ONCORE FIELD DEFINITIONS AND DATA HANDLING GUIDELINES

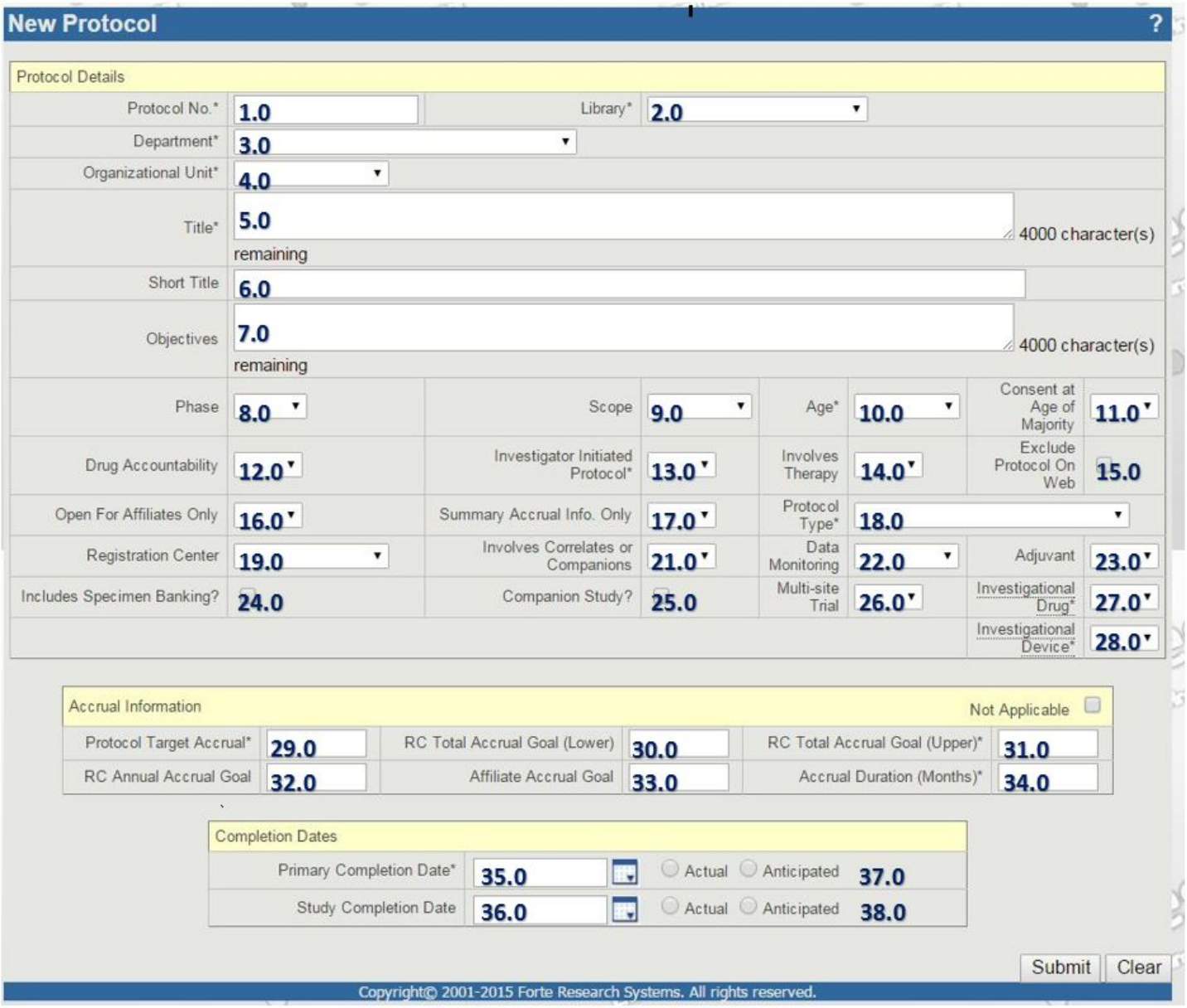
Abstract

This document defines the fields in OnCore and provides guidelines for best practices and standards.

Click on a field in the Table of Contents to go directly to the field definition. Alternatively, Click CTR-F to search for a particular field or word.

Contact Help-OnCore oncore@mcw.edu for questions.

Table of Contents



Note:

*Field with an * are required in OnCore. The New Protocol cannot be Saved (Submit) without completing these fields.*

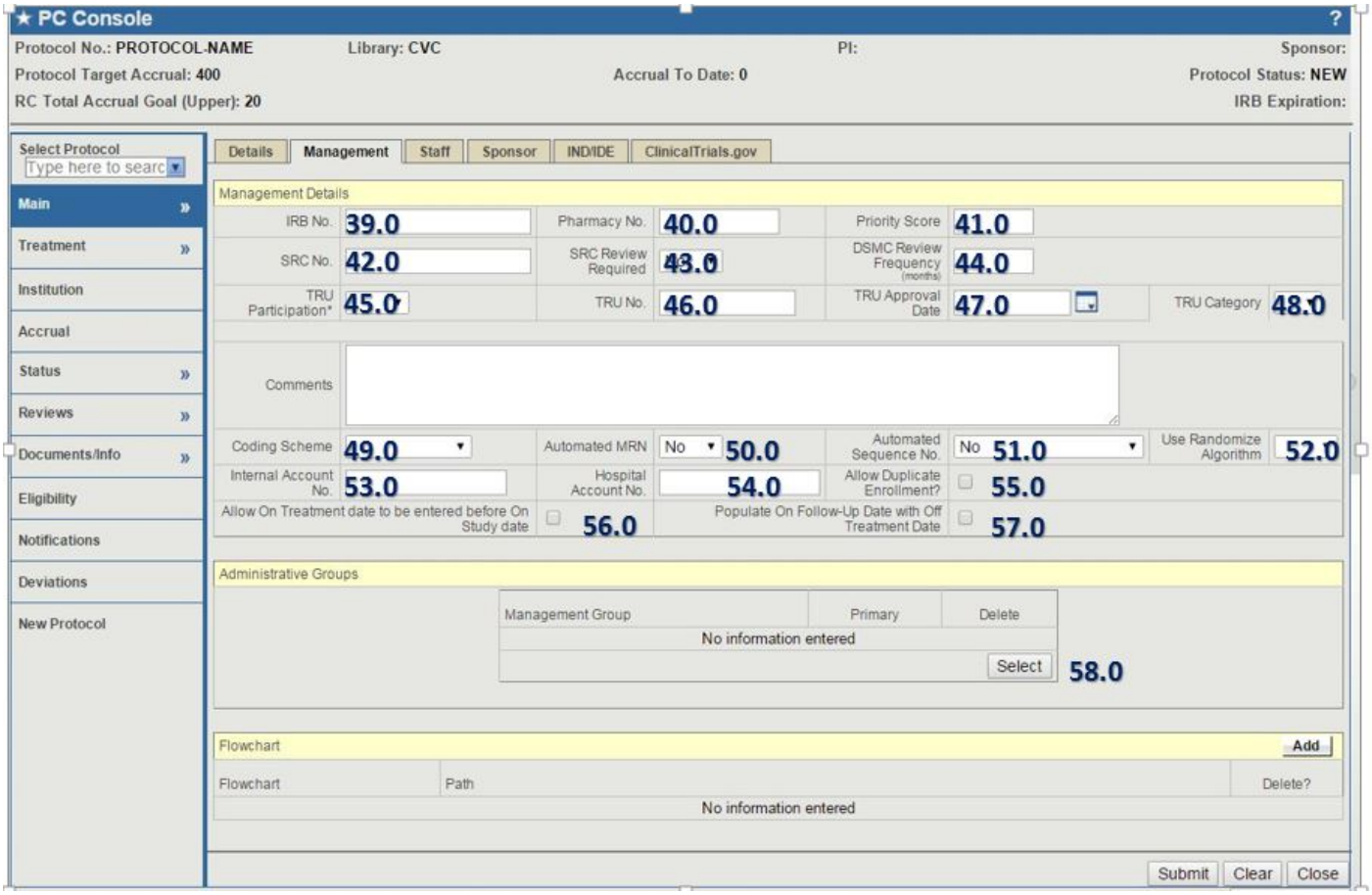
PC Console>Main>Protocol Details			
	Field	**Instruction**	**Comments**
1.0	Protocol No.	This field is the Protocol name. OnCore defaults to Capital Letters. Spaces are not acceptable so use hyphens. This is the field one usually uses to search for a protocol. The guideline below allows you to search by research group, PI, or a specific study. Enter a 2-5 Letter Prefix for the research group followed by: –PI LAST NAME-DESCRIPTOR (SHORT NAME, SPONSOR etc.) There is a 25-character limit so the PI's Last Name may be abbreviated if necessary.	Ex: Dr. Charles is a PI on the xyz101 study in Endocrinology. The Protocol No. would be: ENDO-CHARLESTON-XYZ101
2.0	Library	Select the appropriate Library to which the Protocol belongs. In general, libraries limit what you will see in drop-down lists in addition to the notifications, task list templates and forms which are available for use. NEVER select "Administrative Only"	Select the MCW General Library unless your research group has a designated library of their own.
3.0	Department	Select the appropriate Department and Division if applicable	
4.0	Organizational Unit	Select MCW for ALL non-cancer protocols.	
5.0	Title	This is the full-title	eBridge Q1.2.
6.0	Short Title	This is the short title	eBridge Q1.1
7.0	Objectives	List the Objectives from the Protocol and/or Clinical Trials.gov.	eBridge Q29.0
8.0	Phase	Select the appropriate phase: Drug Studies: I, I/II, II, II/III, III/IV, IV Device: Premarket approval (PMA), 510K Pilot, Feasibility N/A – Ex: Behavioral Interventions	
9.0	Scope	This indicates the Scope of Enrollment. Local = The trial is only open at MCW National = The trial is open at MCW + Other Institutions	
10.0	Age	Select the age of subject participants	

11.0	Consent at Age of Majority	If “Age” is listed as "Children" or "Both", a YES selection will automatically populate this field. OnCore will trigger a warning to reconsent subjects once they reach the age of 18. Select NO if you do not want OnCore to generate this reconsent message.	
12.0	Drug Accountability	Select 'Yes', 'No', or 'N/A' based on whether drugs are being used and recorded within the protocol in OnCore.	
13.0	Investigator-Initiated Protocol	Select “Yes” only if a MCW Investigator authored the protocol regardless of who the Sponsor is. Select No, for example, if this is an industry-sponsored trial or if MCW was issued a subcontract from another institution.	
14.0	Involves Therapy?	Select Yes/No based on the following definition: Therapy (Treatment) is defined here as any intervention for an illness, disorder, or unwanted behavior or condition and includes drug/devices, educational, psychosocial, or community interventions designed to make changes (eg knowledge, change attitudes) - Adapted from eBridge.	
15.0	Exclude Protocol on Web	If the Study Information Portal (SIP) is configured, checking this will exclude the protocol from displaying on the SIP	Always check this box UNTIL the SIP is configured for your research group
16.0	Open for Affiliates Only	Select NO unless the protocol is open ONLY at Affiliate sites in OnCore. Affiliates are defined as other institutions participating in the study excluding MCW or any of MCW’s study sites.	If the study is open only at CHW, select Yes. CHW is an affiliate
17.0	Summary Accrual Only	This field is marked as 'Yes' when only summary subject data will be collected for a protocol. Checking “Yes” disables the *CRA Console>New Subject Registration* page so individual subject information and milestones cannot be entered or tracked. Summary Accrual #s are included in the total if you run a report from the *Protocol>Protocol Search* page and are not differentiated from the total count. Summary Accruals #s are clearly noted and do not count towards the total accrual if you run the report from the *Reports>Accrual Monitoring* page.	Speak with your OnCore Administrator if you plan on reporting Summary Accrual Information Only

18.0	Protocol Type	Select Appropriate type based on the following definitions: **Treatment**: Also called "clinical trials, generally involves an intervention such as medication, psychotherapy, new devices, or new approaches to surgery or radiation therapy. **Diagnostic:** The practice of looking for better ways to identify a particular disorder or condition **Epidemiologic/Observational:** Identify the patterns, causes, and control of disorders in groups of people. **Genetic:** Aims to improve the prediction of disorders by identifying and understanding how genes and illnesses may be related. Research in this area may explore ways in which a person's genes make him or her more or less likely to develop a disorder. This may lead to development of tailor-made treatments based on a patient's genetic make-up. A gene-therapy trial would be classified as "Treatment", not Genetic **Prevention:** Looks for better ways to prevent disorders from developing or returning. Different kinds of prevention research may study medicines, vitamins, vaccines, minerals, or lifestyle changes. **Screening:** Aims to find the best ways to detect certain disorders or health conditions. **Supportive Care:** Also known as "Quality of Life," this research explores ways to improve comfort and the quality of life for individuals with a chronic illness	"Treatment" is the only protocol type with a Parent of Therapeutic. All other types have a Parent category of Non-therapeutic
19.0	Registration Center	Select N/A for Non-Cancer Protocols	
21.0	Involves Correlates or Companions	"Companion" indicates the patients may or must enroll in each study. EX: an Open-Label (separate protocol) phase for a drug trial "Correlative" indicates collect specimen information. EX: a related separate banking protocol Selecting YES causes the PC Console to display the *Correlates & Companions* tab below the *Main* tab on the left hand side so these types of studies can be related to the current protocol.	
22.0	Data Monitoring	Select the party responsible for monitoring the protocol data	
23.0	Adjuvant	Select 'Yes', 'No', or 'N/A' (e.g. device trials). An Adjuvant study drug is thought to enhance or otherwise affecting the impact of another drug	
24.0	Includes Specimen Banking?	Do NOT CHECK, even if the study involves banking or is a banking protocol. This is for MCW Bio-specimen Management only	
25.0	Companion Study	Check only if this protocol is the Companion/Open Label Study	

26.0	Multi-site Trial	Select YES if this is a Multi-Site Trial. If only MCW study sites are involved, select NO.	See 30.0 Comments for MCW Study Sites
27.0	Investigational Drug	Select 'Yes', 'No', or 'N/A'	
28.0	Investigational Device	Select 'Yes', 'No', or 'N/A'	
29.0	Protocol Target Accrual	Total planned accrual at ALL sites = MCW + Affiliates (if a multi-site trial).	
30.0	RC Total Accrual Goal (Lower)	RC (Research Center) = MCW + MCW study sites. Affiliates = Other institutions participating in the study EXCLUDING MCW or any of MCW's study sites. Enter the minimum side of the range for MCW total accrual. If there is no upper goal, enter the total MCW planned accrual in this field. The RC Total Accrual Goal (Lower) drives Accrual Reports.	MCW study sites ➢Froedtert Hospital ➢Community Memorial Hospital ➢St. Joseph's Hospital - West Bend ➢MCW Specialties Clinic - West Bend
31.0	RC Total Accrual Goal (Upper)	Enter the maximum side of the range for MCW total accrual. If there is no range, enter the Lower MCW Total Accrual Goal.	
32.0	RC Annual Accrual Goal	Enter the Annual Accrual Goal based on the Total Upper Accrual goal OR the Total Lower Accrual Goal if the Lower and Upper goals are the same.	
33.0	Affiliate Accrual Goal	Enter the estimated number of subjects that will accrue at the Affiliates running the protocol. This field should exclude MCW and MCW's study sites.	
34.0	Accrual Duration (Months)	The number of months of planned enrollment	
35.0	Primary Completion Date	The date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical trial concluded according to the pre-specified protocol or was terminated.	The date of the last subject, last visit. –CT.gov definition
36.0	Study Completion Date	The final date on which data was or is expected to be collected. This is date of the study's database lock at MCW. If this is a multi-site or Pharma study - the date of the Sponsor's database lock.	
37.0	Primary Date: Actual/Anticipated	Select Anticipated and specify the expected Primary completion date,	
38.0	Study Date: Actual/Anticipated	Select Anticipated and specify the expected Study completion date, updating the date as needed over the course of the study..	Update the Actual Date at the EOS

PC Console>Main>Management

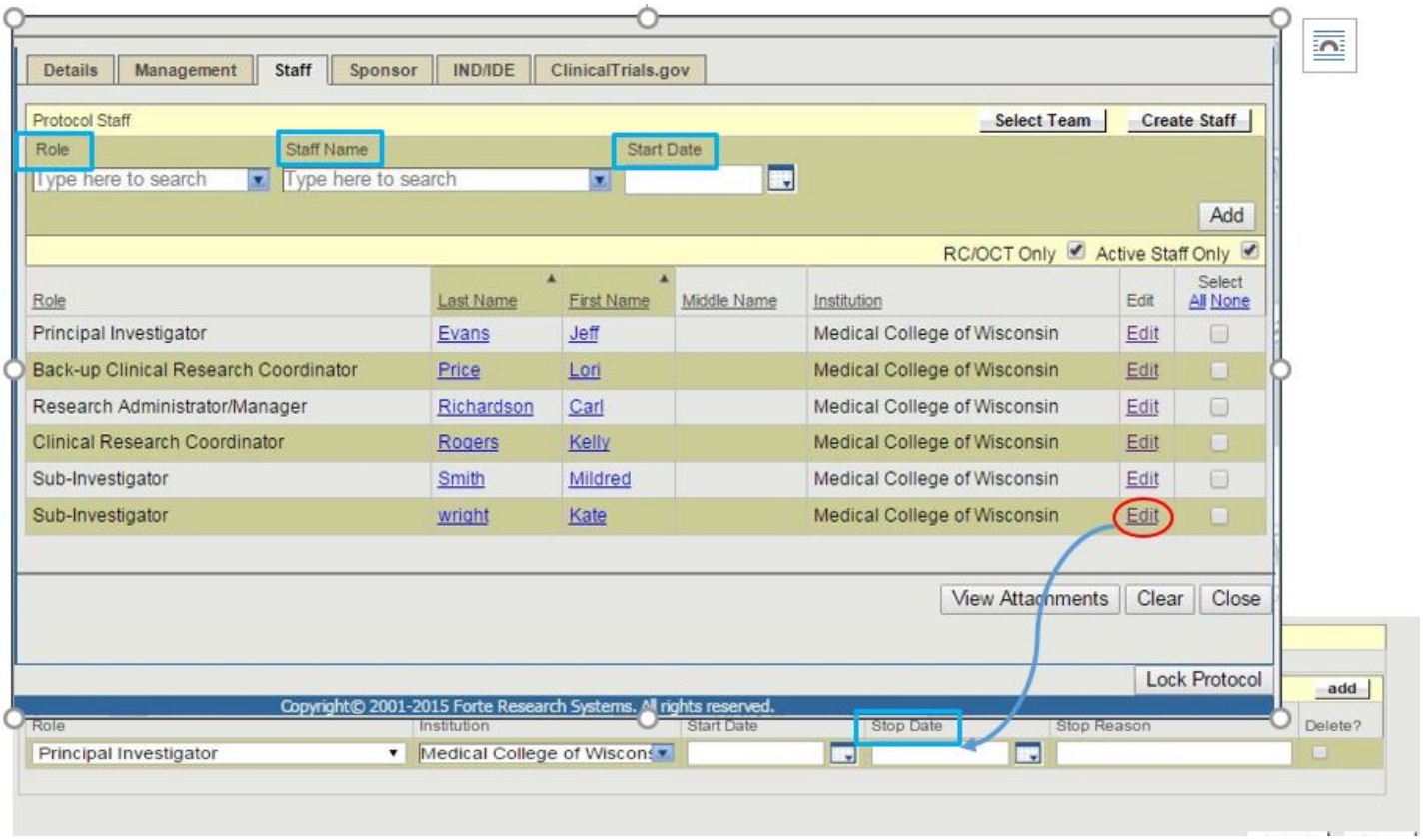


PC Console>Main>Management			
	Field	**Instruction**	**Comments**
39.0	IRB No.	Enter the PRO# exactly as it appears in e-Brdige. PRO000xxxx. This is the standard field data entry method which links e-Bridge, the CDRW and the CTSI database.	
40.0	Pharmacy No.	Enter the Pharmacy Number, if applicable, from the Pharmacy Agreement	
41.0	Priority Score	In general, leave this field blank. If a group, however, calculates a protocol acuity/complexity score, this field may be used to enter this number.	
42.0	SRC No.	Leave Blank.	

43.0	SRC Review	Select NO. Do not leave blank. If you cannot open your study to accrual, make sure "No" is selected. Speak to your OnCore administrator if the protocol WILL be reviewed by a formal SRC process and documented in OnCore	The default response is "YES". This must be changed to "NO" for a study to be Open to Accrual
44.0	DSMC Review	Leave Blank. If your group does have a formal DSMB, the DSMC Review field and configuration will be discussed during implementation.	
45.0	TRU Participation	Select "Yes" if the study will involve any TRU services.	
46.0	TRU No.	Enter the TRU Approval Number	
47.0	TRU Approval Date	Enter the TRU Approval Date	
48.0	TRU Category	If using TRU services, specify: Adult TRU (CTSI) Pediatric & Adolescent TRU (CTSI) Community TRU (CTSI) Zablocki VA Medical Center TRU Nicholas Family Foundation TRU (CC)	
49.0	Coding Scheme	Determines the option list used in Adverse Event (AE) and Serious Adverse Event (SAE) reporting. CTCAE v4.0 is a descriptive terminology which can be utilized for Adverse Event (AE) reporting and is curated by NCI. The Lowest Level Terms (LLTs) of CTCAE v4.0 and MedDRA are harmonized. If a Sponsor requires AEs be coded in terms of MedDRA, The LLTs in each system map to one another. If N/A is selected, the codes will not be available on a *Subject Console>SAEs>Adverse Event Detail*	For more information see: Mapping CTCAE v4 to MedDRA v12 NCI Wiki CTCAE FAQs List of Codes and Values from NCI
50.0	Automated MRN	Select NO, the default for this field. Subject Demographics are automatically pulled into OnCore from EPIC based on search criteria such as name or MRN.	
51.0	Automated Sequence No.	In most situations and for industry- sponsored research, select NO. Ex: for industry-sponsored trials the Sequence No. field in the *Subject Console > On Study* tab will be editable by the user. Select YES only for IIT protocols where OnCore is configured to automatically issue a Sequential Subject ID.	
52.0	Use Randomize Algorithm	Select No unless a randomization algorithm will be configured in OnCore for a protocol. Speak with your OnCore Administrator if a randomization algorithm is required	
53.0	Internal Account No.	Enter the 7-digit Oracle Account Number after it becomes available.	
54.0	Hospital Account No.	Not Applicable, leave blank	

55.0	Allow Duplicate Enrollment	Check only if patient can enroll in this protocol multiple times	
56.0	On Treatment date before On Study	When checked, a subject's On Treatment Date in the *Subject Console > Treatment* tab may be prior to the On Study Date listed in the *Subject Console > On Study* tab.	
57.0	Populate On FU with Off Treatment	When checked, the Follow-Up Start Date on the *Subject Console > Follow-Up* tab will automatically populate with the Off Treatment Date on the *Subject Console > Follow-Up* tab. The Follow-Up Start Date can be removed if needed	

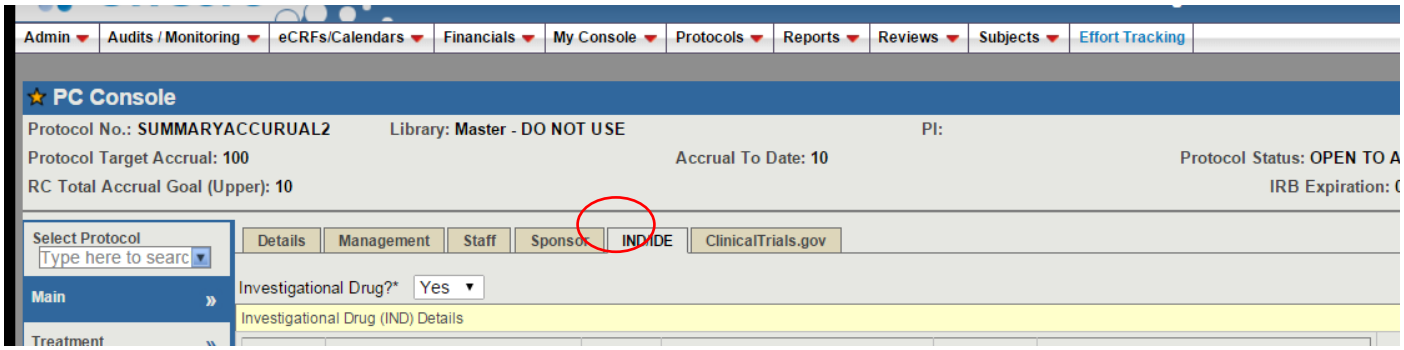
PC Console>Main>Staff



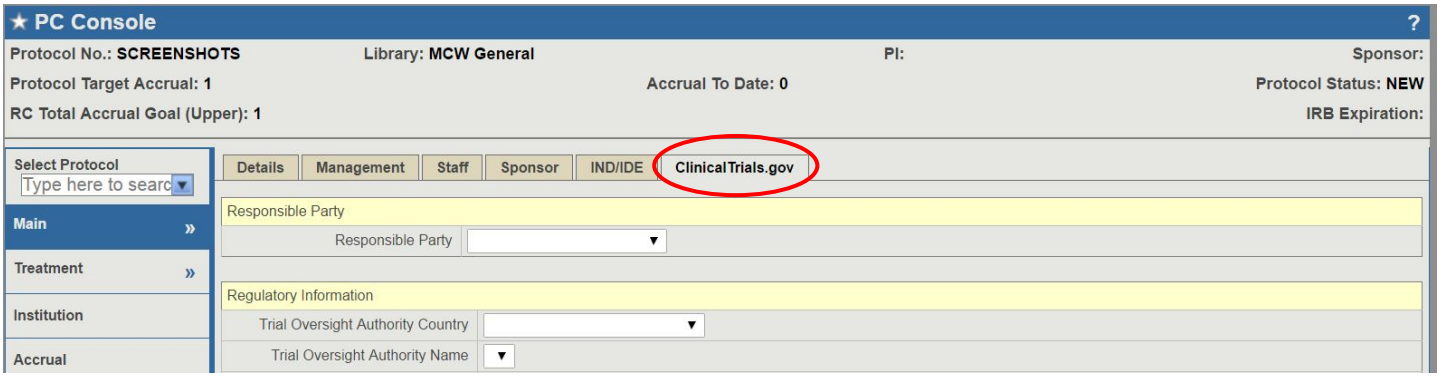
PC Console>Main>Staff		
Field	**Instruction**	**Comments**
Role	**Affiliate Clinical Research Coordinator:** For studies where MCW is the coordinating site. The CRC(s) at an Affiliate institution responsible for coordinating the protocol **Affiliate PI:** The PI at the Affiliate site. This may be for record-keeping only, the Affiliate PI does not need to be an active OnCore user. **Affiliate Site Contact:** For studies where MCW is the coordinating site. The Affiliate's Site Contact, in many cases a research manager. If this role is used and is different than the Affiliate CRC, the Affiliate Site Contact has the overall responsibility for the protocol at the Affiliate **Back-up Clinical Research Coordinator** **Budget/Contract Specialist:** Responsible for budget preparation and e-Bridge Funding Proposal **Clinical Research Assistant** **Clinical Research Coordinator:** Primary CRC on the protocol, usually listed as Primary Study Contact on IRB submissions **Data Monitor/QA:** Role for internal Data Monitors/QA personnel **Laboratory Staff** **Notifications Only:** These are persons associated with the protocol required to receive status update e-mail notifications from OnCore **Principal Investigator:** PI of record in e-Bridge **Program Manager:** **Sub-Investigator:** MCW Investigators/Senior/Key Personnel in B1.0 of e-Bridge FPs. **Protocol Creator:** Whoever "submits" the New protocol will automatically be assigned this role by default in OnCore. **Research Manager:** May be a CRC III in the absence of a designated research manager/administrator for a Department/Division **Regulatory Specialist:** Responsible for Regulatory Documentation and IRB submission	Select an Individual's ROLE on the protocol. Individuals may have multiple roles with separate entries for each role. The Program Manager Role must be currently assigned to the person who will be responsible for opening the protocol in OnCore
Staff Name	If the Staff person does not appear, contact Help-OnCore	
Start Date	An optional field indicating the date that a staff member is considered 'Active' on the protocol.	
Stop Date	"An optional field indicating the final date on which a staff member is considered active on the protocol.	

PC Console>Main>Sponsor		
Field	**Instruction**	**Comments**
Sponsor Name	Use find-as-you-type to select the Sponsor.	If the Sponsor doesn't appear, e-mail Help-OncCore to add the Sponsor
Sponsor Protocol No.	Indicates a number assigned by the sponsor for the protocol.	
Role(s)	Optional. Select the appropriate Sponsor Roles	
Fund Acct No.	Enter the Funding Proposal Number exactly as it appears in e-Bridge FP000XXXX.	
Sponsor Type	The NCI designated Sponsor Type definitions are as follows: **National:** NCI National Clinical Trials Network (NCTN) and other NIH-supported National Trial Networks **Externally Peer-Reviewed:** R01s, U01s, U10s, P01s, CTEP, or any other clinical research study mechanism supported by the NIH or organizations with peer review funding systems. **Institutional:** Investigator-initiated. The MCW investigator has primary responsibility for conceptualizing, designing, and implementing the clinical research study and reporting results. **Industry:** A pharmaceutical or device company controls the design and implementation of these clinical research studies.	When a Sponsor is added to OnCore, the Sponsor type is associated with the Sponsor. Sponsor Type per eBridge definitions will be captured in the MCW protocol annotation form.

PC Console>Main>Sponsor>Add Grant/Contract		
Grant No.	Enter N/A if this is pending. Update the Federal award no. or CFDA no. found in *e-Bridge>Funding Proposal> I. 2.0*	
NCI/NIH Grant	Select whether this is a NIH or NCI sponsored study	SELECT YES ONLY if this protocol is a Federal Grant
NIH/NCI Division	Select the appropriate NIH agency/program	
Grant /Contract Title	Enter the Grant title This may be different than the protocol name especially if it is a sub-project.	



PC Console>Main>IND/IDE		
Field	**Instruction**	**Comments**
IND/IDE Tab	Do not enter any information in this field unless the MCW Principle Investigator is applying for the IND/IDE	Data entered in these fields will display on the DSMC Console.

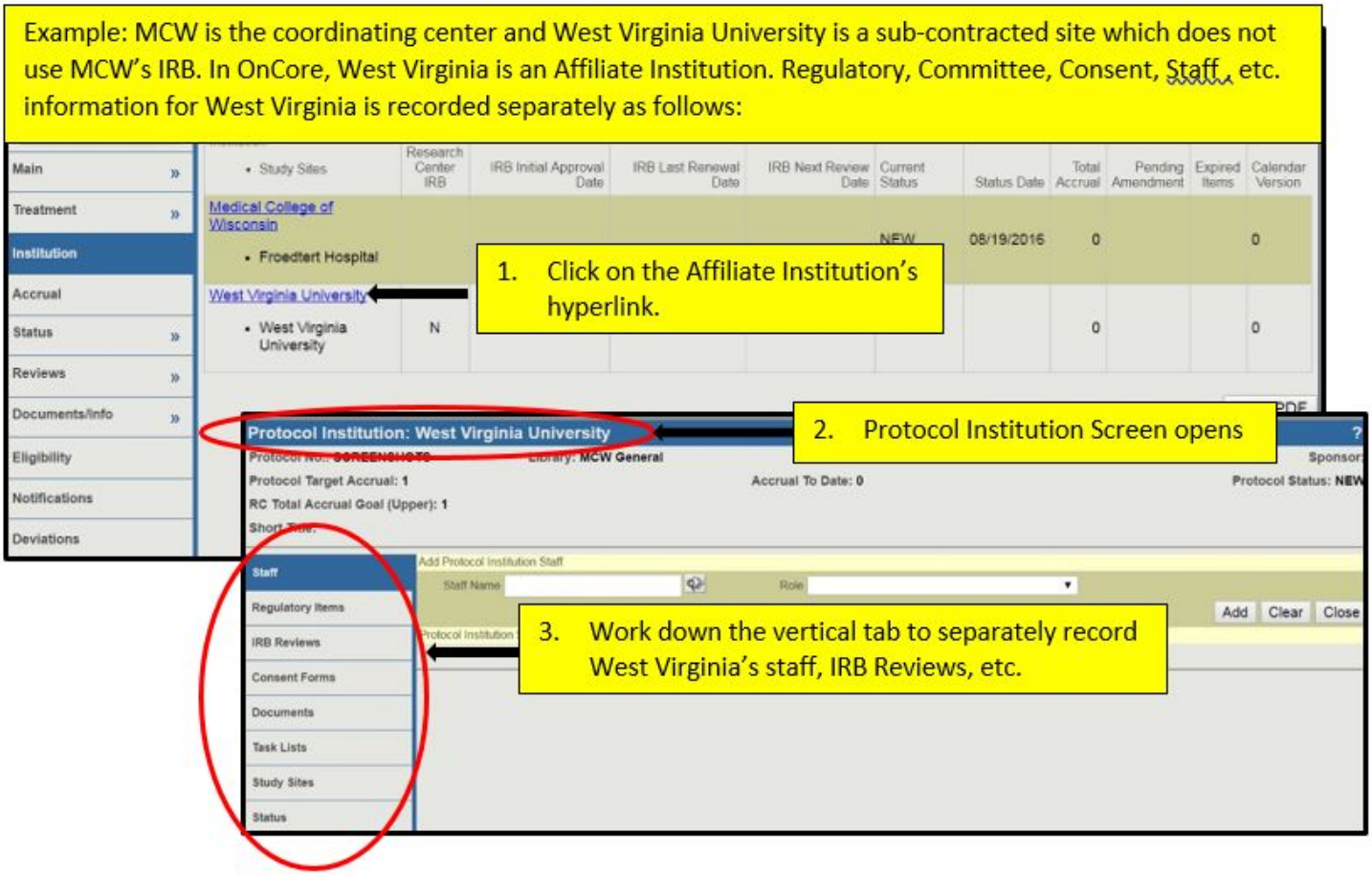


PC Console>Main>ClinicalTrials.gov		
Field	**Instruction**	**Comments**
ClinicalTrials.gov Tab	Do not enter any information UNLESS you are submitting this protocol to ClinicalTrials.gov. Speak with your OnCore Administrator. OnCore can generate a *.xml file for edits to be uploaded to ClinicalTrials.gov	The editable CT.gov file can be generated under *PC Console > Status > ClinicalTrials.gov>* Click Protocol Submissions

PC Console>Treatment>Details		
Field	**Instruction**	**Comments**
Step Code	Defines the step(s) in the protocol.	
Step Type	This designation is for information only and does not drive any functionality, unless the protocol uses the Randomization algorithm.	Speak with your OnCore Administrator if this is and IIT and you want OnCore to randomly assign subjects using a Randomization Algorithm
Arms	Click to add or edit treatment arms within a step	
Arm Code	A short identifier for the Arm such as "A", "B"	Displays in the *Subject Console>Treatment* tab when assigning the subject to an arm
Arm Description	Enter a description of the arm. For double-blind studies, there will be only 1 treatment arm and the description will read EX: (Drug or Placebo)	Displays in the *Subject Console>Treatment* tab when assigning the subject to an arm
Modalities/Drugs/Devices	Click this Hyperlink to add/edit the modalities, drugs or devices for an arm.	Modality is optional.
Levels	In general, DO NOT add levels. They are reserved for only the most complex studies and calendars. Speak with your OnCore Administrator before using levels.	If one arm has levels defined, all arms must have the same number of levels defined
	The information entered under Treatment>Details will affect the calendar build. **Refer to The Protocol Training Manual for more information about adding Arms, Levels and Modalities**	

PC Console> Treatment>Disease/Diagnosis		
Section	**Instruction**	**Comments**
Diagnosis	Click Select to open a pop-up box of Diagnostic groups based on ICD-10. The Diagnostic groups will be collected as part of your groups' initial implementation. Contact Oncore@mcw.edu –if you require additional ICD-10 Groups/Codes be added	Specific ICD-10 codes under the group code appear in the *Subject Console > On Study > Primary Diagnosis* Field

PC Console>Institution		
Field	**Instruction**	**Comments**
Institution	Participating institutions are added to the protocol using the Add block that is visible in Update Mode. In most cases, select the Medical College of Wisconsin	Contact Help-OnCore if you are entering a multi-site protocol and require additional, affiliate institutions be added to OnCore. CHW is an Affiliate Institution because it does not use MCW's IRB.
Study Sites	Beneath the institution name is a bulleted list of those study sites that have been marked as participating on the protocol. Study sites, such as Froedtert Hospital, are where the research study is conducted.	If you select CHW as the "Institution", also select CHW as a Study site. Contact Help-OnCore if you require additional study sites to be added to OnCore.
	Refer to the Graphic below and The Protocol Training Manual for more information about adding Affiliate Institutions and study sites	



PC Console>Accrual		
Field	**Instruction**	**Comments**
Accrual	This page displays differently depending on whether the Summary Accrual Info. Only? was checked Yes or No on the *PC Console > Main > Details tab*.	Click the ? for further information on adding Summary Accrual Information

PC Console>Status		
Field	**Instruction**	**Comments**
Statuses	**New:** Assigned when the protocol is created. **PRMC Approval:** Cancer Center CTO Only **On Hold:** MCW uses this study for Pipeline studies. This status is typically assigned when a sponsor puts the protocol on hold prior to opening to accrual. **Abandoned:** This status indicates no further action is expected for this protocol. **IRB Initial Approval:** The initial IRB review is "approved" in the IRB tab but the study has not been "Open" in the status tab **Open to Accrual:** subjects may be added to the protocol. Suspended protocol is temporarily closed to accrual. OnCore does not allow you to place subjects On Study when a protocol is 'Suspended'. **Closed to Accrual:** Indicates that a protocol is closed to accrual. IRB Study Closure: Typically the final status for the protocol when the expected outcome is successfully completed **Terminated:** This status is typically used when a protocol ends prior to completing the expected outcome, and indicates that no further protocol action is required. **For Affiliates Only** Open at CHW and/or other affiliates only	For pipeline studies, change the status from "New" to "On Hold" You can delete an IRB review record as long as it is removed and the protocol status hasn't advanced beyond the IRB Initial Approval status. Once the status changes to "IRB Approval" the record cannot be removed
Sign-offs	When the protocol has a status of NEW or IRB INITIAL APPROVAL it can be put "On Hold" or "Abandoned"	The MCWPM Signoff must be selected to open the protocol to accrual

See the separate Document "IRB Review Tab Details" for more detailed explanations and requirements

PC Console> Reviews> Update IRB Review> Review Information		
Field	**Instruction**	**Comments**
Review Date	Select the IRB Committee Meeting Date. Type in the month/year to filter the list.	The date shortcuts (t, y, w) do not work in this field. Select the date from the list.
Submit Date	Enter the "Received by IRB Office" date in eBridge.	Do NOT enter the "Submitted Application" date from eBridge.
Committee	Select the appropriate committee	
Review Reason	Select the review reason	
Review Type	Select the Review Type	
Action	Select the appropriate action. Create a Follow-up review if necessary	If a FU review is selected, the "Submit Date" defaults to the original. **Do not change this.**
Action Date	The Action Date is the Date on the IRB Approval Letter	
Expiration Date	The IRB Expiration Date	
Review No.	The Review Nos. may be copied and pasted directly from eBridge. Enter the full IRB number. PRO00010000 AME00010000 RE00100000 CPR00010000	This shows up on the IRB Action History (IRB Tab) Enter the entire number
Summary	Free-text field for additional review information	
	The remaining fields are optional	

PC Console> Reviews> Update IRB Review> Details		
Field	**Instruction**	**Comments**
Amendment No.	Optional.	
Received Date	Leave Blank.	
Version Date	1. Consent: Version date is the Stamped Date 2. Use the IRB Meeting Date of Approval for other documents. The actual version date should be contained in the file name.	The version date is used to identify the most recent document of each document Type for display in "Document Search"
Description	Free-text field for additional document descriptions	
Comments	Free-text field for additional comments	
Global	An amendment may be marked as 'Global' if each participating institution's IRB must approve the amendment as approved by the Research Center's IRB. Checking this box will cause the record to appear as a 'Pending Amendment' on the *PC Console > Institution* tab.	
Reconsent Required?	When an amendment or CPR results an updated consent form, this checkbox can be used to indicate a reconsent requirement for enrolled subjects. Checking this checkbox causes a link to appear. Click the link to indicate whether the reconsent should apply to subjects with a status of On Treatment (including 'On Arm' and 'Off Arm'), subjects with a status of On Follow-Up, or both. This will cause an 'RR' superscript to appear next to each subject's name in the *CRA Console* until the subject has been reconsented.	
Release	A Release checkbox appears after a document has been uploaded. Checking "Release" allows other persons to see the document in either *PC Console > Documents/Info* or the *Protocols > Document Search.*	
PC Console> Reviews> Update Other Committee Actions		
Committee	Other External Committee Actions that review the protocol are displayed and managed here. These include: MRI, IBC, Radiation, Adult TRU and OCRICC	External Committee Actions are for Informational purposes only

PC Console>Documents/Info		
Field	**Instruction**	**Comments**
Document Type	Upload only non-IRB related documents here. The documents will be distinguished by version control in either their name and/or the version date of the document. Contact oncore@mcw.edu if you need to create a new document category	The Document/Info tab shows ALL documents and ALL versions including those uploaded in the IRB Review tab with the Exception of Consents.
Version Date	The version date of the document uploaded. If no version date is available, use the date the document is uploaded	
FAQs	Protocol-specific FAQs may be added here. The "Keywords" field has no functionality and is not a searchable field	
PC Console Eligibility		
Field	**Instruction**	**Comments**
Eligibility	**Creating an Eligibility Questionnaire is Optional. If a questionnaire is created, it will appear in the *Subject Console>Eligibility* tab.**	
PC Console >Deviations>Subject		
Field	**Instruction**	**Comments**
Show Only Unreported Deviations	When this is checked, only deviations without a date entered in the "IRB Reported Date field" are listed. If it's not checked, all subject deviations are displayed	
Update Selected IRB Reported Dates		
	The Subject Deviation page displays Subject Deviations created on the *Subject Console>Deviations*	
PC Console >Deviations>Protocol		
Field	**Instruction**	**Comments**
	The Protocol Deviation page is used to manage and update protocol deviation records.	
Show Only Unreported Deviations	When this is checked, only deviations without a date entered in the "IRB Reported Date field" are listed. If it's not checked, all protocol deviations are displayed.	