



Clinical Trials Registration

OHSU Knight Cancer Institute

Oregon Clinical and Translational Research Institute

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What is the purpose of registration?

- Fulfill ethical obligations to participants and the research community
- Provides information to potential participant and referring clinicians
- Reduce publication bias
- Help editors and others understand the context of study results
- Promote more efficient allocation of research funds
- Help IRBs determine the appropriateness of a research study (ClinicalTrials.gov)

Why do we register trials?

- Because we have to!
 - Section 801 of the Food and Drug Administration Amendments Act (FDAAA 801)
 - it is the law!
 - International Committee of Medical Journal Editors (ICMJE) – you want to publish
 - Centers for Medicare and Medicaid Services (CMS) Billing Rule – you want to have Medicare coverage for your trial
 - NIH requires registration

What happens if you don't register?

- FDAAA 801 establishes penalties including civil monetary penalties and, for federally funded studies, the withholding of federal grant funds **AND**
- You may not get Medicare reimbursement for clinical services provided during a clinical trial **AND**
- You may not be able to publish your result **AND**
- You may not be able to get future grants

What studies need to be registered?

- International Committee of Medical Journal Editors (ICMJE) definition

“Any research project that prospectively assigns people or a group of people to an intervention, with or without current comparison or control groups, to study the cause-and-effect relationship between a health-related intervention and a health outcome (including phase I).”

Who is responsible for registration?

- Responsible Party

<https://prsinfo.clinicaltrials.gov/ElaborationsOnDefinitions.pdf>

- Sponsor of the clinical trial as defined by 21 CFR 50.3 (IND/IDE Holder)
- The Principal Investigator if the PI is conducting the trial, has access to the and control over the data from the trial, has rights to publish the results, and has the ability to meet the requirements

When do I register my study?

- Before the first participant is enrolled – ICMJE
- Within 21 days of enrolling the first participant FDAAA
- You can register it before you have final IRB approval but you must list it as “Not yet recruiting”

How do I register my study?

- If your study is cancer related – the Knight Cancer Institute will register your study under their institutional account (more on this later)
 - This is any study that indicates it involves cancer in your IRB Initial Review Questionnaire
- All other OHSU investigators ...

How do I register my study?

- Apply for an **individual** Protocol Registration and Results System (PRS) Account
 - OHSU IRB Help Sheet - ClinicalTrials.gov Registration Requirements
<http://www.ohsu.edu/xd/about/services/integrity/policies/upload/Clinical-Trials-ClinicalTrials-gov-Registration-Requirements-Help-Sheet.pdf>
 - This document has field by field instructions for the PRSaccount request information
- Once you have your PRSaccount #, you can update or modify your registration through eCRIS or directly in clinicaltrials.gov

You can use eCRIS to help register your study

- You must indicate
 - This in an interventional trial (question in eIRB)
 - PI had a significant role in the design of the study and
 - OHSU PI is the lead PI on OHSU only or a multicenter trials (eCRIS)

1. * Did OHSU Principal Investigator (PI) have significant role in design of study?:

☒ Yes ☐ No [Clear](#)

If Yes, please specify

- ☒ OHSU PI is Lead PI (e.g. "Sponsor" of IND/IDE Study, lead PI of multicenter study)
- ☐ PI is on the study specific Data & Safety Monitoring Board/Data Monitoring Committee
- ☐ PI is on the protocol design committee
- ☒ PI authored protocol
- ☒ Other

If Other, specify role:

PI is one of the medical monitors

eCRIS Clinicaltrials.gov cont.

- You will be asked to fill out smart forms in eCRIS that you can export to and XML file

General Information

Enter the general identifying information concerning the clinical research study.

The grayed out fields originate in eIRB. To change the information, it must be modified in eIRB (Create/Update eCRIS activity or by submitting a modification for an approved study). Click the link to go to the eIRB system.

1. * Did OHSU Principal Investigator (PI) have significant role in design of study?:


☒ Yes ☐ No [Clear](#)


Non-eIRB Affiliate General Information
Ongoing Study Information
General Information
Budget Information
Industry Clinical Trial
Non-Industry Funded
ClinicalTrials.gov
Eligibility
Outcome Measures
Conditions and Keywords
Funded Access Status


- You can upload the XML file into clinicaltrials.gov for initial registration and for updates
- <http://www.ohsu.edu/xd/research/centers-institutes/octri/loader.cfm?csModule=security/getfile&pageid=2308573>


eCRIS Actions – Create XML


AVAILABLE ACTIONS


 Administration


 Prescreen


 Create ClinicalTrials Gov XML


 Record IRB Approval Lapsed


 Import OGA Number


 Terminate


 Close Enrollment


 Upload Contract

 Create Amendment

 ClinicalTrials gov Update

 Hold

 Copy Visit Schedule

 Log Comments

Version:1.0

OGA Numbers:GCARD0236A

OGA Alias:

Initial

Contract

FAID Owner:

Device(s):

Risk

Type

IDE Category

There are no items to display

Drug Study:no

Drug IND:no

IRB Documents:

Click here to get to the Study Documents in eIRB

History

Monitoring

OHSU Facilities

Study Documents

Study Milestones

Submissions

Budgets/

Change

Clinical

Clinical Services

Download XML file from eCRIS

Screenshot of the eCRIS (eClinical Research Information System) interface showing the 'Download XML file' option.

The interface displays a sidebar with navigation options and a main content area with various tabs and a list of activities.

Navigation Sidebar:

- Create Amendment
- ClinicalTrials gov Update
- Hold
- Pre-Study Training - Site Initiation
- Copy Visit Schedule
- Log Comments
- MAINTENANCE ACTIVITIES**
 - Manage Documents
 - Manage Project Editors
 - Edit Study Level Milestones
 - Manage Financial Admins
 - Set Notification Preferences
 - Review Notifications Sent
- EXPORTS**
 - Export Budget

Main Content Area:

FDA Regulatory Information:

Device(s):	Risk	Type	IDE Category	Number
		HDE		null
		HDE		null

Drug Study: no **Drug IND Exempt:** no
Drug IND: no **Drug Receipt Date:**
IND Number: There are no items to display

Statuses:

Billing Qualifying Status: All Services Paid

Budgets and Contracts:

ID	Name	State
CTBud00000401	Budget for Hologic, Inc.	Budget Complete
CTBud00000400	Budget for QIAGEN Marseille S.A.	Budget Complete
DR00000385	Hologic Pap HPV CTA OHSU_Morgan	OGA Setup Complete
DR00000632	Qiagen Pap HPV CTA OHSU_Morgan	OGA Setup Complete

Pre-Study Training/Site Initiation:

Sponsor Contacts:

Name	Phone	Email
Qiagen - Dr. Frederick Jones, PhD		Frederick.Jones@qiagen.com
Hologic - Dr. Philipp Mueller, PhD		Philipp.Mueller@hologic.com

IRB Documents: [Click here to get to the Study Documents in eIRB](#)

History | **Budgets/Visit Schedules** | **Change Log** | **Clinical Information** | **Clinical Services Review** | **Contracts** | **Coverage Analysis** | **Financials**

History | **Knight Cancer Institute** | **Monitoring** | **OHSU Facilities** | **Study Documents** | **Study Milestones** | **Study Sites** | **Study Personnel**

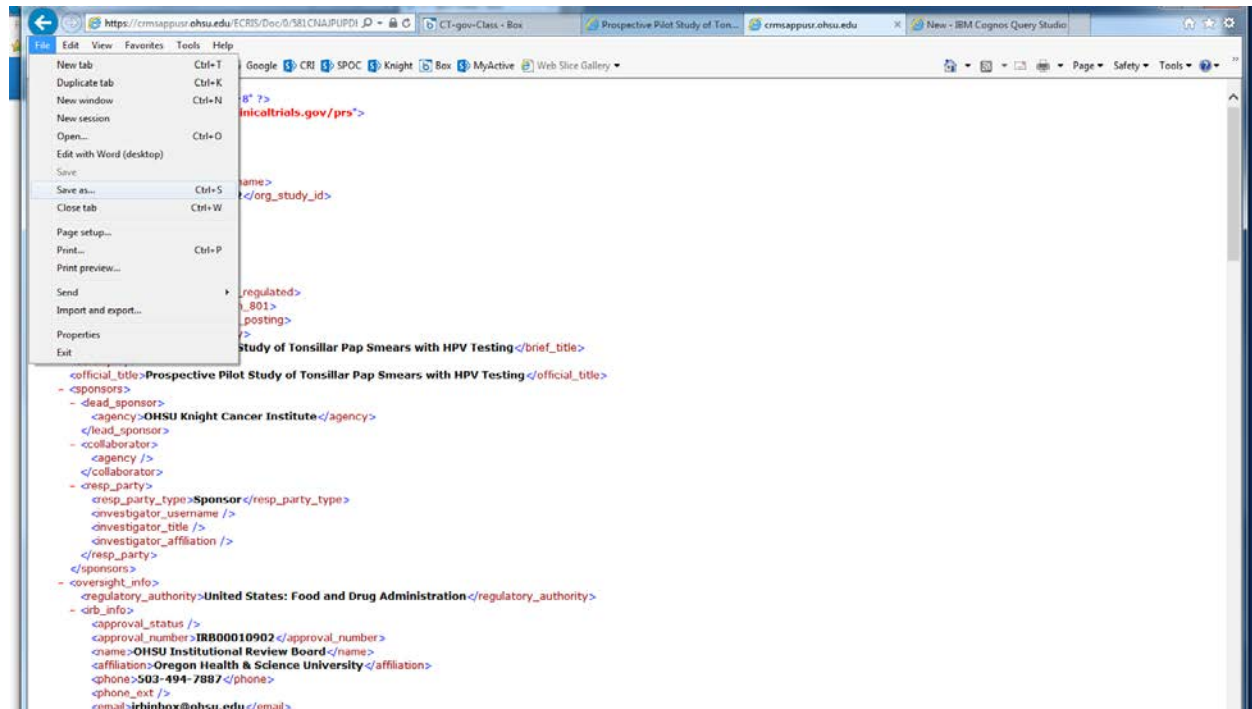
Filter by Activity **Advanced**

Activity	Author	Activity Date
ClinicalTrials Gov XML Created	Fournier, Lara C	11/19/2015 10:12 AM PST
XML Document		
Comments Logged	System Manager, CRBO	11/9/2015 2:15 PM PST
Administratively moved study back to Active, not enrolling per Lara F. request. All subjects have been entered. KStiller	System Manager, CRBO	11/9/2015 2:14 PM PST
Administration	System Manager, CRBO	11/9/2015 2:14 PM PST
Comments Logged	System Manager, CRBO	11/3/2015 2:58 PM PST
Administratively moved study in Enrolling state for Knight Cancer to enter subjects per Lara Fournier request. MHawkins	System Manager, CRBO	11/3/2015 2:58 PM PST
Administration	System Manager, CRBO	11/3/2015 2:58 PM PST
Budget Exported	Grabner, Jerris L	10/19/2015 10:26 AM PDT
Budget Export File		
Research account assigned	Thomson, Tiffany R	3/11/2015 1:31 PM PDT
OGA Number Imported	Administrator, System	3/11/2015 4:00 AM PDT
OGA Number: GPATH0118		
OGA Number Imported	Administrator, System	2/11/2015 4:00 AM PDT

Download (indicated by a red arrow pointing to the 'ClinicalTrials Gov XML Created' entry)

XML File

- Save the file where you can find it so you can upload it in Clinicaltrials.gov
- The file will always be available in eCRIS



Registration Steps

- Go to the ClinicalTrials.gov Login Page
<https://register.clinicaltrials.gov/>

ClinicalTrials.gov
Protocol Registration System



Login

Welcome to the [ClinicalTrials.gov](https://register.clinicaltrials.gov/) Protocol Registration System (PRS).

OMB NO: 0925-0586
EXPIRATION DATE: 04/30/2012
[Burden Statement](#)

Organization:

User Name:

Password: [Forgot password](#)

Login

Clinicaltrials.gov Menu

Check out the “[Quick Links](#)” section for the Problem Resolution Guide
To create a new protocol record, click “[New Record](#)”

To upload your XML export from eCRIS click the Upload Record (XML). There is an XML Upload User Guide (available when you are logged in). Do not attempt to upload other file types. Including XML files created from Microsoft Office using the “Save As” function

ClinicalTrials.gov PRS
Protocol Registration and Results System

Org: OHSUKCI User: LFournier [Logout](#)
Email: fourniel@ohsu.edu [[Update](#)]

Quick Links
[New Record](#)
[Admin Quick Reference](#)
[Problem Resolution Guide](#)

Records Accounts Help
New Record
Problems: LFournier Records
PRS Review Comments
Upload Record (XML)
Upload from NCI CTRP

Showing: 1-10 of 33 records 10

Protocol ID	ClinicalTrials.gov ID	Record Status	Last Update	Record Owner	Responsible Party	Problems
Open R CDR0000540438	NCT0044	Entry Completed	05/14/2015 17:19	eilersk		<ul style="list-style-type: none">• Ready for Review and Approval• Update Not Released• Late Results - per FDAAA
Open U IRB00009211		Entry Completed	06/18/2013 17:29	LFournier	[Sponsor]	<ul style="list-style-type: none">• Record Has 1 Error• Ready for Review and Approval• Never Released
Open U IRB00009203		Entry Completed	06/11/2013 15:47	LFournier	[Sponsor]	<ul style="list-style-type: none">• Record Has 3 Errors• Ready for Review and Approval• Never Released
Open U IRB00009140		Entry Completed	11/16/2012 12:27	LFournier	[Sponsor]	<ul style="list-style-type: none">• Record Has 6 Errors• Ready for Review and Approval

Lara's Nov Test Industry CancerStudy

After XML Upload

- Click Open and address any errors or warnings
- Errors will prevent you from moving forward
- Warning alert you to additional requirements that may apply to your study

The screenshot displays a web interface for managing a clinical trial protocol. At the top, a progress bar shows the stages: In Progress, **Entry Completed**, Approved, Released, PRS Review, and Public. Below this, a green box highlights the 'Next Step: Correct Error(s)'. The interface is divided into two main sections: 'Protocol Section' and 'Results Section'. The 'Protocol Section' contains a table with fields for Record Owner, Last Updated, Initial Release, Access List, Upload, PRS Review, and Public Site. Below this table is a row of links: Spelling, Preview, Draft Receipt (PDF, RTF), Download XML, Delete..., and Admin Only: Copy Protocol, Change Owner. The 'Open' button is circled in red. The 'Protocol Section' also displays a list of identifiers and a brief title. The 'Results Section' is partially visible at the bottom.

In Progress ➡ **Entry Completed** ➡ Approved ➡ Released ➡ PRS Review ➡ Public
[Reset to In-Progress...](#)

Next Step: Correct Error(s)

Record Owner: LFournier	Access List: [] Edit
Last Updated: 11/19/2015 13:24 by LFournier	Upload: Allowed Edit
Initial Release: [Not yet released]	PRS Review: [Not yet released]
	Public Site: [Not yet registered]

[Spelling](#) [Preview](#) [Draft Receipt \(PDF RTF\)](#) [Download XML](#) [Delete...](#) [Admin Only: Copy Protocol Change Owner](#)

[Open](#) **Protocol Section**

Identifiers: [NCT ID not yet assigned] Unique Protocol ID: IRB00010902
Brief Title: Prospective Pilot Study of Tonsillar Pap Smears With HPV Testing

Module Status:

- Study Identification: ✓
- Study Status: 1 Error
- Sponsor/Collaborators: ✓
- Oversight: 1 Warning
- Study Description: ✓
- Conditions: ✓ 2 Notes
- Study Design: 1 Warning
- Arms and Interventions: 1 Error 2 Notes
- Outcome Measures: ✓
- Eligibility: ✓ 1 Note
- Contacts/Locations: 1 Error
- References:

Results Section

Registration Cont.

Click on any underlined word in the left column for the definition and # of characters allowed

<u>Unique Protocol ID:</u> * FDAAA	Enter sponsoring organization's unique identifier. <input type="text"/>
<u>Brief Title:</u> * FDAAA (Special characters)	Use lay language. Example: Safety Study of Recombinant Vaccinia Virus Vaccine to Treat Prostate Cancer <input type="text"/>
<u>Acronym:</u>	If there is an acronym or abbreviation used to identify this study, enter it here. <input type="text"/>
<u>Official Title:</u>	Example: Phase 1 Study of Recombinant Vaccinia Virus That Expresses Prostate Specific Antigen in Metastatic Adenocarcinoma of the Prostate <input type="text"/>
<u>Study Type:</u> * FDAAA	<input type="radio"/> Interventional <input type="radio"/> Observational <input type="radio"/> Expanded Access About expanded access records
<u>FDA Regulated Intervention?</u> (FDAAA)	Indicate whether this trial includes an intervention subject to US Food and Drug Administration regulations. <input type="text" value="--Select--"/>
<u>IND/IDE Protocol?</u> * (FDAAA)	Indicate whether the protocol is subject to US Food and Drug Administration regulations, under an Investigational New Drug (IND) Application or Investigational Device Exemption (IDE). <input type="text" value="--Select--"/>

* = Required

IRB Approval

CT https://register.clinicaltrials.gov/prs/app/template CT ClinicalTrials.gov PRS: Edit ...

File Edit View Favorites Tools Help

Suggested Sites CDE Browser Google CRI SPOC Knight Box MyActive Web Slice Gallery

Protocol Registration and Results System Org: OHSUKCI User: LFourmier

Home > Record Summary > Protocol Section > Oversight

ID: CDR0000467219 Radiation Therapy and Docetaxel in Treating Patients Who Are Undergoing Surgery for Localized Prostate Cancer

Edit Oversight

[Help](#) [Definitions](#)

(†) FDA Regulated Intervention?: Yes
Does this trial involve a drug, biologic or device subject to US Food and Drug Administration (FDA) regulations?

(†) Section 801 Clinical Trial?: Yes
Is this an [applicable clinical trial](#) per FDA Amendments Act (FDAAA)?

(†) Delayed Posting?: No
Allowed only for trial of device not previously approved or cleared.

* (†) IND/IDE Protocol?: No
(Not public) FDA Investigational New Drug (IND) Application or Investigational Device Exemption (IDE)?

* Board Approval: Status: Submitted, approved Approval Number: 1581
If review board does not assign approval numbers, enter date in mm/dd/yyyy format.
Send a signed board approval letter to ClinicalTrials.gov ([address and instructions](#)).

* Board Name: Oregon Health & Science University IRB# 1

* Board Affiliation: Oregon Health & Science University

* Board Contact: Business Phone: 503-494-7887 Extension: Business Email: irbinbox@ohsu.edu
(Not public) Business Address:

Use the FDAAA 801 definition of applicable clinical trial here

OHSU IRB Information:
Go to Appendix 2 of the IRB help sheet on clinical trials registration

Responsible Party Designation

NOTE: The **Sponsor** option should be selected, unless the Investigator has been designated as Responsible Party under the FDA Amendments Act (FDAAA).

Principal Investigator [About Responsible Party...](#)

For Principal Investigator or Sponsor-Investigator only, provide:

Select the PRS account of the investigator. The Full Name from the selected account will be displayed on ClinicalTrials.gov.

Investigator Name [Username]:

[Investigator not in list?](#) [Incorrect name format?](#)

Investigator Official Title:

Investigator Affiliation:

The investigator must be registered with Clinicaltrials.gov to appear on the list - it is organized by **user name**

Responsible Party: **FDAAA**

Sponsor: * **FDAAA**

Collaborators:
(One per line)

Include all additional funding sources.

Enter only the organization names, one per line (no numbers, dashes, bullets, etc.).

Responsible Party vs. Record Owner

- **The Responsible Party (RP)** is responsible for registering their study
- **Record Owner (RO)** can be anyone with an account; the record is stored in RO's account.
- **TIPS:**
 - If the RP is the Principle Investigator (PI), it may be easiest if the PI is also the RO.
 - The RO can use the “access list” to grant additional users access to the specific record for editing purposes (e.g. if the PI is the RO, he/she can provide access to the study coordinator by selecting the study coordinator from the access list.)

Registration Tips

Summary should be in lay language

Abbreviations must be spelled out the first time they are used

The overall recruiting status must match the location recruiting status

Start date and completion dates are required
Keep your primary completion date up to date or you could end up on the “Problem List”

Change the verification date to the current month and year. You are supposed to update every 6 months.

Brief Summary:	How to enter a study record onto ClinicalTrials.gov
Detailed Description:	
NOTE: Detailed Description: data not entered.	
Record Verification Date:	July 2012
Overall Status:	Not yet recruiting
Study Start Date:	August 2012
Primary Completion Date:	September 2013 [Anticipated]
Study Completion Date:	September 2013 [Anticipated]

Entering Outcome Measures

- Be specific
- Outcome title – include the name of the specific measure. Avoid using verbs – do not put “To determine...”
- Time Frame – use a specific metric (hours, weeks, years) do not use “until the end of the study” or “death”
- Description – specify what will be measured not why. If the outcome measure is a scale, provide the range and what a low or high score means
- Is the outcome measure assessing safety

The screenshot shows the ClinicalTrials.gov Protocol Registration System (PRS) interface. The browser window is titled "Design - Windows Internet Explorer" and the address bar shows the URL: <https://register.clinicaltrials.gov/prs/app/template/edit%2C%20Outcome.vm/action/AddListItem?prop=PrimaryOutcomes&wizardmode=Edit&type=gov>. The page header includes the ClinicalTrials.gov logo, the text "Protocol Registration System (Logo)", and a link "Send message to PRS". The navigation bar shows tabs: Title, Oversight, Sponsor, Summary, Status, Design (selected), Interventions, Conditions, Eligibility, Locations, Citations, and Links. The main content area is titled "Primary Outcome Measure" and contains the following fields:

- Title:** * Enter only one distinct outcome measure. (Text input field)
- Time Frame:** (FDA) (Text input field)
- Description:** (Text input field)
- Safety Issue:** (FDA) Does this outcome measure assess a safety issue? (Dropdown menu with "--Select--")

At the bottom of the form, there are "OK" and "Cancel" buttons. A footer note states: *

- FDA** Required by ClinicalTrials.gov
- FDA** Required to comply with US Public Law 110-85, Section 801
- FDA** May be required to comply with US Public Law 110-85, Section 801

The browser status bar at the bottom shows the URL: <https://register.clinicaltrials.gov/prs/app/template/MainMenu.vm?uid=U0000VYS&sz=12&id=S0002YKM&cx=at&ye6> and the page is zoomed to 100%.

Objectives vs Outcomes

- This Outcomes information will pull into the results module later so define them well
- Objectives are not the same as outcomes
 - Object example = evaluate safety and tolerability
 - Outcome = Grade 3 and higher adverse events measured at 24 months

What is wrong with this primary outcome?

Primary Outcome Measure

Tip: Refer to the [Protocol Review Criteria](#) to avoid problems with specification of Outcome Measures.

Title: *	Enter only one distinct outcome measure. Nausea
Time Frame: (FDAAA)	During schedule treatment period
Description:	Nausea Scale
Safety Issue? (FDAAA)	Does this outcome measure assess a safety issue? --Select--

Title and time frame are not specific
How will the study measure nausea?
When will it be measured?

If the outcomes are unclear, you may
receive comments from QA reviewers
and registration could be delayed

A Well Defined Primary Outcome

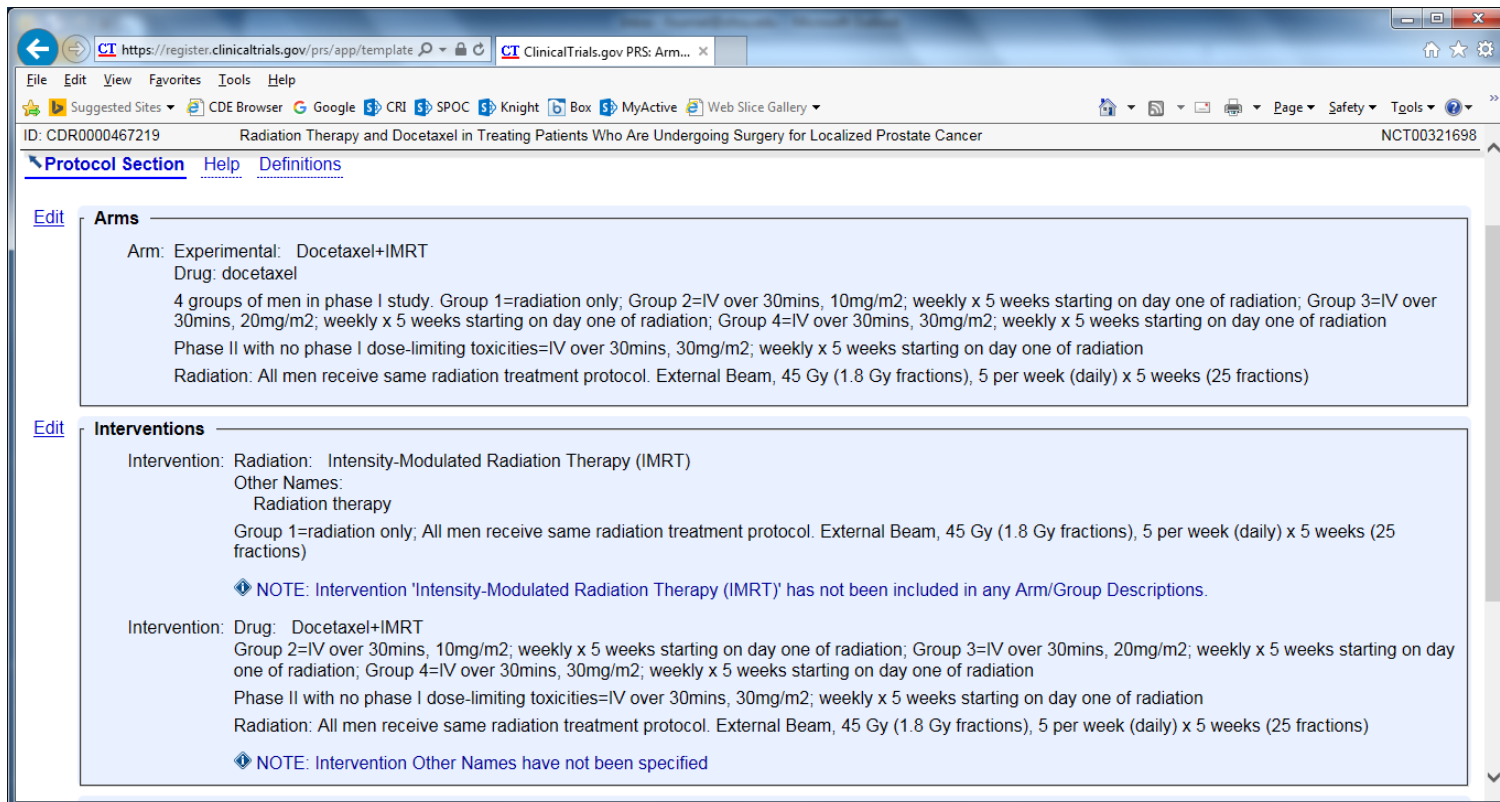
Primary Outcome Measure

Tip: Refer to the [Protocol Review Criteria](#) to avoid problems with specification of Outcome Measures.

Title: *	Enter only one distinct outcome measure. Number of Participants improved on the nausea scale
Time Frame: (FDALL)	8 weeks
Description:	Nausea scale range: 1 (severe) to 10 (none). Change: score at 8 weeks minus score at baseline. "Improved" = greater than 3 point difference in nausea scale.
Safety Issue? (FDALL)	Does this outcome measure assess a safety issue? No

Entering Arms/ Interventions

If the same intervention is used in multiple arms, enter the information once and then use the Cross-Reference section to specify which arm(s) the intervention is associated with



The screenshot shows a web browser window with the URL <https://register.clinicaltrials.gov/prs/app/template>. The page title is "ClinicalTrials.gov PRS: Arm...". The browser's address bar shows the URL. The page content is divided into two main sections: "Arms" and "Interventions".

Arms Section:

Arm: Experimental: Docetaxel+IMRT
Drug: docetaxel
4 groups of men in phase I study. Group 1=radiation only; Group 2=IV over 30mins, 10mg/m²; weekly x 5 weeks starting on day one of radiation; Group 3=IV over 30mins, 20mg/m²; weekly x 5 weeks starting on day one of radiation; Group 4=IV over 30mins, 30mg/m²; weekly x 5 weeks starting on day one of radiation
Phase II with no phase I dose-limiting toxicities=IV over 30mins, 30mg/m²; weekly x 5 weeks starting on day one of radiation
Radiation: All men receive same radiation treatment protocol. External Beam, 45 Gy (1.8 Gy fractions), 5 per week (daily) x 5 weeks (25 fractions)

Interventions Section:

Intervention: Radiation: Intensity-Modulated Radiation Therapy (IMRT)
Other Names:
Radiation therapy
Group 1=radiation only; All men receive same radiation treatment protocol. External Beam, 45 Gy (1.8 Gy fractions), 5 per week (daily) x 5 weeks (25 fractions)
NOTE: Intervention 'Intensity-Modulated Radiation Therapy (IMRT)' has not been included in any Arm/Group Descriptions.

Intervention: Drug: Docetaxel+IMRT
Group 2=IV over 30mins, 10mg/m²; weekly x 5 weeks starting on day one of radiation; Group 3=IV over 30mins, 20mg/m²; weekly x 5 weeks starting on day one of radiation; Group 4=IV over 30mins, 30mg/m²; weekly x 5 weeks starting on day one of radiation
Phase II with no phase I dose-limiting toxicities=IV over 30mins, 30mg/m²; weekly x 5 weeks starting on day one of radiation
Radiation: All men receive same radiation treatment protocol. External Beam, 45 Gy (1.8 Gy fractions), 5 per week (daily) x 5 weeks (25 fractions)
NOTE: Intervention Other Names have not been specified

Contact/Location Information

Central Contact

List the person providing centralized recruitment information

Locations

List all study sites (multicenter)

Recruitment status should match overall recruiting status

Keep this up to date and provide complete contact information so that participants and others know who to call

Protocol Section

Help

Definitions

Contacts/Locations

Edit

Overall Contacts

Central Contact: Mark Garzotto, MD garzotto@ohsu.edu

Central Contact Backup: Paige E Farris, MSW farris@ohsu.edu

Overall Study Officials: Principal Investigator Mark Garzotto, MD Knight Cancer Institute at Oregon Health and Science University

Copy locations... from a master list, extracted from this organization's records.

Set multiple Locations' Recruitment Status...

United States, Oregon

Edit

Location

OHSU Knight Cancer Institute

Portland, Oregon, United States, 97239-3098

Edit

Location

Veterans Affairs Medical Center - Portland

Portland, Oregon, United States, 97207

Contact: Mark Garzotto, MD garzotto@ohsu.edu

Contact: Paige E Farris, MSW farris@ohsu.edu

+ Add Location

Sort Locations...

How do I register my study? - Cancer/Oncology Studies

- Go through the OHSU Knight Cancer Institute, Contact ctrp-admin@ohsu.edu with protocol, consent form, IRB approval memo and completed checklist document
- National Cancer Institute abstracts the protocol for you
- The PI will review and approve a trial summary report (TSR)
- It takes NCI staff 10 days to provide the TSR for review
- Once it is approved NCI provides XML format for upload to CT.gov
- The Knight registration staff will do the upload for you
- What is a cancer study? Indicated in IRB IRQ.
 - Studies with focus on cancer or subject population primarily made up of cancer patients.
 - Studies with intent to treat, prevent, diagnose cancer or improve comfort /quality of life of cancer patients. Includes Epidemiologic/Observational/Outcomes/Lab-based studies that assess cancer risk, outcomes or therapy response.

Clinical Trial Registration Process - Cancer/Oncology Studies

- NCI expects all interventional trials that are conducted in NCI-Designated Cancer Centers to be registered
- Knight-sponsored interventional cancer trials are to be registered with CTRP first, before ClinicalTrials.gov
- After CTRP registration, Knight CTRP staff will upload a data file to ClinicalTrials.gov per the [Knight SOP](#)

NCI Clinical Trials Reporting Program (CTRP)

- NCI launched a new system to replace PDQ® system - the Clinical Trials Reporting Program (CTRP).
- Fulfills a recommendation made by the NCI Clinical Trials Working Group (CTWG) to the National Cancer Advisory Board.
- The purpose of CTRP is to establish a comprehensive database containing regularly updated information on all NCI-funded clinical trials.

Transfer of Study Registration(s) on Cancer/Oncology Studies

- Knight CTRP staff will periodically audit all OHSU-associated studies registered in Clinicaltrials.gov under individual accounts to see if they are cancer-related. When these are discovered, these study records will be transferred to the OHSU Knight Cancer Institute's organizational account:
- **NOTE:** Record transfer does not change level of access, editing or the NCTID (Clinicaltrials.gov ID number). However, if the study originally had the PI as the responsible party, this will be changed to the Knight Cancer Institute so that we can release study records for publication to the Clinicaltrials.gov web site.

CTRP Clinical Trial Record Maintenance: Amendments (CTRP requirements)

- Amendments are any change that substantively alters the trial protocol document and require IRB approval
- Clinical trial records are to be amended within **20 business days** of IRB approval of protocol amendment

CTRP Clinical Trial Record Maintenance: Amendments (Knight Process, Pt 1)

1. Per [Knight SOP](#), within five (5) business days after a protocol amendment/modification IRB approval, Knight CTRP staff will gather following items:
 - Amended protocol (clean copy)
 - Change memo detailing the changes to protocol or tracked changes version of protocol
 - IRB approval memo

CTRP Clinical Trial Record Maintenance: Amendments (Knight Process, Pt 2)

2. Knight CTRP Staff submit documents to NCI CTRP
3. NCI's CTRP staff provide revised trial summary report (TSR) for review
4. Knight CTRP staff will email TSR to study record owner for review

CTRP Clinical Trial Record Maintenance: Amendments (Knight Process, Pt 3)

5. Study staff will note changes to TSR using Word tracked changes and return revised TSR to Knight CTRP Staff at ctrp-admin@ohsu.edu
 - If no response is received within 5 days, it will be assumed TSR is correct
6. Repeat steps 4-6 until TSR is accurate and complete
7. Knight CTRP Staff will finalize amendment with NCI CTRP and upload amended CTRP information to ClinicalTrials.gov

CTRP Clinical Trial Record Maintenance: Updates (CTRP Requirements)

- Updates are changes that don't impact the way clinical trial is conducted (e.g. change in PI contact information or change in Anticipated Primary Completion Date)
- At a minimum, updates should be reported every 6 months

CTRP Clinical Trial Record Maintenance: Updates (Knight Process, Pt 1)

1. Per [Knight SOP](#), within five (5) business days after a minor change to a clinical trial (e.g. change in Primary Completion Date or trial status), Knight CTRP staff will gather following items:
 - o List of all minor changes made to protocol since last amendment
2. Knight CTRP Staff updates trial information in NCI's CTRP
3. NCI's CTRP staff provide revised trial summary report (TSR) for review

CTRP Clinical Trial Record Maintenance: Updates (Knight Process, Pt 2)

4. Knight CTRP staff will email TSR to study record owner for review
5. Study staff will submit changes as needed in tracked changes doc to Knight CTRP staff
6. Repeat steps 4-6 until TSR is accurate and complete
7. Updated CTRP information will be uploaded to [ClinicalTrials.gov](https://clinicaltrials.gov)

Maintenance- All Responsible Parties

- Update your study records within 30 days a change to any of the following:
 - Changes in recruitment status
 - Not yet recruiting, recruiting, enrolling by invitation, active – not recruiting, completed, suspended, terminated, withdrawn
 - Completion date
 - Changes in contact personnel
 - Every 6 months it is strongly recommended that you verify information is correct
 - At least annually
 - Non substantive protocol amendments (e.g. change to statistical plan)

Frequent Registration Problems

- Who at OHSU registers my trial? Keeps track of my password?
 - You OR
 - **The Knight Cancer Institute**
- Oops I didn't register my study, now what?
 - Register as soon as possible
- My study doesn't meet the definition of a clinical trial but the journal wants me to register
 - Register as soon as possible
- I registered my study but I can't find it?
 - May not be released yet because of errors – check you email and your spam
 - Missing from cancer.gov notify the Knight registration staff, they can help you
- I received an email from the eIRB telling me I need to register but my study doesn't meet the definition, now what?
 - If your study doesn't meet the ICMJE definition you don't need to register

How to search results

- Allows you to look for results of studies that may not have had publishable results.
- This may help with protocol design and scientific justification
- Go to the Find Studies and click Advanced Search
- Enter your topic area
- Select “Studies with Results” from the study results drop down list
- If studies have results posted the status will state “Has Results”

[+ Show Display Options](#)

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☐ Include only open studies ☐ Exclude studies with Unknown status

Rank	Status	Study
1	Completed Has Results	Purge Vs no Purge in Living Donor Liver Transplantation Recipients Condition: Ischemia Reperfusion Injury Intervention: Other: Purge of graft contents out of the circulation

References and Additional Resources

- Clinicaltrials.gov information <https://www.clinicaltrials.gov/ct2/about-site/results>
- Questions register@clinicaltrials.gov
- FDAA <https://www.clinicaltrials.gov/ct2/manage-recs/fdaaa>
- CMS – Mandatory Reporting of NCT #s on Medicare Claims Q&A
<https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/Downloads/Mandatory-Clinical-Trial-Identifier-Number-QsAs.pdf>
- PRS User's Guide XML section (must be logged in to PRS to access)
<https://register.clinicaltrials.gov/prs/app/template/ReferenceGuide.vm?popup=true&uid=U0000W56&ts=3&cx=-pf1azb#xml>
- OHSU Knight Clinical Trial Registration SOPs: CR007, CR013 -
- <https://bridge.ohsu.edu/research/knight/policies/SitePages/Home.aspx>
- Knight CTRP staff ctrp-admin@ohsu.edu
- OHSU ClinicalTrials.gov IRB Help Sheet:
<http://www.ohsu.edu/xd/about/services/integrity/policies/upload/Clinical-Trials-ClinicalTrials.gov-Registration-Requirements-Help-Sheet.pdf>

Some of the slides were adapted with permission from the work of the Clinical and Translational Science Awards (CTSA) program's Clinical Trials Registration Workgroup of the Regulatory Knowledge Key Function Committee. Original slides available at Harvard Catalyst
<https://catalyst.harvard.edu/programs/regulatory/clinical-trial-reg.html>

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Thank You

