I will be subject to possible disciplinary action, reporting to federal or state authorities, criminal prosecution, and/or civil penalties.

By clicking Next, you agree to the above statements.

HIPAA Attestation

The information listed in the waiver application is accurate and all research staff will comply with the HIPAA regulations and the waiver criteria. I assure that only the minimum amount of protected health information necessary to complete the study aims will be used and/or disclosed during the conduct of this research. I assure that PHI obtained as part of this research will not be reused or disclosed to any other person or entity other than those listed on this form, except as required by law. If at any time I want to reuse this information for other purposes or disclose the information to other individuals or entity I will seek approval by the IRB.

INSTRUCTIONS TO RESEARCHERS

[top]

This **CHI - Research Application** form is an on-line document that must be completed for all applications to any CHI Institutional Review Board.

Additionally, please contact the CHI Institute for Research and Innovation (CIRI) office for more information regarding your review type selection.