

# Enrolling Consented Subjects

## Subjects>CRA Console

Use pull-down or type in protocol name to select the correct protocol.  
Click on New Subject Registration.

The screenshot displays the OnCore CRA Console interface. At the top, the user is identified as Sandra Johnson (ADMIN) at the Medical College of Wisconsin-OCT. The navigation menu includes options like Admin, Audits / Monitoring, eCRFs/Calendars, Financials, My Console, Protocols, Reports, Reviews, Specimens, Subjects, and Effort Tracking. The 'Subjects' menu is expanded, showing 'CRA Console', 'Pre-Screening', 'Subject Console', and 'Subject Search'. A red arrow points to the 'CRA Console' option. Below the navigation, the CRA Console section is visible, with fields for Protocol No., Library, Protocol Target Accrual, RC Total Accrual Goal (Upper), Short Title, Accrual To Date, Sponsor, and Protocol Status. On the left sidebar, there are sections for 'Select Protocol', 'Select Subject', and 'Accrual'. The 'New Subject Registration' link is circled in red.

OnCore is linked with the EPIC EMR system. As such, demographic data, including those listed on the New Subject console, should not be entered by study staff, but searched for through the Find function. Enter the Study Site and the subject MRN then click the Find button.

★ Required

**New Subject** ?

Protocol No.: **RTOG-1005**      Library: **Oncology**      PI: **Currey, Adam**      Sponsor: **RTOG**  
Protocol Target Accrual: **2312**      Accrual To Date: **21**      Protocol Status: **OPEN TO ACCRUAL**  
RC Total Accrual Goal (Upper): **55**  
Short Title: **Hypofractionated WBI vs. standard WBI for Early Stage Breast Cancer**

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**Study Site\*** ★

**Find Fields**

★ **MRN\***

Last Name

Birth Date

**New Subject Details**

MRN*	<input type="text"/>
Last Name*	<input type="text"/>
First Name*	<input type="text"/>
Middle Name	<input type="text"/>
Suffix	<input type="text"/>
Birth Date*	<input type="text"/> <input type="button" value="Calendar"/>
	<input type="checkbox"/> Approx? <input type="checkbox"/> Not Avail?
Gender*	<input type="text"/> <input type="button" value="Dropdown"/>
Ethnicity*	<input type="text"/> <input type="button" value="Dropdown"/>
SSN	<input type="text"/>
Expired Date	<input type="text"/> <input type="button" value="Calendar"/>
	<input type="checkbox"/> Approx?
Last Known Alive Date	<input type="text"/> <input type="button" value="Calendar"/>

**Race\***

American Indian or Alaska Native

Asian

Black or African American

Native Hawaiian or Other Pacific Islander

Unknown

White

## New Subject



Protocol No.: RTOG-1005

Library: Oncology

PI: Currey, Adam

Sponsor: RTOG

Protocol Target Accrual: 2312

Accrual To Date: 25

Protocol Status: OPEN TO ACCRUAL

RC Total Accrual Goal (Upper): 55

Short Title: Hypofractionated WBI vs. Standard WBI for Early Stage Breast Cancer

Study Site\*

MCW/Froedtert

### Find Fields

MRN: 70000390

Last Name:

Birth Date:

Clear

Find

### New Subject Details

MRN\*

Last Name\*

First Name\*

Middle Name

Suffix

Birth Date\*

Approx?

Not Avail?

Gender\*

Ethnicity\*

Expired Date

Approx?

Last Known Alive Date

Race\*

American Indian or Alaska Native

Asian

Black or African American

Native Hawaiian or Other Pacific Islander

Unknown

White

Add

Clear All

Close

### Subject Find Results

Count: 1

MRN	Addl Subj IDs	Last Name	First Name	Middle Name	Suffix	Gender	Birth Date
<a href="#">70000390</a>	70000390, 2700307, E2007222	TEST	REFERRAL			F	01/01/1970

If the MRN was entered correctly the patient information should appear under the Subject Find Results section on the bottom of the page.

Confirm it is the correct subject, then click the subject hyperlink to populate the required Subject Details.

## New Subject

Protocol No.: RTOG-1005

Library: Oncology

PI: Currey, Adam

Sponsor: RTOG

Protocol Target Accrual: 2312

Accrual To Date: 25

Protocol Status: OPEN TO ACCRUAL

RC Total Accrual Goal (Upper): 55

Short Title: **Hypofractionated WBI vs. Standard WBI for Early Stage Breast Cancer**

Study Site\*  
MCW/Froedtert

Find Fields

MRN	<input type="text" value="70000390"/>
Last Name	<input type="text"/>
Birth Date	<input type="text"/>

New Subject Details

MRN*	<input type="text" value="70000390"/>	
Last Name*	<input type="text" value="TEST"/>	
First Name*	<input type="text" value="REFERRAL"/>	
Middle Name	<input type="text"/>	
Suffix	<input type="text"/>	
Birth Date*	<input type="text" value="01/01/1970"/>	<input type="checkbox"/> Approx? <input type="checkbox"/> Not Avail?
Gender*	<input type="text" value="Female"/>	
Ethnicity*	<input type="text" value="Non-Hispanic"/>	
Expired Date	<input type="text"/>	<input type="checkbox"/> Approx?
Last Known Alive Date	<input type="text"/>	

Race\*

- American Indian or Alaska Native
- Asian
- Black or African American
- Native Hawaiian or Other Pacific Islander
- Unknown
- White

Additional Subject Details  
None

Subject Find Results Count: 1

MRN	Addl Subj IDs	Last Name	First Name	Middle Name	Suffix	Gender	Birth Date
<a href="#">70000390</a>	70000390, 2700307, E2007222	TEST	REFERRAL			F	01/01/1970

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Once all information has been populated, click the Add button to add the subject to the protocol.

In the event that subject Race/Ethnicity information is incomplete in EPIC it will come across to OnCore as blank (missing) information. When this is the case you must include Race/Ethnicity as it is required for subject entry – if not you will receive this error message.

If this happens please email [EnterpriseRegistrationQA\\_Training@froedtert.com](mailto:EnterpriseRegistrationQA_Training@froedtert.com) with information regarding the missing information (include MRN, name and correct Race/Ethnicity value) and EPIC will be updated.

The page at <https://octest.mcw.edu> says:

Ethnicity is a required field.  
Race is a required field.

OK

# Subjects>CRA Console>Consent Tab

Do NOT complete Demographics Tab.

Available Consents

★ Signed Date **Date consent signed** **Select Consents**

Existing Consents

Type	Description	Version Date	Approved Date	Expiration Date	Signed Date	Status	Delete?
No Subject Consent Found							

Available Consents

After selections are made, clicking Save will add the selected consents and refresh the page.

Type	Description	Version Date	Approved Date	Expiration Date	Signed Date	Status	Include?
+ Treatment Consent	Treatment Consent	05/14/2013	05/14/2013	05/13/2014	10/11/13	<input checked="" type="radio"/> Accepted <input type="radio"/> Refused	<input type="checkbox"/>

Available consent, filtered by consent date, will appear. Where only 1 consent is available, only 1 will appear. Hit Accepted button and Include will auto fill. Hit Save when done. Any comments about the consent process (i.e. Spanish language) can be entered in the Comments field.

**Save** **Cancel**

Available Consents

After selections are made, clicking Save will add the selected consents and refresh the page.

Type	Description	Version Date	Approved Date	Expiration Date	Signed Date	Status	Include?
Consent (NOS)	Consent - AME #10989 Supplemental 06-18-13	06/18/2013	06/18/2013	02/07/2014	10/11/13	<input checked="" type="radio"/> Accepted <input type="radio"/> Refused	<input type="checkbox"/>
+ Screening Consent	Consent - AME #10989 Screening 06-18-13	06/18/2013	06/18/2013	02/07/2014	10/11/13	<input type="radio"/> Accepted <input type="radio"/> Refused	<input type="checkbox"/>
+ Treatment Consent	Consent - AME #10989 Main 06-18-13	06/18/2013	06/18/2013	02/07/2014	10/11/13	<input type="radio"/> Accepted <input type="radio"/> Refused	<input type="checkbox"/>

Example for multiple consents, the date for all consents is auto-filled - click the Accepted button **ONLY** for the applicable consent(s) for that day. Consent Refused **ONLY** used in rare cases – i.e. separate consent for blood that is not in the main treatment consent and must be signed with a yes or no response.

# Subjects>CRA Console>Eligibility Tab

<b>Switch Subject</b> Type here to search <b>Summary</b> <b>Demographics</b> <b>Consent</b> <b>Eligibility</b>	New Subject Eligibility		
	Version Date	Not required	Eligibility Status: Eligible/Not Eligible
	Verified By	Not required	Status Date
	Comments	Not required, but can be used to document further details about ineligibility– i.e. lab values, prior diagnosis, etc..	
			Date determined to be eligible/Not eligible based on checklist/questionnaire
			<input type="button" value="Submit"/> <input type="button" value="Close"/>

Subject Eligibility Update					
Version Date	<input type="text"/>	Verified By	<input type="text"/>	Status Date: 12/16/2013	Eligibility Status: Not Eligible
Comments	<input type="text"/>				
Reason Withdrawn	<input type="text"/>	Reason Not Eligible	Required for Not Eligible Subjects		
			Diagnosis Lab Values Inability to Consent Performance Status Investigator Determination Ineligible Other Refused Randomization Receiving Treatment Elsewhere Interested in Other Protocol Time Commitment Subject Refused Concomitant Medication(s) Insurance/cost concerns Procedure Parameters Not Met Expired Prior Therapy/Therapies Prior/Concurrent Cancer Out of Treatment Window Age		

After hitting the Submit button, if the patient was determined to be Not Eligible, a new field will appear (Reason Not Eligible) - choose from the pull-down the most important reason for ineligibility. For example, patient refused randomization is more important than lab values. Hit the Submit button again once selection is made.

# Subjects>CRA Console>On Study Tab

## ★ Subject Console

Protocol No.: AACVPR

Protocol Status: OPEN TO ACCRUAL

Subject Status: ELIGIBLE

MRN: DAAA6GK

Subject Name: Jane Doe

Sequence No.: 6LPSLNTR58

[Epic](#)

- Switch Subject
- Summary
- Demographics
- Consent
- Eligibility
- On Study**
- Treatment
- Follow-Up
- SAEs
- Payments
- Deviations
- Documents/Info
- Protocols
- MRN
- CRA Console
- PC Console

Subject On Study Update			
★ Sequence No.	Case number assigned by sponsor/OnCore seq. no. etc	★ On Study Date (MM/DD/YYYY)	Date randomized/enrolled
★ Primary Diagnosis	<input type="text" value="Type here to search"/>	Ready for Registration	<input type="checkbox"/>
Secondary Diagnosis	<input type="text" value="Type here to search"/>		
Diagnosis Date	<input type="text"/> <input type="text"/>		
ZIP at Registration	##### ZIP at registration		
Study Site	Froedtert Hospital	Transferred Date (MM/DD/YYYY)	Transfer IN ONLY
Comments	<input type="text"/>		

Additional Protocol Subject Identifiers		
Identifier Type	Identifier	
<input type="text"/>	<input type="text"/>	<a href="#">Add</a> <a href="#">Cancel</a>
No information entered		

Subject Staff				<a href="#">See All</a>
Role	Staff Name	Start Date		<a href="#">Team</a>
★ Treating Physician	<input type="text" value="Type here to search"/>	<input type="text"/>		<a href="#">Add</a>
No information entered				

The Treating Physician is the doctor that gets credit for enrolling the patient on the trial, NOT necessarily the PI. All other doctors responsible for protocol related care can be added as Co-Treating Physician(s).

No information entered
<a href="#">Select</a>
<a href="#">Submit</a> <a href="#">Clear</a> <a href="#">Close</a>

# Subjects>CRA Console>Treatment Tab

Subject Treatments <span style="float: right;">Add</span>					
Step Code	Arm	On Arm Date	On Treatment Date	Off Arm Date	
Use pull-down to choose Randomization/Registration arm subject was assigned to. Subject can be on multiple arms, either at same time or at different times.		Date subject assigned arm, for Sponsored studies the date of randomization	Date subject gets first dose of drug, a device, or other protocol specified treatment. This can be left blank if not yet known.	Date all procedures for a specific protocol treatment arm have been completed. Multi-arm protocols: switching to another arm does not mean Off-Treatment	<a href="#">Save</a> <a href="#">Cancel</a>
No Records Found.					

# Subjects>CRA Console>Follow-Up Tab

Subject Off Treatment Update			
★ Off Treatment Date (MM/DD/YYYY)		★ Off Treatment Reason	Choose most important reason for off-treatment
Explain	Date decision is made to end protocol specified treatment, i.e. last day of treatment,, withdrawal, death etc. If off treatment for anything other than end of protocol specified treatment, enter date of last dose and any other important information		
Subject Off Study Update			
★ Off Study Date (MM/DD/YYYY)		★ Off Study Reason	Choose most important reason for off-study
Explain	Date no longer in treatment or follow-up. Often the last visit date. If off study for anything other than protocol defined follow-up complete, enter any important information as to reason for off-study		
Subject Follow-Up Update			
★ Follow-Up Start Date (MM/DD/YYYY)	If a follow-up period follows the Off Treatment Date, enter here.	Transferred to (Study Site)	<input type="text"/>
Last Follow-Up Date (MM/DD/YYYY)		Next Follow-Up Date (MM/DD/YYYY)	Not required
Expired Date (MM/DD/YYYY)	<input type="text"/> <input type="checkbox"/> Approx?	Last Date Known Alive (MM/DD/YYYY)	Not required
Alternate MRN			<input type="text"/>
Last Known Survival Status			Type here to search
QA Date (MM/DD/YYYY)			Not required
Comments	<input type="text"/>		
4000 character(s) remaining			
Evaluable for Analysis <b>For IIT Trials</b>			
Evaluable	<input type="text"/>	Reason	<input type="text"/>
			Submit Reset Close

# Adding Subject Documents

## Subjects>CRA Console>Documents/Info Tab

<b>Switch Subject</b> Type here to search <input type="text"/>	<b>Subject Demographics</b> <span style="float: right;">History</span>										
<b>Summary</b>	MRN	6YSOGP3									
<b>Demographics</b>	Last Name	Doe	First Name	Jane	Middle Name	W	Suffix				
<b>Consent</b>	Birth Date	07/23/1908	Expired Date	01/12/2007			Last Date Known Alive				
<b>Eligibility</b>	Gender	F	Ethnicity	Non-Hispanic							
<b>On Study</b>	Race	White									
<b>Treatment</b>	Subject Comments										
<b>Follow-Up</b>	<b>Additional Subject Identifiers</b>										
<b>SAEs</b>	Identifier Type	Identifier			Identifier Owner						
<b>Calendar</b> »	No information entered										
<b>Additional Visits</b>	<b>Subject's Contact Information</b>										
<b>Payments</b>	Name	Primary	Address		City	State	ZIP	County	Country	Phone No.	Email Address
<b>Deviations</b>	Jane w Doe		Qytcjunccestltdhzwt		Oxizstgiszbuassdrbbr		89014				
<b>Documents/Info</b> »	<b>Emergency Contacts</b>										
<b>Protocols</b>	Name	Primary	Address		City	State	ZIP	County	Country	Phone No.	Email Address
<b>MRN</b> <input type="text"/>	No information entered										
<b>CRA Console</b>											
<b>PC Console</b>											

# Subjects>CRA Console>Documents/Info>Attachments Tab

Switch Subject [Type here to search]

Archive/Notes **Attachments** Click the Add button **Add**

Subject Attachments

Document Type	File Name / URL	Description	Version Date	Created Date	Created User	Edit	Delete?
No Records Found.							

Submit Clear

Archive/Notes **Attachments**

Add Attachment

Document Type [Consent] Choose Appropriate Document Type Version Date [Date uploading document]

Attach a **File** or URL

Description [Include under Description visit name]

Subject Attachments **Add**

Document Type	Description	Version Date	Created Date	Created User	Edit	Delete?
No Records Found.						

Archive/Notes **Attachments**

Add Attachment

Document Type [Consent] Version Date [06/22/2015]

Attach a **File** or URL

Description [Screening Visit - Consent]

**Click File button, browse for the file** Add Cancel

Subject Attachments **Add**

Document Type	File Name / URL	Description	Version Date	Created Date	Created User	Edit	Delete?
No Records Found.							

Submit Clear

Archive/Notes Attachments

Add Attachment

Document Type: Consent Version Date: 06/22/2015

Attach a File or URL

Screening Visit - Consent

Click File button, browse for the file

Add Cancel

Subject Attachments Add

Document Type	File Name / URL	Description	Version Date	Created Date	Created User	Edit	Delete?
No Records Found.							

Submit Clear

Archive/Notes Attachments

Add Attachment

Document Type: Consent Version Date: 06/22/2015

Attach a File Choose File No file chosen or URL

Description: Screening Visit - Consent

Click Choose File to browse your computer for the pdf

Add Cancel

Subject Attachments Add

Document Type	File Name / URL	Description	Version Date	Created Date	Created User	Edit	Delete?
No Records Found.							

Submit Clear

Archive/Notes Attachments

Add Attachment

Document Type: Consent Version Date: 06/22/2015

Attach a File: Choose File ICF - Subje...Imaging.pdf or URL

Description: Screening visit - Consent

Once attached click the Add button

Add Cancel

Subject Attachments Add

Document Type	File Name / URL	Description	Version Date	Created Date	Created User	Edit	Delete?
No Records Found.							

Once attached, Attachments will appear under the Attachments Tab. As many attachments as needed can be added and will appear under the tab. To Edit or Delete an attachment click the appropriate hyperlink/button. Attachments should be saved as .pdf documents for attachment.

Archive/Notes		Attachments						
Subject Attachments								Add
Document Type	File Name / URL	Description	Version Date	Created Date	Created User	Edit	Delete?	
Consent	<a href="#">ICF - Subject for PRO 22426 - Prostate Imaging.pdf</a>	Screening Visit - Consent	06/22/2015	06/22/2015	SAJOHNSON	<a href="#">Edit</a>	<input type="checkbox"/>	

# Subjects>CRA Console>Deviations Tab (Subject)

Subject deviations must be entered through the Subject console, as they are attached to a patient. Protocol Deviations are attached through the PC Console, usually by Regulator Staff.

Subject Deviation Create				
Date Discovered (MM/DD/YYYY)	12/16/2013	Date Discovered and Reported By are auto-entered, can be over written	Reported By	Sandra Johnson
★ Deviation Date* (MM/DD/YYYY)	Date error occurred or date missed	★ Category*	Type here to search	
★ Treating Physician	Select from pull-down	★ Date Reviewed by Treating Physician (MM/DD/YYYY)	Date of review	
★ Description of Deviation	4000 character(s) remaining			
★ Effect on Patient Safety	1000 character(s) remaining			
★ Action Taken	4000 character(s) remaining			
★ Did the deviation put the participant or others at increased risk and/or negatively affect the primary study aims?	<input type="checkbox"/>			
★ Report to IRB?	Select from pull-down	Date Reported to IRB (MM/DD/YYYY)	Leave blank if not know, reg staff can complete later	
Report to Sponsor?	<input type="checkbox"/>	Date Reported to Sponsor (MM/DD/YYYY)		
				<input type="button" value="Submit"/> <input type="button" value="Clear"/> <input type="button" value="Close"/>

# Subjects>CRA Console>SAE Tab

SAE's are to be reported after completing all necessary SAE reporting to sponsors/NCI, etc. Copy and paste information from the original report into the OnCore report. Answer as many fields as you can. Initial and Final reporting is all that is required, unless the study is an IIT.

Subject SAE Update: Status: Not Complete

★ Event Date* (MM/DD/YYYY)	<input type="text"/>	Event End Date (MM/DD/YYYY)	<input type="text"/>	★ Reported Date* (MM/DD/YYYY)	<input type="text"/>	Reported By	<input type="text"/>
Death Date	<input type="text"/>	Death Occurred	<input type="text"/>	Did the SAE occur at your site or at a site for which the PI is responsible? <input type="checkbox"/>			
Event Narrative							
Treating Physician Comments							
PI Comments							
★ Protocol Attribution	<input type="text"/>	★ Outcome*	Select from pull-down	Consent Form Change Required		<input type="checkbox"/>	
SAE Classifications <i>Multi-Select</i>							
Report to IRB? <input type="text"/>							

Toxicity (Required fields are only required when adding a toxicity.)

Course Start	<input type="text"/>	★ Category*	Use search tool	★ Toxicity*	Use search tool	★ Grade*	<input type="text"/>	<a href="#">Select Toxicity...</a>
★ Unexpected*	<input type="text"/>	DLT†	<input type="text"/>	Action	<input type="text"/>	Therapy	<input type="text"/>	
Comments								
3000 character(s) remaining								
Source				Attribution				
Investigational Tx				<input type="text"/>				
Non-Investigational Tx				<input type="text"/>				
Disease				<input type="text"/>				
Other				<input type="text"/>				

†DLT - Dose Limiting Toxicity

The Add button is to add Toxicities, it is not the save button. After entering each toxicity hit Add.

**Tracking Details**

Action	Action Date
DSMC Reviewed	<input type="text"/>
IRB Approved	<input type="text"/>
Notified Disease Team Lead	<input type="text"/>
Notified FDA	<input type="text"/>
Notified IRB	<input type="text"/>
Notified PI	<input type="text"/>
Notified Sponsor	<input type="text"/>
Team Reviewed	<input type="text"/>

Enter as much information as is known and hit Submit to save the SAE.

**Additional SAE Identifiers**

Identifier Type*	Identifier*	Identifier Owner	
<input type="text"/>	<input type="text"/>	<input type="text"/>	<a href="#">Add</a> <a href="#">Cancel</a>
No information entered			

To find SAE, Subjects> CRA Console>select Protocol and Subject>SAE. A list of all SAE's for the subject will appear. Click Event No hyperlink to go back into the SAE.

SAE Details Filter:  Page 1 of 1

Event No.	Event Date	Follow-Up No.	Arm Code	Hospitalization	Death Occurred (days)	Additional Identifiers	Toxicity   Grade   Attribution	Delete?
<a href="#" style="border: 2px solid red; border-radius: 50%; padding: 2px;">2440</a>	12/16/2013			N				<a href="#">Delete</a>

When entering a follow-up (final) SAE click Create Follow-Up button. If updating the original report click Update. SAE Report can be printed out to put into subject chart or to send to IRB.

SAE Details

RTF  [Subject SAE](#)

SAE Report