•
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •
 •

Creating a Study Webpage on the RESEARCH STUDIES WEBSITE

Clinical Research Recruitment Program

Last Updated April 2025





Clinical Research Recruitment Program

UNIVERSITY OF COLORADO ANSCHUTZ MEDICAL CAMPUS



GETTING STARTED MENU

Please use the below shortcuts to skip to the sections of the instructions that apply to you.

Each slide will have a rin the upper lefthand corner that will allow you to navigate back to this slide.

WHAT IS THE CU ANSCHUTZ RESEARCH STUDIES WEBSITE?

A little background

HOW TO USE ONCORE TO CREATE A STUDY WEBPAGE?

It can be little confusing

HOW TO USE THE RESEARCH ADMIN TOOL?

To customize your OnCore study webpage

HOW TO USE THE RESEARCH ADMIN TOOL?

To create a Non-OnCore study webpage

REVIEW AND APPROVAL PROCESS

A second pair of eyes is always a plus





WHAT IS THE CU ANSCHUTZ RESEARCH STUDIES WEBSITE?



A LITTLE BACKGROUND

Tuniversity of Colorado Anschutz Medical Campus

Home Find a Research Study What is Clinical Research How to Join a Study About CU Anschutz For Research Teams



Already know what you're looking for?

Find a study by keyword, condition, or topic Q

Research helps many people including you, your loved ones and many others. By joining a study, you can help to advance new scientific discoveries that benefit all people. Whether you are healthy or have a health condition, your participation makes a difference.

By joining a study, you may:

Participate in Research at

CU Anschutz

BE A PART OF TOMORROW'S BREAKTHROUGHS

- Get compensated for your time
- Access new treatments and medicines
- Learn vital data about your health
- · Support research that improves lives



- The CU Anshutz Research Studies Website was created in 2020 and is managed by the Clinical Research Recruitment Program.
- The main goal is to share open clinical research studies on a public facing website for anyone from the community to see, search for, and contact research teams if interested.
- Research teams are responsible for maintaining their study webpages, and ensuring information is accurate and understandable.



Clinical Research Recruitment Program OFFICE OF THE VICE CHANCELLOR FOR RESEARCH UNIVERSITY OF COLORADO ANSCHUTZ MEDICAL CAMPUS



IT'S ALL IN THE NUMBERS









LANGUAGE REQUIREMENTS

Having a study webpage that is understandable and informative to the community we serve is the most important aspect of creating a public-facing website for your study because it increases trust and participation in clinical research.

Language Requirements

- Your study webpage must be at or close to an 8th grade reading level.
- The content of your study webpage must use **plain language**, which is designed to be understood quickly and easily by the reader.
- This means that you should not use medical jargon, complex scientific words, or any abbreviations.

Plain Language Resources

- Plain Language Section of University of Buffalo Recruitment Resources Toolkit
- Plain Language in Clinical Research by Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard
- University of Michigan Plain Language Medical
 Dictionary
- Plain Language Guide by the JRP Working Group for Equitable Research
- Make It Clear: The Use of Lay Language in Research Recruitment by North Carolina Translational and <u>Clinical Science Institute</u>





HOW TO USE ONCORE TO CREATE A STUDY WEBPAGE?

Did you know that there are **two places** in OnCore that need to be updated for your study to have a study webpage on the CU Anschutz Research Studies Website?



PC Console > Main > Details: "Exclude Protocol on Web"



SIP Console > Select Configure Tab > Display Protocol?



OPT OUT OF THE CU RESEARCH STUDIES WEBSITE: PC CONSOLE

-

PC Console > Main > Details: "Exclude Protocol on Web"

 If you do not want your study to be on the CU Research Studies Website, this box should be checked.

Navigate to the PC Console.

2

3

Click the 'update' button on the right-hand side of the screen.

Make sure the box next to 'Exclude Protocol on Web' is checked. After you click the 'update' button again, 'Yes' will appear next to 'Exclude Protocol on Web'.

Clinical Research Recruitment Program OFFICE OF THE VICE CHANCELLOR FOR RESEARCH UNIVERSITY OF COLORADO ANSCHUTZ MEDICAL CAMPUS

1 A A A							100	A.S		1 A A A	
PC Console											1
rotocol No.: X18-9999	/ 🗋 1	Lib	rary: Health Affair	5			PI: Barna	ard, Deborah		Sponsor	r: Abbvi
rotocol Target Accrua	d: 100				Accru/	al To Datr	e: 16		Protoco'	I Status: OPEN TO AC	CCRUA
C Total Accrual Goal ((Upper): 1	100		_						IRB Expiration: 05	5/21/202 [°]
Select Protocol X18-9999	De	stails Manageme	ent Staff Spc	onsor		linicalTria	ls.gov				
	Prot	locol Details								Hi	istory
Main >		Protocol No	λ X18-9999					NCT Number	NCT0000001		
Correlates &	»	Library	y Health Affairs					Department	CTR-WebbWaring	9	
Companions		Organizational Unit	It Health Affairs								
freatment	»	Title	This is a testing r	protocol-2	2						
		Short Title	This is a short titl	<i>i</i> e							
nstitution		Objectives	3 1. Test the System	wi				1			
Accrual		Phase	Feasibility		Scope	Local		Age	Both 3	Consent at Age on Wajonty	Yes
Status	<u></u>	Drug Accountability	/ Yes	Invest	tigator Initiated Protoco	, Yes		Involves Therapy	Yes	Exclude Protocol on Web	Yes
	- Or	pen For Affiliates Only	y No	Summar	ry Accrual Info. Only	No		Protocol Type	Treatment		_
(eviews ,	<u>'</u>	Registration Center	Research Center	Involve	s Correlates or Companion	s Yes		Data Monitoring	External	Adjuvant	Yes
Documents/Info	<u> </u>	Includes Specimen Banking'	1 Yes	Con	mpanion Study	? No	j	Multi-site Trial	Yes	Investigational Drug	, Yes
Eligibility		Precision Tria	al Yes		Precision Tria' Classificatio	Umbre'	/la	Pilot		Investigational Device	i No
Protocol Calendar		Rare Disease	e	(Certificate(s) o' Confidentialit	1	j				
Notifications			·								
	-1	Acr	crual Information								
Deviations			Protocol Target	t Accrual	100	RC Tot	al Accrual Goal (Lo	Jwer) 1 RC Tr	stal Accrual Goal (Upp	Jer) 100	
New Protocol	7		RC Annual Accr	ual Goal	15		Affiliate Accrual of	Goal A/	ccrual Duration (Montr	ns) 60	
Specimen Collection	»		1	Completion	n Dates						
Configuration			Ļ	P	Primary Comple	stion Date	08/17/2023 (Anti	.ticipated)			
					Study Comple	tion Date				-	
										2	
											pdate
_	-			_	-		_	_	_	Lock Pre	otoco
											-

OPT OUT OF THE CU RESEARCH STUDIES WEBSITE: SIP CONSOLE

SIP Console > Select Configure Tab > Display Protocol?

• If you do not want your study to be on the CU Research Studies Website, select 'No' from the dropdown menu.



OPT IN OF THE CU RESEARCH STUDIES WEBSITE: PC CONSOLE

PC Console > Main > Details: "Exclude OnCo Protocol on Web"

 If you want your study to be on the CU Research Studies Website, this box should be unchecked.

Navigate to the PC Console

Click the 'update' button on the right-hand side of the screen.

2

3

Make sure the box next to 'Exclude Protocol on Web' is unchecked. After you click the 'update' button again, 'No' will appear next to 'Exclude Protocol on Web'.

Oncore.	1	by Advarra enu		C Console of	P Console	specific	cations	CRA	Console Financ	ciais	Console					
★ PC Console					1					÷						
Protocol No.: X18-9999	[<u>1</u>	Library	y: Health Affai	rs				I	PI:					Sponso	: Abb
Protocol Target Accrua	I: 10	0				Acc	crual T	o Date	e: 20			Proto	col Sta	atus: OPI	EN TO A	CCRU
RC Total Accrual Goal ((Upp	oer): 100											П	RB Expir	ation: 0	5/21/20
	_															
Select Protocol	n I	Details Manage	ement	Staff Staff	onsor	IND/IDE	Clini	calTria	ls.gov							
X18-9999		Protocol Details													H	eton
Main y	»	Protocol	No X	12-0000							NCT Number	NCT0000001				story
		Fiolocoi	narv H	Health Affairs							Department	CTR-WebbWar	ina			
Correlates &) Companions	»	Organizational	Unit H	Health Affairs							2007					
Treatment	-		Title T	This is a testing	protocol-2	2										
) (inclusion in the second sec	»	Short	Short Title This is a short title													
Institution		Object	tives 1	1. Test the Syst	em!											
A	-	Ph	nase F	Feasibility		Sc	cope L	.ocal			Age	Both		Consent	at Age of Majority	Ves
Accrual	4	Drug Accountal	bility Y	Yes	Inve	stigator Initia Prote	iated tocol	(es			Involves Therapy	Yes	3)(Exclude Pr	rotocol on Web	No
Status)	»	Open For Affiliates (Only N	No	Summary Accrual Info. Only No		Protocol Type Treatment									
Reviews)	»	Registration Ce	enter F	Research Center	Involves Correlates or Companions Yes				Data Monitoring	External	Adjuva		Adjuvant	Yes		
Documents/Info	»	Includes Speci Bank	men ing?	Yes	Companion Study? No			Multi-site Trial		Yes	Investigational E		onal Drug	Yes		
Eligibility		Precision	Trial Y	Yes	Precision Trial Classification Umbrella			Pilot		In	vestigation	al Device	No			
Protocol Calendar		Rare Dise	ease			Certificate(s Confidenti	(s) of tiality				Pragmatic Trial					
Notifications		Exclude Prot From Analy	ytics	No												
Deviations			0	-1 lefe tie												
	-		Accrua	Protocol Tara	et Accrual	100		DC To	tal Accrual Goal (Los	wor)	1 PCT	otal Accrual Goal /I	Inner)	100		
New Protocol				RC Annual Ac	crual Goal	15		RO IO	Affiliate Accrual C	Goal		Accrual Duration (M	onths)	60		
Specimen Collection	»												,			
Configuration					Completio	n Dates										
					I	Primary Cor	mpletion	n Date	08/17/2023 (Anti	icipat	ted)					
						Study Cor	mpletion	n Date						_		
														6		
														4	U	pdate
														l	_ock Pr	otocol
					Δ			<u>k</u> @ 20	025 Advarra Inc							
									520 Mavarra, 116.		~				100	

Clinical Research Recruitment Program office of the vice chancellor for research UNIVERSITY OF COLORADO ANSCHUTZ MEDICAL CAMPUS

OPT IN OF THE CU RESEARCH STUDIES WEBSITE: SIP CONSOLE

SIP Console > Select Configure Tab > Display Protocol?

• If you want your study to be on the CU Research Studies Website, select 'Yes' from the dropdown menu.







If you opt-in to have a study webpage on the CU Anschutz Research Studies Website, you need to complete the following fields:

- Title
- Objective
- Primary Contact
- Description
- Eligibility (Detailed or Key, not both)







Title: PC Console > Main > Details > Title

Note: You can change the 'Short Title' to be something more lay person friendly and then select this to be displayed as the title for your study webpage by selecting it from the 'Display Title' dropdown menu in the SIP Console.

- Primary Contact: PC Console > Main > Staff
- Objective: SIP Console > Configure Button > Display Protocol? > Select 'Yes' from dropdown menu > Objective

Note: If you check the box next to 'Use Default Objective?' then the information from the objective field from the PC Console > Main > Details > Objective will override any information entered in the Objective field in the SIP Console.

- **Description:** SIP Console > Description
- Eligibility: SIP Console > Detailed Eligibility or Key Eligibility

Note: You can use either option but please only enter the eligibility criteria in one location otherwise it will duplicate the information on the website.

OnCore_ By Advarra Menu = PC Console SIP Console Specifications CRA Console Financials Console

1.00																
* PC Cor	sole															?
Protocol No.	X18-999	9	1	L	ibrary: Healt	th Affairs			PI: Ba	rnard, [Debor	ah			Sponsor	: Abbvi
rotocol Tar	et Accru	al: 1	00				A	Accrual	To Date: 16				Protocol	Status: O	PEN TO AC	CRUA
C Total Acc	ual Goa	l (Up	per): 100											IRB Exp	iration: 05	/21/202:
		_														
Select Protocol	1		Details	Manage	ement Staf	ff Sponsor	IND/IDE	E Cli	nicalTrials.gov							
×10-3355		<u> </u>	Protocol Details									History				
lain		»		Protocol	No. X18-999	99						NCT Number	NCT0000001			
Correlates &		»		Lib	rary Health A	lealth Affairs						Department	CTR-WebbWaring			
Companions			Organi	zational	Unit Health A	fairs										
reatment		,,		1	Title Does Ea	ating a Protein Ri	ch Diet d	during th	e 3rd Trimester Help	with Ge	statio	nal Diabetes?				
		_		Short 1	Fitle This is a	short title										
nstitution				Objecti	ves 1. lest t	ne systemi		_						Conse	nt at Age of	
Accrual				Ph	ase Feasibili	ity		Scope	Local			Age	Both	001100	Majority	Yes
Status			Drug A	ccountab	ility Yes	Inve	Investigator Initiated Protocol Yes				Involves Therapy		Yes Exclude Protocol on Web		Yes	
lata s		»	Open For A	Affiliates C	Only No	Summ	Summary Accrual Info. Only No				Protocol Type Treatment					
Reviews		»	Registr	ration Cer	nter Researd Center	h Involv	Involves Correlates or Companions			Data Monitoring		External	Adjuvant		Yes	
Documents/Info	io	»	Include	es Specir Banki	nen ng? Yes	Co	mpanion	Study?	No			Multi-site Trial	Yes	Investiga	tional Drug	Yes
Eligibility			P	recision 1	Trial Yes		Precisio	on Trial fication	Umbrella			Pilot		Investigatio	onal Device	No
Protocol Calen	ıdar		F	Rare Dise	ase		Certificat Confide	te(s) of entiality								
lotifications																
		_			Accrual Inform	ation										
Deviations					Proto	ocol Target Accrual	100		RC Total Accrual Goa	(Lower)	1	RC To	otal Accrual Goal (Upp	er) 100		
lew Protocol					RC Ar	nual Accrual Goal	15		Affiliate Acc	ual Goal		A	ccrual Duration (Month	s) 60		
Specimen Colle	ection					Completio	on Dates									
Configuration	conon	»					Primary (Completi	on Date 08/17/2023	Anticipa	ated)					
							Study (Completi	on Date							
															U	odate
															Lock Pro	tocol

ADVARRA © 2024 Advarra,

Clinical Research Recruitment Program OFFICE OF THE VICE CHANCELLOR FOR RESEARCH UNIVERSITY OF COLORADO ANSCHUTZ MEDICAL CAMPUS

- **Title:** PC Console > Main > Details > Title
 - **Note:** You can change the 'Short Title' to be something more lay person friendly and then select this to be displayed as the title for your study webpage by selecting it from the 'Display Title' dropdown menu in the SIP Console.
- **Primary Contact:** PC Console > Main > Staff
- Objective: SIP Console > Configure Button > Display Protocol? > Select 'Yes' from dropdown menu > Objective

Note: If you check the box next to 'Use Default Objective?' then the information from the objective field from the PC Console > Main > Details > Objective will override any information entered in the Objective field in the SIP Console.

- **Description:** SIP Console > Description
- Eligibility: SIP Console > Detailed Eligibility or Key Eligibility

Note: You can use either option but please only enter the eligibility criteria in one location otherwise it will duplicate the information on the website.

Protocol Target Accruai '20' Accrual To Date: '2' Protocol Xext: OPENTOACCRUAI RC Total Accruai Goal (Upper): '10' IRE Explainton: \$67:1202. IRE Explainton: \$67:1202. Select Protocol Select Configuration The sub of the select for the sel	Protocol No.: X18-9999	Libra	ry: Health Affairs	PI:		Sponsor	: Abbvie			
RC total Accurate Goal (Upper): 103 Short Title: This is a short title Select Protocol Select	Protocol Target Accrual: 100		.,	Accrual To Date: 19	Protocol Sta	tus: OPEN TO A	CCRUAI			
Select Protocol Select Select Protocol Select Select Protocol Select	RC Total Accrual Goal (Upper): 100	n			11010001 014	B Expiration: 05	21/2023			
Select Protocol Select Protocol Select Protocol Select Protocol Select Protocol Select Protocol Select Select Protocol Select Select Protocol Select	Short Title: This is a short title				Config	uration Status: C	omnlete			
Select Protocol Parking Protocol Parking Protocol Parking Protocol Protocol Protocol Protocol Protocol	short fille. This is a short the				comp	anation status. C	ompiete			
Display Title Title Protocor? Yes Display Title This study wants to see if vomen with gestational diabetes eat a protein-rich diet during their third Display Title Objective This study wants to see if vomen with gestational diabetes eat a protein-rich diet during their third Operation 3839 character(s) remaining Operation Operation Operation Treatment 1024 character(s) remaining Operation Operation This study wants to understand how diet can help pregnant women with gestational diabetes. If you join by the put not one of two groups. The first group will eat a diet that is high in protein. The second group will eat their normal diet. Display Onugs? Display Onugs?<	Select Protocol	SIP Configurati	on							
This study wants to see if women with gestational diabetes eat a protein-rich diet during their thid Stort Title Objective This study wants to see if women with gestational diabetes eat a protein-rich diet during their thid Stort Title 3539 character(s) remaining Override cancer Override cancer Override cancer Treatment 1024 character(s) remaining Override cancer Control? This study wants to understand how diet can help pregnant women with gestational diabetes. If you join this study you will be put into one of two groups. The first group will eat a diet that is high in protein. The second group will eat their normal diet. Diaplay Drugs? Diaplay Drugs? <td></td> <td>Display Protocol?</td> <td>Yes 🗸</td> <td>D</td> <td>Display Title</td> <td>Title 🗸</td> <td>]</td>		Display Protocol?	Yes 🗸	D	Display Title	Title 🗸]			
Objective This study wants to see if women with gestational diabetes eat a protein-rich diet during their third trimester have befter blood sugar control and weight gain. Short Title Opplation T 3339 character(s) remaining Override Cancer Override Cancer The atoment This study wants to understand how diet can help pregnant women with gestational diabetes. If you join this study, you will be put into one of two groups. The first group will eat a diet that is high in protein. The second group will eat their normal diet. Description Vou will have up to 8 visits depending on when you have your baby. The visits will be every other week until you deliver. You will have one visit after you have your baby when your baby is between 1 to 3 months old. Description At each visit, your blood sugar, height and weight, and waist circumference will be measured. You will full or S240 if you complete all visits. Display Drugs? Display Drugs? 3259 character(s) remaining 3259 character(s) remaining Display Drugs? Display Drugs? 3259 character(s) remaining 3259 character(s) remaining Display Drugs? Display Drugs? 3259 character(s) remaining 3259 character(s) remaining Display Drugs? Display Drugs? 3259 character(s) remaining Stort the second timester (between 14-27 weeks pestational diabetes. Stort the second timester (between 14-27 weeks pestational diabetes. Belability 4000 character(s) rem	v	Filase				Title				
339 character(s) remaining Override Cancer Treatment 1024 character(s) remaining This study wants to understand how diet can help pregnant women with gestational diabetes. If you join his study, you will be put into one of two groups. The first group will eat a diet that is high in protein. The second group will eat their normal diet. Vou will have up to 3 visits depending on when you have your baby. The visits will be every other week until you deliver. You will have one visit after you have your baby when your baby is between 1 to 3 months old. Description At each visit, your blood sugar, height and weight, and waist circumference will be measured. You will first will take about 60-90 minutes each. You will get \$30 after each visit, for a logially "The apies?" 2559 character(s) remaining Aduit women aged 18-35 years old who are pregnant, in their second trimester (between 14-27 weeks gestation), and have gestational diabetes. 4000 character(s) remaining Mouter study is remaining Detailed Image: Study is a state is one of the overrides defined Bisease / Diagnosis Override No overrides defined Protocol Attachments Select		Objective	This study wants to see trimester have better bl	Short Title						
Treatment Override Cancer Override Cancer Override Cancer 1024 character(s) remaining This study wants to understand how diet can help pregnant women with gestational diabetes. If you join this study you will be put into one of two groups. The first group will eat a diet that is high in protein. The second group will eat their normal diet. Insplay you will be put into one of two groups. The first group will eat a diet that is high in protein. The second group will eat their normal diet. Description Vou will have up to 8 visits depending on when you have your baby. The visits will be every other week until you divier. You will put its will have about 60-90 minutes each. You will get \$30 after each visit, for a total of \$240 if you complete all visits. Display Drugs? D			3839 character(s) remainin	ng		0.0,00010.				
1024 character(s) remaining It is study wants to understand how diet can help pregnant women with gestational diabetes. If you join this study, you will be put into one of two groups. The first group will eat a diet that is high in protein. The second group will eat their normal diet. Description Vou will have one visit after you have your baby. The visits will be every other week until you deliver. You will have one visit after you have your baby when your baby is between 1 to 3 months old. Description At each visit, your blood sugar, height and weight, and waist circumference will be measured. You will filt out several surveys. The visits will take about 60-90 minutes each. You will get \$30 after each visit, for a total of \$240 if you complete all visits. 3259 character(s) remaining It is addut women aged 18-35 years old who are pregnant, in their second trimester (between 14-27 weeks gestational diabetes. Key Eligibility Addut women aged 18-35 years old who are pregnant, in their second trimester (between 14-27 weeks gestational diabetes. Belaided It is a diabeter(s) remaining Descase / Diagnosis Override No overrides defined Protocol Attachments Select		Treatment				Override Cancer Control?				
This study wants to understand how diet can help pregnant women with gestational diabetes. If you join this study, you will be put by those or you groups. The first group will eat a diet that is high in protein. The second group will eat a diet that is high and weight, and waist circumference will be measured. You will find units each visit, for a total of \$20 diverses. The visits will take about 60-90 minutes each. You will get \$30 after each visit, for a getation, and have gestational diabetes. 2259 character(s) remaining Adult women aged 18-35 years old who are pregnant, in their second trimester (between 14-27 weeks gestation), and have gestational diabetes. Select 4000 character(s) remaining No overrides defined			1024 character(s) remainin	ng		~				
You will have up to 8 visits depending on when you have your baby. The visits will be every other week until you deliver. You will have one visit after you have your baby when your baby is between 1 to 3 months old. Display Drugs?			This study wants to und this study, you will be p second group will eat th	derstand how diet can help pregnant wor ut into one of two groups. The first group heir normal diet.	men with gestational diabetes. If you join o will eat a diet that is high in protein. The	•				
Description At each visit, your blood sugar, height and weight, and waist circumference will be measured. You will fill out several surveys. The visits will take about 60-90 minutes each. You will get \$30 after each visit, for a total of \$240 if you complete all visits. Display Therapies? 3259 character(s) remaining Adult women aged 18-35 years old who are pregnant, in their second trimester (between 14-27 weeks gestation), and have gestational diabetes. Select Very Eligibility 3859 character(s) remaining Detailed Select Potocol Attachments No overrides defined Select Protocol Attachments No Records Found. Select			You will have up to 8 vi until you deliver. You wi months old.	sits depending on when you have your b ill have one visit after you have your bab	baby. The visits will be every other week by when your baby is between 1 to 3	Display Drugs?				
3259 character(s) remaining Adult women aged 18-35 years old who are pregnant, in their second trimester (between 14-27 weeks gestational diabetes. 3859 character(s) remaining Detailed Eligibility 4000 character(s) remaining Disease / Diagnosis Override No overrides defined Select Protocol Attachments No Records Found. Select		Description	At each visit, your bloo out several surveys. Th total of \$240 if you com	d sugar, height and weight, and waist cirr ne visits will take about 60-90 minutes ea plete all visits.	cumference will be measured. You will fil ich. You will get \$30 after each visit, for a	Display Therapies?				
3259 character(s) remaining Adult women aged 18-35 years old who are pregnant, in their second trimester (between 14-27 weeks gestation), and have gestational diabetes. 3859 character(s) remaining Detailed Eligibility 4000 character(s) remaining Disease / Diagnosis Override No overrides defined Select Protocol Attachments No Records Found. Select Undo Complete Submit						4				
Key Eligibility gestation), and have gestational diabetes. 3859 character(s) remaining Detailed Eligibility 4000 character(s) remaining Disease / Diagnosis Override No overrides defined Select Protocol Attachments No Records Found. Select Undo Complete Select			Adult women aged 18-	ng 35 years old who are pregnant in their sy	econd trimester (between 14-27 weeks	7				
3859 character(s) remaining Detailed Eligibility 4000 character(s) remaining Disease / Diagnosis Override No overrides defined Select Protocol Attachments No Records Found. Select Lindo Complete Submit Clear Close		Key Eligibility	gestation), and have ge	estational diabetes.						
Detailed Eligibility 4000 character(s) remaining Disease / Diagnosis Override No overrides defined Select Protocol Attachments No Records Found. Select			3859 character(s) remainin	ng						
Eligibility 4000 character(s) remaining Disease / Diagnosis Override No overrides defined Select Protocol Attachments No Records Found. Select Undo Complete Submit Clear Close		Detailed				7				
Disease / Diagnosis Override No overrides defined Select Protocol Attachments No Records Found. Select Lindo Complete Submit Clear Close		Eligibility	4000 abarratar(a) as mainin			4				
No overrides defined Select Protocol Attachments No Records Found. Select Lindo Complete Submit Clear Close		Disease / Diagr	nosis Override	I9						
Protocol Attachments No Records Found. Select Lindo Complete Submit Clear Close				No overrides de	fined					
Protocol Attachments No Records Found. Select Undo Complete Submit Clear Close										
Protocol Attachments No Records Found. Select						S	elect			
No Records Found. Select Undo Complete Submit Clear Close		Protocol Attach	ments							
Select			No Records Found.							
Undo Complete Submit Clear Close						S	elect			
					Undo Complete Submit	Clear	Close			



• Title: PC Console > Main > Details > Title

Note: You can change the 'Short Title' to be something more lay person friendly and then select this to be displayed as the title for your study webpage by selecting it from the 'Display Title' dropdown menu in the SIP Console.

Primary Contact: PC Console > Main > Staff

 Objective: SIP Console > Configure Button > Display Protocol? > Select 'Yes' from dropdown menu > Objective

Note: If you check the box next to 'Use Default Objective?' then the information from the objective field from the PC Console > Main > Details > Objective will override any information entered in the Objective field in the SIP Console.

- **Description:** SIP Console > Description
- Eligibility: SIP Console > Detailed Eligibility or Key Eligibility

Note: You can use either option but please only enter the eligibility criteria in one location otherwise it will duplicate the information on the website.

OnCore_ By Advarra Menu = PC Console SIP Console Specifications CRA Console Financials Console

★ PC Console							?
Protocol No.: X18-9999	1 Library: Health Affairs		PI:	Barnard, Deborah		S	ponsor: Abbvie
Protocol Target Accrual:	100	Accrual	To Date: 16			Protocol Status: OPE	TO ACCRUAL
RC Total Accrual Goal (Up	pper): 100					IRB Expirat	ion: 05/21/2023
	1						
Select Protocol	Details Management Staff Spon	sor IND/IDE Clin	icalTrials.gov				
¥18.9999	Protocol Staff						
Main »			V	iew Staff Organization	Access 🗌 🛛 H	Hide Affiliates 🗹 🛛 Activ	e Staff Only 🔽
Correlates &	Role	Last Name	A First Name	Middle Name	Organization		Select
Companions "	Principal Investigator	Barnard	Deborah	initial riterite	Colorado Resea	rch Center	
Treatment »	Other	Graemick	Zachany		Colorado Resea	rch Center	
1	Other	Macri	Marieea		Colorado Resea	rch Center	
Institution	Clinical Decearch Manager	Naughton	Niek		Colorado Resea	rch Center	
Accrual		Davah	Inch		Colorado Resea		
Status	Project Analyst	Peugn	Jeremian		Colorado Resea	rch Center	0
	Primary Contact	Vander Vvyst	Kiley		Colorado Resea	rch Center	
Reviews »							
Documents/Info »						View Attachments	Update
Eligibility							
Protocol Calendar							
Notifications							
Deviations							
New Protocol							
Specimen Collection » Configuration	1						
						Lo	ck Protocol
		A ADVARR	∆ © 2024 Advarra,	, Inc.			



• **Title:** PC Console > Main > Details > Title

Note: You can change the 'Short Title' to be something more lay person friendly and then select this to be displayed as the title for your study webpage by selecting it from the 'Display Title' dropdown menu in the SIP Console.

Primary Contact: PC Console > Main > Staff

Objective: SIP Console > Configure Button > Display Protocol? > Select 'Yes' from dropdown menu > Objective

Note: If you check the box next to 'Use Default Objective?' then the information from the objective field from the PC Console > Main > Details > Objective will override any information entered in the Objective field in the SIP Console.

- **Description:** SIP Console > Description
- Eligibility: SIP Console > Detailed Eligibility or Key Eligibility

Note: You can use either option but please only enter the eligibility criteria in one location otherwise it will duplicate the information on the website.

OnCore. By Adva	rra <mark>Menu</mark> ≡	PC Console SIP Console Specifications CRA Console Financials Console		
Protocol No.: X18-9999	Libra	ry: Health Affairs PI:	Sponsor:	Abbvie
Protocol Target Accrual: 100		Accrual To Date: 19 Protocol Statu	IS: OPEN TO ACC	RUAL
RC Total Accrual Goal (Upper): 10	0	IRE	Expiration: 05/2	1/2023
Short Title: This is a short title		Configu	ation Status: Co	mplete
	_	-		
Select Protocol	SIP Configuration	on		
	Display Protocol?	Yes 🗸 Display Title	Title 🗸	
*	Phase	✓	Title	
	Objective	This study wants to see if women with gestational diabetes eat a protein-rich diet during their third trimester have better blood sugar control and weight gain.	Short Title	
		3839 character(s) remaining	Objective :	
	Treatment		Override Cancer Control?	
		1024 character(s) remaining		
		This study wants to understand how diet can help pregnant women with gestational diabetes. If you join this study, you will be put into one of two groups. The first group will eat a diet that is high in protein. The second group will eat their normal diet.		
		You will have up to 8 visits depending on when you have your baby. The visits will be every other week until you deliver. You will have one visit after you have your baby when your baby is between 1 to 3 months old.	Display Drugs?	
-	Description	At each visit, your blood sugar, height and weight, and waist circumference will be measured. You will fill out several surveys. The visits will take about 60-90 minutes each. You will get \$30 after each visit, for a total of \$240 if you complete all visits.	Display Therapies?	
		2250 character/e) remaining		
	Key Eligibility	Adult women aged 18-35 years old who are pregnant, in their second trimester (between 14-27 weeks gestation), and have gestational diabetes.		
		3859 character(s) remaining		
	Detailed			
	Eligibility	4000 character(s) remaining		
	Disease / Diagr	nosis Override		
		No overrides defined		
			Se	lect
	Protocol Attach	ments		
		No Records Found.	Se	lect
			36	
		Undo Complete Submit	Clear Cl	ose
		A ADVARRA' © 2025 Advarra, Inc.		



• Title: PC Console > Main > Details > Title

Note: You can change the 'Short Title' to be something more lay person friendly and then select this to be displayed as the title for your study webpage by selecting it from the 'Display Title' dropdown menu in the SIP Console.

- Primary Contact: PC Console > Main > Staff
- Objective: SIP Console > Configure Button > Display Protocol? > Select 'Yes' from dropdown menu > Objective

Note: If you check the box next to 'Use Default Objective?' then the information from the objective field from the PC Console > Main > Details > Objective will override any information entered in the Objective field in the SIP Console.



Description: SIP Console > Description

 Eligibility: SIP Console > Detailed Eligibility or Key Eligibility

Note: You can use either option but please only enter the eligibility criteria in one location otherwise it will duplicate the information on the website.

otocol No.: X18-9999		Libra	ry: Health Affairs		PI:		Sponsor	: Abbvie
otocol Target Accrual: 100				Accrual To Date: 19		Protocol Stat	tus: OPEN TO AC	CRUAL
Total Accrual Goal (Upper): 10	D				IR	B Expiration: 05	/21/2023
ort Title: This is a short title	е					Configu	uration Status: C	omplete
		SIP Configuration	on					
lect Protocol	_	Display	Yes 🗸		Display Title		Title 🗸]
	*	Protocol? Phase					Title	í
		Objective	This study wants to se trimester have better b	This study wants to see if women with gestational diabetes eat a protein-rich diet during their third trimester have better blood sugar control and weight gain.				
			3839 character(s) remaini	ng			D Objective :	_
		Treatment					Override Cancer	
			1024 character(s) remaini	ng				
		Description	This study wants to un this study, you will be r second group will eat t You will have up to 8 v until you deliver. You w months old. At each visit, your bloo out several surveys. Ti total of \$240 if you con	derstand how diet can help pregnant out into one of two groups. The first gr heir normal diet. isits depending on when you have you vill have one visit after you have your l have one visit after you have your l d sugar, height and weight, and waist he visits will take about 60-90 minutes nplete all visits.	women with gestational roup will eat a diet that i ur baby. The visits will b baby when your baby is baby when your baby is t circumference will be r s each. You will get \$30	I diabetes. If you join s high in protein. The be every other week between 1 to 3 measured. You will fill after each visit, for a	Eisplay Drugs? Eisplay Therapies?	
			3259 character(s) remaini	ng			2	
		Key Eligibility	Aduit women aged 18- gestation), and have g	35 years old who are pregnant, in the estational diabetes.	ir second trimester (bet	ween 14-27 weeks		
			3859 character(s) remaini	ng			2	
•		Detailed Eligibility						
		Englishity	4000 character(s) remaini	ng			_	
		Disease / Diagr	iosis Override	No ovorridos	defined			
				No overnues	denneu		_	
							S	elect
		Protocol Attach	ments					
				No Records	Found.		_	
							S	elect
					Undo Comple	Submit	Clear	Close



• Title: PC Console > Main > Details > Title

Note: You can change the 'Short Title' to be something more lay person friendly and then select this to be displayed as the title for your study webpage by selecting it from the 'Display Title' dropdown menu in the SIP Console.

- Primary Contact: PC Console > Main > Staff
- Objective: SIP Console > Configure Button > Display Protocol? > Select 'Yes' from dropdown menu > Objective

Note: If you check the box next to 'Use Default Objective?' then the information from the objective field from the PC Console > Main > Details > Objective will override any information entered in the Objective field in the SIP Console.

• **Description:** SIP Console > Description

Eligibility: SIP Console > Detailed Eligibility or Key Eligibility

Note: You can use either option but please only enter the eligibility criteria in one location otherwise it will duplicate the information on the website.

Protocol No.: X18-9999	Libra	ry: Health Affairs		PI:		Spon	sor: A	bbv
Protocol Target Accrual: 100			Accrual To Date: 19		Protocol State	us: OPEN TO	ACC	RU/
RC Total Accrual Goal (Upper): 10	0				IRE	B Expiration:	05/21	/20
Short Title: This is a short title					Configu	ration Status	: Com	ipl
	_				_			_
Select Protocol	SIP Configurat	on						
	Protocol?	Yes 🗸		Display Title		Title	~	
¥	Phase	~				Title		
	Objective	This study wants to see if w trimester have better blood	Short Title					
		3839 character(s) remaining				,		
	Treatment					Override Car	cer	٢
		1024 character(s) remaining			//) Control?		
		This study wants to underst this study, you will be put int second group will eat their n	and how diet can help pregnar to one of two groups. The first normal diet.	nt women with gestational d group will eat a diet that is l	iabetes. If you join high in protein. The			
	Description	You will have up to 8 visits of until you deliver. You will hav months old.	depending on when you have y ve one visit after you have you	your baby. The visits will be Ir baby when your baby is b	every other week etween 1 to 3	Display Drug	s?	٢
	Description	At each visit, your blood sug out several surveys. The vis total of \$240 if you complete	gar, height and weight, and wa its will take about 60-90 minut e all visits.	ist circumference will be me es each. You will get \$30 af	asured. You will fill ter each visit, for a	Display Therapies?		C
		3259 character(s) remaining						
	Key Eligibility	Adult women aged 18-35 ye gestation), and have gestati	ears old who are pregnant, in ti ional diabetes.	heir second trimester (betw	een 14-27 weeks			
		3859 character(s) remaining				,		
	Detailed							
	Eligibility	4000 character(s) remaining			//	,		
	Disease / Diag	nosis Override						
			No overrid	es defined				
							Sele	ect
	Protocol Attach	ments						
			No Record	ds Found.				
							Sele	ect
				Undo Complete	e Submit	Clear	Clo	se
				Ondo Oompiete	2 Oubline	orcui	010	٦

Clinical Research Recruitment Program OFFICE OF THE VICE CHANCELLOR FOR RESEARCH UNIVERSITY OF COLORADO ANSCHUTZ MEDICAL CAMPUS



Flowchart: PC Console > Main > Management

The flowchart is how you assign the different categories to your study.

The abbreviated category name will appear as **tags** as part of the study preview on the 'Find a Research Study' webpage.

CBD for Individuals with Mild Cognitive Impairment and at Risk for Alzheimer's Disease

Our study is seeking individuals aged 55-85, who have been diagnosed with Mild Cognitive Impairment (MCI) and are at risk for Alzheimer's Disease. The goal of the study is to see whether cannabidiol (CBD) can improve MCI symptoms.

Mental Health	٠	Brain
Adult		

The full category name will appear at the bottom of the study webpage.

Categories

Brain and Nervous System

Behaviors and Mental Health



Clinical Research Recruitment Program OFFICE OF THE VICE CHANCELLOR FOR RESEARCH UNIVERSITY OF COLORADO ANSCHUTZ MEDICAL CAMPUS

	OnCore.	E	y Advarra Menu	■ PC Console SI	P Console Specific	cations CRA Console	e Financials Conso	le						
< (1			10-	.7		S Car			() all				
: PC	Console									?				
otoc	l No.: X18-9999)	1	Library: Health Affai	rs		PI:			Sponsor: Abbvie				
otoc	l Target Accrua	al: 10	0		Ace	crual To Date: 20			Protocol Status: C	PEN TO ACCRUAL				
C Tot	l Accrual Goal	(Upp	er): 100						IRB Ex	piration: 05/21/2023				
elect I	rotocol		Details Manag	ement Staff Sp	onsor IND/IDE	ClinicalTrials.gov								
A10-3			Management Details History											
ain		»	IRB No.	20189999	Pharmacy No.		Priority Score							
orrela	es &		PRMS/SARC No.	18-xx	PRMS/SARC		DSMC Review							
ompa	ions	″	CTDC Dedicination	Vac			CTRC Approval		CTDC Catagory					
eatm	nt	»	CTRC Participation	res	CTRC NO.		Date		CTRC Calegory					
otitut			Comments											
Sutur		_	Cadina Sahama	CTCAE v4.0	Occurrente MDN	Ontional	Automated	No	Use					
ссгиа			Coding Scheme	CTCAE V4.0	Generate MRN Optional		Sequence No.	NO	Algorithm					
tatus		»	Internal Account No.	630xxxxxx	Hospital Account No.		Allow Duplicate Enrollment?	Yes						
		-	Allow On Treatr	nent date to be entered	No	Populate On Fo	llow-Up Date with Off	No						
eview		»		before On Study date			Treatment Date							
ocum	nts/Info	»	Administrative Group	s										
igibili					Management Group									
Igibii	y	_			Med-InfectDisease	(Primary)								
rotoco	l Calendar				Anesthesiology	(
otifica	tions													
		-h												
eviati	ns		Flowchart											
ew Pr	otocol	1	Flowchart		Path									
pecim	en Collection	»	Cancer Care		/Cancer Care/Blade	der Cancer/Urothelial	Cancer							
onfigu	iration													
										Update				
										Lock Protocol				
										Look Trotocol				
					A ADV	ARRA © 2025 Advar	ra, Inc.							



HOW TO USE THE RESEARCH ADMIN TOOL TO CUSTOMIZE AN ONCORE STUDY WEBPAGE

RESEARCH ADMIN TOOL: ACCESS



Use your University credentials to log into the website.

If you are not the Primary Contact for the study in OnCore then no studies will appear in the 'OnCore Studies' dropdown menu.

If you have not been added as the study editor for a study that has already been customized, then it will not appear under 'Customized Studies' list.

🔁 Uı	niversity of	Colorado Anschutz Medic	al Campus			Webmail	UCD Acces	s Can	vas Sign Out
Rese	earch St	udies Admin							
HOME	FOCUS STU	JDIES PARTICIPANT SCREENING	PARTICIPANT DATA						
Rese	earch St	udies							
On Selec webs	Core Stu ct an OnCore s site or add an e lect OnCore Si	dies study to customize for the Research editor to customize a study.	n Studies	Non-(Add a No Studies the	OnCore St on-OnCore St hat are NOT	Studies udy to the Rese in OnCore.	earch Studies	website	e. Only add
Cu Custo Filter	omized S	y Add Editor							
Custo Filter	omized S	y Add Editor tudies	11	Updated	Expires 1	SIP Deleted⊺↓			
Custo Filter	omized S Protoco # 23-1505	y Add Editor tudies Study Title Giving Standardized Estradiol Th Women to Research Interactions GET IT RIgHT Study View on Research Stur	t↓ erapy in Transgender with HIV Therapy: the dies website	Updated 8/22/2024	Expires †↓	SIP Deleted	2	ß	•
Custo Filter	Protoco #: 23-1505	y Add Editor tudies Study Title Giving Standardized Estradiol Th Women to Research Interactions GET IT RIgHT Study View on Research Stur AWARE Study	tl erapy in Transgender with HIV Therapy: the dies website	Updated 8/22/2024 4/21/2025	Expires 1	SIP Deleted	 ••••••••••••••••••••••••••••••••••••	ď	• •
Custo Filter	Protocol #1 23-1505 24-2018 24-1867	y Add Editor tudies Study Title Giving Standardized Estradiol Th Women to Research Interactions GET IT RIgHT Study View on Research Stur AWARE Study The Media, Alcohol, Technology, (MATCH) Project	ثل erapy in Transgender with HIV Therapy: the dies website Couples, and Health	Updated ↑↓ 8/22/2024 4/21/2025 4/21/2025	Expires the	SIP Deleted 4/16/2025	* 0 * 0	C C	
Custo Filter 11	Protocol # 23-1505 24-2018 24-1867 23-2327	y Add Editor tudies Study Title Giving Standardized Estradiol Th Women to Research Interactions GET IT RIgHT Study View on Research Stur AWARE Study The Media, Alcohol, Technology, (MATCH) Project Pregnant Women Needed for a C Supplements View on Research Stur	TJ erapy in Transgender with HIV Therapy: the dies website Couples, and Health Clinical Trial of Choline dies website	Updated : 8/22/2024 4/21/2025 4/21/2025 4/16/2025	Expires î↓	SIP Deleted	 ▲ ● ●	8	



RESEARCH ADMIN TOOL: CUSTOMIZING AN ONCORE STUDY

Once you find the study that you wish to customize, select it from the dropdown menu, it will now appear as the selected study.

Click the 'Customize Study' button.

Research Studies Admin

 HOME
 FOCUS STUDIES
 PARTICIPANT SCREENING
 PARTICIPANT DATA

Non-OnCore Studies

Studies that are NOT in OnCore.

OnCore Studies

Select an OnCore study to customize for the Research Studies website or add an editor to customize a study.

Add Editor

Tuniversity of Colorado Anschutz Medical Campus

22-1372: Menstrual profiles and cardiovascular disease risk amo 🗢

IMPORTANT

Customize Study

Only studies that you are listed as the **Primary Contact** in OnCore will appear in this dropdown menu.

If you are not listed as the Primary Contact in OnCore, then you will need to reach out to that person and have them add you as an Editor using the Research Admin Tool.

Add Non-OnCore Study

Add a Non-OnCore Study to the Research Studies website. Only add

Webmail | UCD Access | Canvas | Sign Out

Read the Instructions section before you start to make any customizations to your study webpage. It is important that you use plain language and that the content of your study webpage is at or close to an 8th grade reading level.

If you need any help with this, please reach out to the Clinical Research Recruitment Team at <u>ResearchStudies@cuanschutz.edu</u>

COMIRB does not review or approve the content on this website. This is the responsibility of the Clinical Research Recruitment Program. Please review Section 13.9.2 of the COMIRB's Policy and Procedure document.

Instructions

This tool allows you to customize a study webpage that uses OnCore. The sections in this tool make it easy for you to create or customize your study webpage.

All content on the CU Anschutz Research Studies website needs to use plain language and be at or close to an 8th grade reading level. The language of your study webpage should be in second person. For example, instead of saying "Participants in this study will be put into one of two groups". It should read, "You will be put into one of two groups".

The Clinical Research Recruitment Program will help revise your content to ensure it meets the necessary language requirements. There are several required sections. These sections are indicated by an asterisk. If you have any questions or need help using this tool, please research out to the Clinical Research Recruitment Team at researchstudies@cuanschutz.edu.

IRB APPROVAL FOR RECRUITMENT ON PUBLIC-FACING WEBSITE

The CU Anschutz Research Studies website is a form of recruiting human participants to clinical research studies. You should work with your study's Institutional Review Board (IRB) of Record to see if they require review and approval of your study webpage content.

COMIRB does not review or approve the content on this website. This is the responsibility of the Clinical Research Recruitment Program. Please review Section 13.9.2 of COMIRB Policies and Procedures document.





RESEARCH ADMIN TOOL: CUSTOMIZING AN ONCORE STUDY

- Your **study title** does not need to match your IRB-approved study title. This is because the IRB-approved study title is lengthy, complex, and not easily understood by the general population.
- Your **primary objective** is not the primary objective from your protocol or grant, but instead a clear and concise **1-2 sentence statement** of the main purpose of your study. This will appear directly under your study title in the study preview box on the 'Find a Research Study' page and on the individual study webpage.

Title and Objective

TITLE (REQUIRED)

We do not recommend using the IRB approved title because that title usually is very complex and uses scientific jargon. The public will not understand this title. For studies with lengthy titles, it is acceptable and appropriate to revise the title. We recommend revision of titles, so they provide useful information for the public. This includes information about the population of interest, the outcomes of interest, and the disease or condition being studied.

Study Comparing Lifestyle Changes Alone vs. Lifestyle Changes with Metformin for Men with Prostate Cancer to Improve Metabolism

PRIMARY OBJECTIVE (REQUIRED)

Text from the [SIP Configuration Console: Objective] field in OnCore will be displayed unless new text is entered below. This text will appear underneath the title both in the study preview on the 'Find a Research Study' page and on the individual study webpage. It will not be labeled as a separate section. This section must be less than two sentences. If your primary objective is more than two sentences it will be cut off in the study preview. This is not a primary objective from your protocol or grant but instead 1-2 sentences about who you are recruiting, why you are doing the studying, and what you are studying.

This study looks at whether men with prostate cancer improve their metabolism more with lifestyle changes alone or with lifestyle changes plus metformin.

It is important that you use plain language for your title and to summarize the primary objective of the study. You should not use complex scientific language, abbreviations, or medical jargon. Please see the plain language resources provided on <u>slide 6</u> or the plain language resource document provided on the CU Anschutz Research Website.





Describe why your study is important, such as additional background information about the disease, population, or treatment.



Use this section to separate out the lengthy details about the study and include information about what the person will need to do if they join the study. *This section is only available in the Research Admin Tool.*

It is important that you use plain language to describe your study. You should not use complex scientific language, abbreviations, or medical jargon. Please see the plain language resources provided on slide 6.

Why this Research Matters (required)

Text from the [SIP Console: Description] field in OnCore will be displayed unless new text is entered below. This section can provide more information about why the study is important such as background about the disease or condition being studied, information about the drug or treatment under investigation, and details about whether participants will be randomized or not.

We are inviting men with prostate cancer at UCHealth and in the Prostate Cancer Consortium to join a study of how to care for men with prostate cancer who are at risk for metabolic problems. To join this study, you must be an UCHealth patient and use MyHealthConnection.

What to Expect (required)

This section is only available if you use the Research Admin Tool to customize your study webpage. This section should have information about what the person will need to do if they join the study. This may include number, type, and frequency of study visits; what the individual will need to do at the study visits; what the person will need to do in between the study visits; and any other information that you feel is important.

To join this study, you must first agree to be part of the Prostate Cancer Consortium. This is a patient registry, which is a list of people who have prostate cancer. A patient registry is a place where health data is gathered and stored for research. Being in the registry means you agree to let researchers review your health records and use your data for research without extra doctor visits. You also agree to be contacted about future research studies. The patient registry and any future studies will use information and tools already available in your medical record for the study. These studies are called electronic medical record embedded studies.



Clinical Research Recruitment Program OFFICE OF THE VICE CHANCELLOR FOR RESEARCH UNIVERSITY OF COLORADO ANSCHUTZ MEDICAL CAMPUS

RESEARCH ADMIN TOOL: CUSTOMIZING AN ONCORE STUDY

Clearly state the study duration. You also can use this section to let people know the number, type, and frequency of study visits. *This section is only available in the Research Admin Tool.* Study Duration (required)

This section is only available if you use the Research Admin Tool to customize your study webpage. This section should have information about the total duration of the study. You also can include total duration of the study visits, and number, type, and frequency of study visits here instead of in the section above.

10 years

This section should be used for your inclusion and exclusion criteria. You should not list all your eligibility criteria but instead an abbreviated list of the most important inclusion criteria. The Research Admin Tool allows you to use font enhancements that are not available in OnCore.

It is important that you use plain language to for your inclusion criteria. You should not use complex scientific language, abbreviations, or medical jargon. Please see the plain language resources provided on <u>slide 6</u>.

Who can Participate (required)	
GE	
Adult	

Text from the [SIP Console: Detailed Eligibility] OR [SIP Console: Key Eligibility] will be displayed, unless new text is entered below. Please note if you entered the study eligibility criteria in both places in the SIP Console it will be duplicated on your study webpage. Please only enter your eligibility criteria in one place.

The Research Admin Tool allows you to use font enhancements in this section, including creating a bullet or number list or bolding or underlining font. This allows the eligibility criteria to be more easily understood by the public. This section should not include your entire inclusion/exclusion criteria list but instead an abbreviated version. If you have an extensive list, you can add a sentence such as "Additional criteria will be checked by a doctor or study staff at your first visit".

$B I \underline{U} \times_{a} \times^{a} \underline{I}_{x} | \Omega | \stackrel{\text{\tiny def}}{=} \stackrel{\text{\tiny def}}{=} \frac{1}{2} | \stackrel{\text{\scriptstyle def}}{=} \frac{1$

You may be able to join the study if you:

- Are 18 or older
- Have prostate cancer
- Get care from a UCHealth doctor
- Have a MyHealthConnection Account
- · Impaired glucose tolerance and/or overweight, and appropriate to receive metformin,
- · In the past year, you must have had at least one of these
 - An HbA1c level between 5.7% and 6.4%
 - BMI (Body Mass Index) of 25 or higher

More details about who can ioin are on clinicaltrials.gov. Your doctor or study team member will review the full requirements with you. Click the NCT



10

11

Clinical Research Recruitment Program office of the vice chancellor for research UNIVERSITY OF COLORADO ANSCHUTZ MEDICAL CAMPUS



13

14

RESEARCH ADMIN TOOL: CUSTOMIZING AN ONCORE STUDY

- 12 It is important to include the exact compensation amount that participants will receive, or state that no compensation will be provided. *This section is only available in the Research Admin Tool.*
 - The section is where you can list the PI's name and credentials and upload an alternative photo.
 - If the PI does not have a CUDoctors.com profile (this will be true of any investigator that is not a clinician) then using the Research Admin Tool to upload a professional photo is important.
 - This section can be used to upload a study flyer or other participant facing recruitment materials. *This section is only available in the Research Admin Tool.*

Compensation Information

COMPENSATION (REQUIRED)

Please provide the exact compensation amount that participants may earn. If they will only be compensated that amount if they complete all study visits, then say, "Earn up to \$800" or "Compensated up to \$500 if you complete all study visits". If there is no compensation provided, then please enter "No compensation provided". If you do not want to provide the exact compensation amount but there is compensation, then enter "You will be compensated for your participation". This field is required.

No compensation provided.

TRAVEL COMPENSATION



The Principal Investigator name, credentials, and photo will be pulled from CUDoctors.com based on email, or an alternate photo can be uploaded below. Please use only professional headshots.







RESEARCH ADMIN TOOL: CUSTOMIZING AN ONCORE STUDY

- 15
- It is important to select the correct categories as this is how people will find your study. The categories that you chose in the Flowchart of the Management tab in OnCore will automatically appear here, but you can change the categories if you want.
- 16 It is a great idea to provide the link to your study screener. Interested people will be redirected to the study screener after they complete the webform. *This section is only available in the Research Admin Tool.*
 - Here you have the option to include links to a variety of other websites. Please make sure that the website(s) are CU-affiliated. *This section is only available in the Research Admin Tool.*

Categories (required)

The categories listed in the [PC Console: Main > Management > Flowchart] section of OnCore will be displayed, unless they are revised below. Drag and drop categories to change order. Drag category out of list to delete.

Selec	t a Category	\$
۰	Cancer	0

Study Screener Link

Please provide a link to your study specific screener. This is usually a REDCap or Qualtrics survey or questionnaire. By providing this link, your potential participant will be redirected to complete your study screener after they complete the CU Anschutz Research Studies webform.

https://mychart.uchealth.org/MYCHART/Home/LogOut?postloginurl=fdire

Additional Fields Consider adding other helpful links, such as a Department website. If you add additional websites, please make sure that they are CU-affiliated.
FACEBOOK LINK
TWITTER LINK
ADDITIONAL LINK DESCRIPTION
Prostate Cancer Consortium Video ADDITIONAL LINK
https://vimeo.com/723103191/fd1c1bcb50



Review the information that you submitted and make sure that there are no spelling or grammar errors.

Additionally, make sure that you are using plain language, and information is at or below an 8^h grade reading level.

Check that all required sections, indicated by an asterisk, are completed.

If your study webpage is complete, then hit the submit button.

By submitting, I am attesting that the following are true:

- The content does not state or imply a certainty of favorable outcome or other benefits beyond what is in the consent document and protocol.
- · The content does not make claims, either explicitly or implicitly, that the investigational treatment is safe or effective.
- The content does not use terms such as "new treatment", "new medication", or "new drug", without explaining that the treatment offered is investigational.
- The content does not include an exculpatory language whereby the sponsor or investigator appears to waive subjects' rights to payment for research related injuries.
- · The content does not describe risks and benefits.
- · The content uses plain language and is at or close to an 8th grade reading level.

ADMINISTRATION COMMENTS

ADDITIONAL COMMENTS







HOW TO USE THE RESEARCH ADMIN TOOL TO CREATE A NON-ONCORE STUDY WEBPAGE

RESEARCH ADMIN TOOL: ACCESS



- Use your University credentials to log into the website.
- 3

If you are using this tool to create a study webpage for a study that is not in OnCore, then you will need to click the 'Add Non-Oncore Study' button.

se	arch St	udie	s Admin							
ME	FOCUS ST	UDIES	PARTICIPANT SCREENING	PARTICIPANT DATA						
se	arch St	udie	S							
n(Core Stu	dies			Non-0	OnCore S	Studies			
elec ebsi	t an OnCore ite or add an o	study to editor to	customize for the Research customize a study.	h Studies	Add a No Studies t	on-OnCore St hat are NOT	udy to the Rese in OnCore.	earch Studies	s website	e. Only ad
Seid	ect OnCore S	tudy			Add No	on-OnCore S	itudy			
Cus										
	stomize Stud	y A	Add Editor							
	stomize Stud	ly A	Add Editor							
	stomize Stud	ly A	Add Editor							
sto	omized S	studie	Add Editor							
sto	omized S	Studie	Add Editor							
stc r 11	omized S	Studie Study	Add Editor	11	Updated 1↓	Expires †↓	SIP Deleted†↓			
stc r îl	Protocol #12 23-1505	Studie Study Giving Wome GET IT	Add Editor 2S Title Standardized Estradiol Th n to Research Interactions I RIgHT Study View on Research Stud	tuerapy in Transgender with HIV Therapy: the dies website	Updated ↓ 8/22/2024	Expires ↑↓	SIP Deleted↑↓ 4/16/2025	ت ا	ď	
stc r î	Protocol #10 23-1505 24-2018	Studie Study Giving Wome GET IT AWAR	Add Editor 2S Title Standardized Estradiol Th n to Research Interactions T RIgHT Study View on Research Stur E Study	t erapy in Transgender with HIV Therapy: the dies website	Updated 8/22/2024 4/21/2025	Expires ↑↓	SIP Deleted 4/16/2025	* 0 * 0	ď	• 0
stc r	Protocol # 23-1505 24-2018 24-1867	Studie Study Giving Wome GET II AWAR The M (MATC	Add Editor 2S Title Standardized Estradiol Th n to Research Interactions I RIgHT Study View on Research Stud E Study edia, Alcohol, Technology, CH) Project	t↓ erapy in Transgender with HIV Therapy: the dies website Couples, and Health	Updated 8/22/2024 4/21/2025 4/21/2025	Expires 1	SIP Deleted 4/16/2025		8	
stc r	23-1505 24-2018 23-2327	Studie Study Giving Wome GET IT AWAR The M. (MATC Pregna Supple	Add Editor 2S Title Standardized Estradiol Th n to Research Interactions I RIgHT Study View on Research Stur E Study edia, Alcohol, Technology, CH) Project ant Women Needed for a C ements View on Research Stur	tuerapy in Transgender with HIV Therapy: the dies website Couples, and Health Dinical Trial of Choline dies website	Updated 8/22/2024 4/21/2025 4/21/2025 4/16/2025	Expires ↑↓	SIP Deleted↑↓ 4/16/2025	* 0 * 0 * 0	C C C	



Enter the study's COMIRB# and then click 'submit'.

If you are creating a separate study webpage for a healthy volunteer cohort, then use the same COMIRB# as the main study webpage but add an 'x' at the end.

🔁 Univ	Diversity of Colorado Anschutz Medical Campus						Webmail UCD Access Canvas Sign Out		
Resea	arch Studie	es Admin							
HOME	FOCUS STUDIES	PARTICIPANT SCREENING	PARTICIPANT DATA						
Add N	lon-OnCor	re Study Verify Proto	col Number						
		•	Submit	Cancel					



Read the Instructions section before you start to make any customizations to your study webpage. It is important that you use plain language and that the content of your study webpage is at or close to an 8th grade reading level. If you need any help with this, please reach out to the Clinical Research Recruitment Team at ResearchStudies@cuanschutz.edu

COMIRB does not review or approve the content on this website. This is the responsibility of the Clinical Research Recruitment Program. Please review Section 13.9.2 of the <u>COMIRB's Policy and</u> Procedure document.

Instructions

This tool allows you to customize a study webpage that uses OnCore. The sections in this tool make it easy for you to create or customize your study webpage.

All content on the CU Anschutz Research Studies website needs to use plain language and be at or close to an 8th grade reading level. The language of your study webpage should be in second person. For example, instead of saying "Participants in this study will be put into one of two groups". It should read, "You will be put into one of two groups".

The Clinical Research Recruitment Program will help revise your content to ensure it meets the necessary language requirements. There are several required sections. These sections are indicated by an asterisk. If you have any questions or need help using this tool, please research out to the Clinical Research Recruitment Team at researchstudies@cuanschutz.edu.

IRB APPROVAL FOR RECRUITMENT ON PUBLIC-FACING WEBSITE

The CU Anschutz Research Studies website is a form of recruiting human participants to clinical research studies. You should work with your study's Institutional Review Board (IRB) of Record to see if they require review and approval of your study webpage content.

COMIRB does not review or approve the content on this website. This is the responsibility of the Clinical Research Recruitment Program. Please review Section 13.9.2 of COMIRB Policies and Procedures document.





RESEARCH ADMIN TOOL: NON-ONCORE STUDY WEBPAGE

- Your **study title** does not need to match your IRB-approved study title. This is because the IRB-approved study title is lengthy, complex, and not easily understood by the general population.
- Your **primary objective** is not the primary objective from your protocol or grant, but instead a clear and concise **1-2 sentence statement** of the main purpose of your study. This will appear directly under your study title in the study preview box on the 'Find a Research Study' page and on the individual study webpage.

Title and Objective

TITLE (REQUIRED)

We do not recommend using the IRB approved title because that title usually is very complex and uses scientific jargon. The public will not understand this title. For studies with lengthy titles, it is acceptable and appropriate to revise the title. We recommend revision of titles, so they provide useful information for the public. This includes information about the population of interest, the outcomes of interest, and the disease or condition being studied.

Study Comparing Lifestyle Changes Alone vs. Lifestyle Changes with Metformin for Men with Prostate Cancer to Improve Metabolism

PRIMARY OBJECTIVE (REQUIRED)

Text from the [SIP Configuration Console: Objective] field in OnCore will be displayed unless new text is entered below. This text will appear underneath the title both in the study preview on the 'Find a Research Study' page and on the individual study webpage. It will not be labeled as a separate section. **This section must be less than two sentences**. If your primary objective is more than two sentences it will be cut off in the study preview. This is not a primary objective from your protocol or grant but instead 1-2 sentences about who you are recruiting, why you are doing the studying, and what you are studying.

This study looks at whether men with prostate cancer improve their metabolism more with lifestyle changes alone or with lifestyle changes plus metformin.

It is important that you use plain language for your title and to summarize the primary objective of the study. You should not use complex scientific language, abbreviations, or medical jargon. Please see the plain language resources provided on <u>slide 6</u> or the plain language resource document provided on the CU Anschutz Research Website.





information about the disease, population, or treatment.



Describe why this study is important, such as additional background

It is important that you use plain language to describe your study. You should not use complex scientific language, abbreviations, or medical jargon. Please see the plain language resources provided on slide 6.

Why this Research Matters (required)

Text from the [SIP Console: Description] field in OnCore will be displayed unless new text is entered below. This section can provide more information about why the study is important such as background about the disease or condition being studied, information about the drug or treatment under investigation, be randomized or not

We are inviting men with prostate cancer at UCHealth and in the Prostate Cancer Consortium to join a study of how to care for men with prostate cancer who are at risk for metabolic problems. To join this study, you must be an UCHealth patient and use MyHealthConnection

What to Expect (required)

This section is only available if you use the Research Admin Tool to customize your study webpage. This section should have information about what the person they join the study. This may include number, type, and frequency of study visits; what the individual will need to do at the study visits; what the person will need to do in between the study visits; and any other information that you feel is important.

To join this study, you must first agree to be part of the Prostate Cancer Consortium. This is a patient registry, which is a list of people who have prostate cancer. A patient registry is a place where health data is gathered and stored for research. Being in the registry means you agree to let researchers review your health records and use your data for research without extra doctor visits. You also agree to be contacted about future research studies. The patient registry and any future studies will use information and tools already available in your medical record for the study. These studies are called electronic medical record embedded studies



RESEARCH ADMIN TOOL: NON-ONCORE STUDY WEBPAGE

Clearly state the study duration. You also can use this section to let people know the number, type, and frequency of study visits. *This section is only available in the Research Admin Tool.* Study Duration (required)

This section is only available if you use the Research Admin Tool to customize your study webpage. This section should have information about the total duration of the study. You also can include total duration of the study visits, and number, type, and frequency of study visits here instead of in the section above.

10 years

This section should be used for your inclusion and exclusion criteria. You should not list all your eligibility criteria but instead an abbreviated list of the most important inclusion criteria. The Research Admin Tool allows you to use font enhancements that are not available in OnCore.

It is important that you use plain language for your inclusion criteria. You should not use complex scientific language, abbreviations, or medical jargon. Please see the plain language resources provided on <u>slide 6</u>.

Who can Participate (required	I)
AGE	
Adult	

Text from the [SIP Console: Detailed Eligibility] OR [SIP Console: Key Eligibility] will be displayed, unless new text is entered below. Please note if you entered the study eligibility criteria in both places in the SIP Console it will be duplicated on your study webpage. Please only enter your eligibility criteria in one place.

The Research Admin Tool allows you to use font enhancements in this section, including creating a bullet or number list or bolding or underlining font. This allows the eligibility criteria to be more easily understood by the public. This section should not include your entire inclusion/exclusion criteria list but instead an abbreviated version. If you have an extensive list, you can add a sentence such as "Additional criteria will be checked by a doctor or study staff at your first visit".

$\mathbf{B} \quad \underline{\mathbf{U}} \quad \mathbf{x}_{\mathbf{a}} \quad \mathbf{x}^{\mathbf{a}} \quad \underline{\mathbf{I}}_{\mathbf{x}} \mid \boldsymbol{\Omega} \mid \underline{\mathbf{a}} \equiv \quad \mathbf{z} \equiv \quad \mathbf{z} \equiv \quad \mathbf{y} = \quad \mathbf{y}$

You may be able to join the study if you:

- Are 18 or older
- Have prostate cancer
- Get care from a UCHealth doctor
- Have a MyHealthConnection Account
- · Impaired glucose tolerance and/or overweight, and appropriate to receive metformin
- · In the past year, you must have had at least one of these
 - An HbA1c level between 5.7% and 6.4%
 - BMI (Body Mass Index) of 25 or higher

More details about who can ioin are on clinicaltrials.cov. Your doctor or study team member will review the full requirements with you. Click the NCT



10

11



13

14

RESEARCH ADMIN TOOL: NON-ONCORE STUDY WEBPAGE

- 12 It is important to include the exact compensation amount that participants will receive, or state that no compensation will be provided. *This section is only available in the Research Admin Tool.*
 - The section is where you can list the PI's name and credentials and upload an alternative photo.
 - If the PI does not have a CUDoctors.com profile (this will be true of any investigator that is not a clinician) then using the Research Admin Tool to upload a professional photo is important.
 - This section can be used to upload a study flyer or other participant facing recruitment materials. *This section is only available in the Research Admin Tool.*

Compensation Information

COMPENSATION (REQUIRED)

Please provide the exact compensation amount that participants may earn. If they will only be compensated that amount if they complete all study visits, then say, "Earn up to \$800" or "Compensated up to \$500 if you complete all study visits". If there is no compensation provided, then please enter "No compensation provided". If you do not want to provide the exact compensation amount but there is compensation, then enter "You will be compensated for your participation". This field is required.

No compensation provided.

TRAVEL COMPENSATION



The Principal Investigator name, credentials, and photo will be pulled from CUDoctors.com based on email, or an alternate photo can be uploaded below. Please use only professional headshots.







RESEARCH ADMIN TOOL: NON-ONCORE STUDY WEBPAGE

15

17

- It is important to select the correct categories as this is how people will find your study. The categories that you chose in the Flowchart of the Management tab in OnCore will automatically appear here, but you can change the categories if you want.
- 16 It is a great idea to provide the link to your study screener. Interested participant will be redirected to the study screener after they complete the participant contact and demographic web form. *This section is only available in the Research Admin Tool.*
 - Here you have the option to include links to a variety of other websites. Please make sure that the website are CU-affiliated. *This section is only available in the Research Admin Tool.*

Categories (required)

The categories listed in the [PC Console: Main > Management > Flowchart] section of OnCore will be displayed, unless they are revised below. Drag and drop categories to change order. Drag category out of list to delete.

Selec	t a Category	\$
•	Cancer	0

Study Screener Link

Please provide a link to your study specific screener. This is usually a REDCap or Qualtrics survey or questionnaire. By providing this link, your potential participant will be redirected to complete your study screener after they complete the CU Anschutz Research Studies webform.

https://mychart.uchealth.org/MYCHART/Home/LogOut?postloginurl=fdire

→	Additional Fields	
	Consider adding other helpful links, such as a Department website. If you add additional v	websites, please make sure that they are CU-affiliated
	FACEBOOK LINK	
	TWITTER LINK	
	ADDITIONAL LINK DESCRIPTION	
	Prostate Cancer Consortium Video	
	ADDITIONAL LINK	

https://vimeo.com/723103191/fd1c1bcb50

Clinical Research Recruitment Program

Review the information that you submitted and make sure that there are no spelling or grammar errors.

Additionally, make sure that you are using plain language, and information is at or below an 8^h grade reading level.

Check that all required sections, indicated by an asterisk, are completed.

If your study webpage is complete, then hit the submit button.

By submitting, I am attesting that the following are true:

- The content does not state or imply a certainty of favorable outcome or other benefits beyond what is in the consent document and protocol.
- · The content does not make claims, either explicitly or implicitly, that the investigational treatment is safe or effective.
- The content does not use terms such as "new treatment", "new medication", or "new drug", without explaining that the treatment offered is investigational.
- The content does not include an exculpatory language whereby the sponsor or investigator appears to waive subjects' rights to payment for research related injuries.
- · The content does not describe risks and benefits.
- · The content uses plain language and is at or close to an 8th grade reading level.

ADMINISTRATION COMMENTS

ADDITIONAL COMMENTS







222

REVIEW AND APPROVAL PROCESS



The study webpage will be reviewed by the Clinical Research Recruitment Team.

During the review process we are evaluating your study webpage for the following criteria:

- ✓ All required sections are complete.
- ✓ There are no spelling and grammar mistakes.
- Complete sentences are used.
- The information is summarized using plain language and it is at or below the 8th grade reading level.
- All medical or study procedures are explained in a clear and understandable way.

Your study webpage will not be approved until all the requirements above are met.







THANK YOU





For more information, check out our website at research.cuanschutz.edu/cros/recruitment

The Clinical Research Recruitment Program is partially funded by the Colorado Clinical and Translational Sciences Institute (CCTSI) through NIH/NCATS grant UM1TR004399.



Clinical Research Recruitment Program OFFICE OF THE VICE CHANCELLOR FOR RESEARCH UNIVERSITY OF COLORADO ANSCHUTZ MEDICAL CAMPUS



Office of the Vice Chancellor for Research UNIVERSITY OF COLORADO DENVER | ANSCHUTZ MEDICAL CAMPUS



Colorado Clinical and Translational Sciences Institute (CCTSI)