OnCore Clinical Research Management

Data Entry Guidance Document

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Definitions

Accrual	An accrual is the count of subjects on a study. A subject is considered an accrual per the sponsor's criteria, usually after consent, eligibility and any screening procedures are complete.
Affiliate	Another institution or site that is conducting clinical trials where WVU is the coordinating center.
KC (Kuali Coeus)	The electronic data submission software used by the WVU IRB.
Cancer Center	Mary Babb Randolph Cancer Center
CRA Console	Clinical Research Administration Console
CRO	Contract Research Organization, A company hired by another company or research center to take over certain parts of running a clinical trial. The company may design, manage, and monitor the trial, and analyze the results.
CTCAE	Common Terminology Criteria for Adverse Events – The NCI CTCAE is a descriptive terminology which can be utilized for Adverse Event (AE) reporting.
CRU	WVU Cancer Institute's Clinical Research Unit
CTSI	WV Clinical and Translational Science Institute
Deviation	A variance from the approved protocol procedures.
DSTC	Data Safety and Toxicity Committee – The DSTC has the responsibility for continued review and monitoring of all clinical trials at MBRCC. This committee provides oversight of study progress and safety by review of accrual and adverse events.
ePRMS	Electronic Protocol Review and Monitoring System
HSC	Health Sciences Center at West Virginia University
ICF	Informed Consent Form
Institution	Institutions are the logical business units of clinical trials that participate in a protocol.
Investigator Initiated	A protocol that is developed and written by the Investigator.
IRB	Institutional Review Board, a group of scientists, doctors, clergy, and consumers that reviews and approves the action plan for every clinical trial.
MBRCC	Mary Babb Randolph Cancer Center at West Virginia University
EPIC	WVU Hospital's electronic medical record system.
MRN	Medical Record Number
NCI	National Cancer Institute
NCT Number	The protocol identifier assigned by ClinicalTrials.gov

Notification	An automated email that is sent out when certain criteria are met.
OnCore Administrator	The staff assigned to maintain the OnCore database.
OSP	Office of Sponsored Programs – The institutional signatory power that negotiates and monitors compliance of contracts with sponsors.
PC Console	Protocol Coordinator Console
PI	Principle Investigator, A principal investigator is responsible for the overall conduct of the clinical trial at his/her site.
PRMC	Protocol Review and Monitoring Committee - The PRMC reviews all cancer protocols conducted at the institutions affiliated with MBRCC.
PRMC Coordinator	The PRMC Coordinator manages the PRMC meeting agendas, tracks submissions, tracks committee decisions, and manages communications between the investigators and the PRMC.
RNI	Rockefeller Neuroscience Institute
SAE	Serious Adverse Event (SAE): Any untoward medical occurrence that at any dose results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, or is a congenital anomaly/birth defect or requires medical or surgical interventions to prevent any of the above outcomes.
Sponsor	Organization or company supporting the trial, including financial, drug supply, data management, etc.
Study Site	Location associated with an Institution where subjects will be treated or registered.
Submitter	The staff (on behalf of a Principal Investigator) entering and submitting a new protocol and associated documents to the PRMC for review or into OnCore.
Summary 3	An NCI report that shows patient accrual data for a 12 month period at an institution. The report includes data on cancer site, demographics, etc.
Data Table 4	An NCI report that shows the clinical research trials that are open during a 12 month period at an institution. The report includes data on study type, sponsor type, principal investigator, accruals, etc.
Toxicity	Refers to harmful side effects caused by the agent or intervention being tested.
Treating Physician	The physician that is treating the subject while they are on the study.
WVCTN	West Virginia Clinical Trials Network – Most cancer affiliates are part of the WVCTN.

OnCore® Clinical Research Management		
PA-101	Title: **ePRMS Submission**	
Revision:	Effective Date:	OnCore Version
1	07/16/2012	12.0
2	10/21/2014	13.5
3	03/19/2015	13.5 Enterprise
4	03/17/2016	14.1 Enterprise
5	02/20/2017	14.1 Enterprise
6	11/12/2019	14.2 Enterprise
7	05/12/2020	16.0
8	11/24/2020	16.0.8

PA-101 ePRMS Submission

Purpose

This document describes the procedure to enter and submit a protocol to the PRMC – Protocol Review and Monitoring Committee via the ePRMS Submission Console in OnCore for initial review of cancer related protocols.

Non-Cancer protocols are entered via the PC Console; refer to PA-103.

Scope

The initial review process begins with the Submitter entering the protocol data into the ePRMS Submission Console and ends with the protocol staff being notified of the PRMC's decision.

Responsibility

Study Coordinators or designated protocol coordinators are responsible for entering and submitting a new protocol into the ePRMS Submission Console for initial review.

Procedures

Send a Submission for Review

Fields with an * are required fields in OnCore. All fields should be completed as appropriate.

1. Choose ePRMS, Submission Console from the OnCore menu across the top of the screen.

2. On the left-hand menu, under Create Submission, choose Initial Review.

3. ***Library** – Choose **Oncology** from the drop-down list.

4. Choose the review type based on the table below.

Full	Investigator Initiated, Industry or other protocol that requires a full review per the PRMC Chairman.
Admin	Cooperative Group protocols that will be administratively reviewed by the PRMC Chairman.
Expedited	Chart review or other protocols that qualify as Exempt with the IRB.

5. Enter the protocol information into the Submission Form as follows:

***Protocol No.**	The sponsor protocol number
***Department**	The Department the Principal Investigator is associated with. Refer to the HSC Directory http://directory.hsc.wvu.edu/ and http://home.hsc.wvu.edu/ ; choose the appropriate School's website and Department list for clarification.
***NCT Number**	Enter the NCT number from ClinicalTrials.gov or N/A
***Organizational Unit**	For cancer protocols this should default to Cancer Center.
***Title**	Title of the protocol, copy and paste from the protocol if possible
***Short Title**	Include the phase, drug or treatment and disease
Objectives	Copy and paste the main objective from the protocol to this field. (Review the paste for spacing and extra lines and correct as needed)
Phase	Select the phase of the protocol from the drop-down list
Scope	National is nationwide or international. Local is only at this institution or its affiliates, usually an investigator-initiated protocol
***Age**	Select the age group for eligible subjects
Consent at Age of Majority	If Adults are chosen in the Age field, this field is grayed out and cannot be changed. If Children or Both are selected in the Age field, the default changes to Yes. Yes means, children should be re-consented near their 18th birthday. No means, no re-consent will be required for children when they reach 18.
Drug Accountability	Yes - the sponsor will supply the drugs No - the drugs are standard of care/commercially available N/A - no drugs are involved in the protocol

***Investigator Initiated Protocol**	No - if it is an industry or cooperative group protocol exclusively. Yes - if a WVU Investigator has written the protocol, even if it is sponsored by industry or cooperative group
Involves Therapy	Yes - Therapeutic, Prevention, Supportive Care type trials No - Registries, Screening, Early detection, Lab correlate trials N/A - Chart reviews, Surveys
Exclude Protocol on Web	Check the checkbox if the protocol should not show on the CRU website. This should be checked for chart reviews, surveys and secondary companion studies.
Open for Affiliates Only	No - for MBRCC protocols even if an affiliate will also participate in the study. If an Affiliate will be the only participant in the study, after the necessary signoffs are completed prior to Open, then YES can be chosen.
Summary Accrual Info. Only	Choose No, unless only the number of subjects accrued is going to be recorded, such as chart reviews or survey type protocols.
***Protocol Type**	Select the appropriate protocol type as described in Appendix 1.
Cancer Control	Select Yes if one of the objectives of the protocol is to control cancer otherwise choose No
Cancer Prevention	Select Yes if one of the objectives of the protocol is to prevent cancer otherwise choose No
***Data Table 4 Report Type**	Select the appropriate Data Table 4 Report type as described in Appendix 2.
Registration Center	External for Industry/Cooperative Group registrations; Cancer Center for Investigator Initiated/local only protocols.
Involves Correlates or Companions	Select Yes if another protocol is directly related to this protocol and subjects must be registered to both protocols.
Data Monitoring	External for a CRO or Sponsor DSTC is for Investigator Initiated protocols
Adjuvant	Select whether this protocol is adjuvant from the dropdown list. N/A should be selected for chart reviews, surveys, etc.
Includes Specimen Banking?	Check the checkbox if the protocol collects specimens for banking.

Companion Study	If subjects are required to be enrolled to this study, prior to being eligible for another study, check this box. (Contact the OnCore Administrator if this is required.)
Multi-Site Trial	Does this trial recruit form two or more study sites? Yes or No
***Investigational Drug**	Select whether this study utilizes investigational drugs from the dropdown list.
Precision Trial	Yes, if this is classified as a precision trial No, if not a precision trial
Precision Trial Classification	**Basket** - for trials that allow the study of multiple molecular subpopulations of different tumor or histologic types all within one study. **Umbrella** - for trials using a design that focuses on a single tumor type or histology. **Targeted** - for trials designed to evaluate treatments targeted at one or two molecular populations in single or multiple disease type. **Other Adaptive Trials** - for other studies believed to be precision medicine trials based on non-traditional study design not identified above, limited inclusion criteria, and emphasis on patient-centric treatment.
Pilot	Yes or No, to indicate if this is a Pilot study
***Investigation Device**	Select whether this study utilizes investigational devices from the dropdown list.
Rare Disease	Yes or No, to indicate whether the protocol relates to a rare disease
GCRC	Should be NO, WVU does not have a General Clinical Research Center

Accrual Information	
***Protocol Target Accrual**	Enter the total number of subjects for the entire study. (all sites)
***RC Total Accrual Goal (Lower)**	The lower total accrual goal for WVU
***RC Total Accrual Goal (Upper)**	The upper total accrual goal for WVU
***RC Annual Accrual Goal**	The prospective number of accruals per year

Affiliate Accrual Goal	The prospective number of accruals for all affiliate institutions. **Note**: If this is an Affiliate Only protocol the above accrual information also needs to be filled in based on the affiliate's accrual goals.
***Accrual Duration (Months)**	The estimated length of time that the study will be open to accrual
***Primary Completion Date**	Select Anticipated and specify the expected completion date. The date that the Sponsor expects to complete the primary objective of the study.
Study Completion Date	Not necessary to be completed at initial protocol entry.

6. Click the **Save** button to save changes up to this point. The submission form will expand to display additional sections and fields.

Click the **Save** button often to save changes while filling in this form. When work is saved, the Submitter can log-out of OnCore and complete the submission at a later time without having to start over.

7. Fill in the **Administrative Groups section** of the form as defined below:

Program Areas	Click Select and choose the relevant program area(s) from the popup window by checking the appropriate checkbox and clicking the Add button. Check the **Primary** checkbox for the one that will be primarily responsible. Allen Lung Cancer Breast Cancer EMT & Metastasis Health Services and Intervention Research Non-Aligned Obesity and Cancer Osborn Hem Malignancy and Transplantation Translational Tobacco Reduction Research

Disease Team	Click Select and choose the relevant oncology disease team(s) from the popup window by checking the appropriate checkboxes and clicking the Add button. Check the **Primary** checkbox for the one that will be primarily responsible. Biospecimen BMT Brain/CNS Breast Cancer Control Drug Development GI GU Gynecologic Head and Neck Hem Malignancy (non-BMT) Hematology (benign) Lung Melanoma Other Peds Oncology Population Science Surgical Oncology
Management Group **This is the management group you have been assigned to, based on the type of trials you manage and your OnCore access.**	Click Select and choose the management group(s) from the popup window by checking the appropriate checkboxes and clicking the Add button. Check the **Primary** checkbox for the one that will be primarily responsible. **(CRU-CT for the Clinical Research Unit or Peds Oncology)** Add additional Management Groups for those groups that will need access to the protocol. (Affiliate sites, Rad/Onc, Lung etc.)

8. **Disease Sites section** of the form, click the Select button to choose all the disease sites that are eligible for the protocol from the popup window by checking the appropriate checkboxes and clicking the Add button.

9. **Institution section** of the form, click the Select button to choose West Virginia University and any other participating institution(s) from the popup window by checking the appropriate checkboxes and clicking the Add button.

10. **Study Site** – For a cancer protocol conducted at MBRCC make sure only the MBRCC is checked. **Uncheck** all other study sites.

11. **Sponsor section** of the form, click the Select button to choose the sponsor and click **Add.** *(Note, there is a bug with Internet Explorer that this function may not work, use Chrome or Firefox if needed)*

    If the Sponsor is not in the list, contact the OnCore Administrator to add the sponsor to the list. Enter the Sponsor Protocol Number. Check the box for the **Principal** sponsor.

Additional sponsors with designated roles may also be added.
For the CRU - Add the CRO and designate the Role as CRO.

12. **Competing Protocols section** of the form, list competing protocols by entering their protocol numbers and clicking the Add button.
    If there are no competing protocols, check the No Competing Protocol checkbox.

13. **Documents section** of the form, attach the following documents to be included with the submission;
    - Protocol, Investigative Brochure, Consent form or Consent form template and any other documents that may be relevant to the initial review of the protocol.

      Version date should be the version date on the respective document. Expiration Date is not needed.

    Click the Browse button and locate where the document is that you are uploading.

    Click the Add button after uploading each document.

14. **Protocol Staff section** of the form, choose the following staff that will be performing study related duties on the protocol (Delegation of Authority Log) using the Add button after each selection:

Principal Investigator	The Principal Investigator of the protocol
Co-Investigator	All Co-Investigators listed on the protocol
Study Coordinator-Primary	The Research Nurse or Coordinator of the protocol
Study Coordinator-Backup	Backup Coordinator(s) on your disease team
Data Manager	The Data Manager assigned to the protocol
Lab Staff	Bio-specimen Processing Core staff
Pharmacist	Investigational Pharmacist(s)
Pharmacy Staff	Pharmacy administrative staff
Regulatory-Primary	The Regulatory person assigned to the protocol
Regulatory-Backup	Any additional Regulatory staff that will be trained on the protocol
Other Staff	Any other staff that should be listed on the Delegation Log for this protocol.
Affiliate Sites add the following	
Affiliate Principal Investigator	The Principal Investigator of the protocol
Affiliate Co-Investigator	All Co-Investigators listed on the protocol
Affiliate Coordinator	The Research Nurse or Coordinator of the protocol

Notice that you, as the person creating this submission, are automatically added to the staff list as Submitter. **You must add yourself** to the staff with the appropriate role (i.e. Study Coordinator)

15. Click the Save button.

16. When the form is complete, click the Send button to send the form to the PRMC Coordinator.

17. The PRMC Coordinator will review the submission for completeness. If it is complete, the protocol will be placed on an agenda. If there are inquiries a query will be generated.

COMPLETE THE PROTOCOL SET UP IN ONCORE USING THE GUIDANCE DOCUMENT PA-102 ADDITIONAL PROTOCOL DETAILS.

Respond to a Query

Prior to scheduling the submission for a PRMC meeting, the PRMC Coordinator checks the submission for completeness and may have questions about the submission. If there are questions or clarifications needed, you will receive an email notification when the submission has been queried.

At any time, you can view whether a response is required in the Active tab of the Submission Console.

1. Click the Detail hyperlink for the submission. The Query Detail page is displayed.

2. Click Edit to review the query.

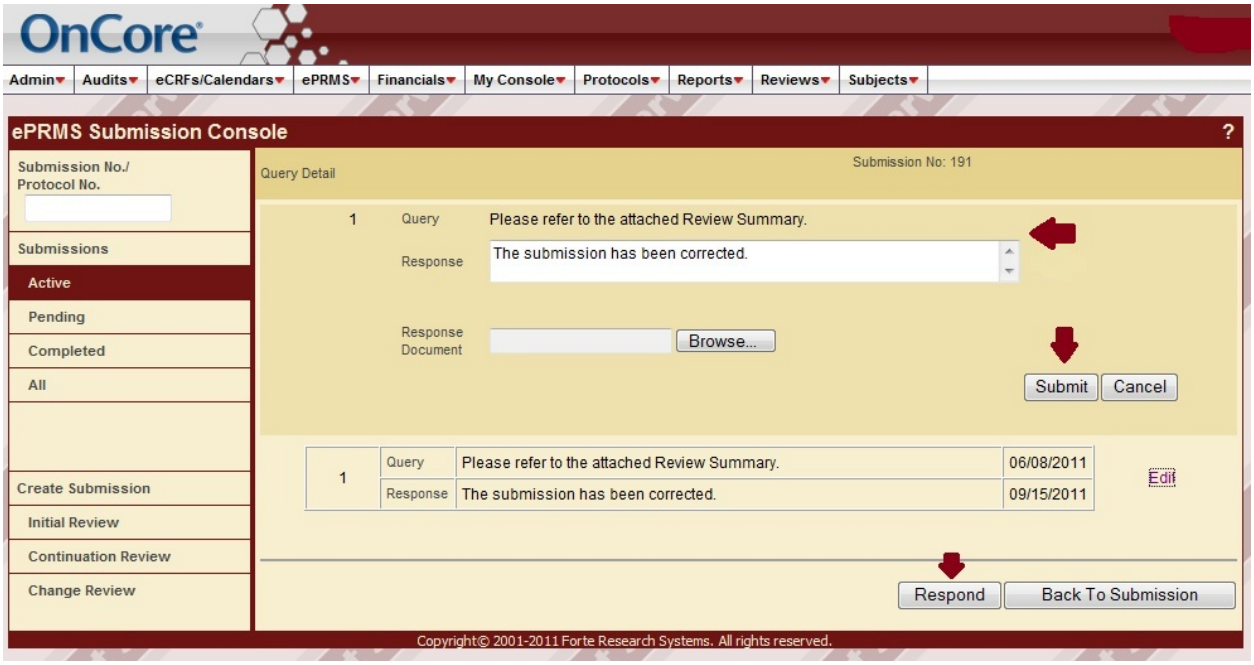
3. To make changes or updates to the submission, click the ‘Back to Submission’ button, then the Update button as needed.

4. Once the issues have been addressed, click Save. To return to the Query Detail click the Query Detail button at the bottom of the page.

5. In the Query Detail page, click the Edit hyperlink next to the Query. The Response box is displayed at the top of the page.

6. Type a message detailing how the Query was addressed. If more information is required, attach a document addressing the query here. Then, click the Submit button to save the response.

7. When all the Queries have been addressed, click the **Respond** button to re-send the submission with the relevant responses back to the PRMC Coordinator. The PRMC Coordinator will review the query response. If the submission is complete, the PRMC Coordinator assigns reviewers to the protocol and puts the protocol on a PRMC agenda.



At any point prior to the PRMC review meeting, the submission may be withdrawn by clicking the Withdraw button. This will remove the submission from the ePRMS Coordinator

Console. The submission then has the status of Withdrawn. This status may be reset to Submitted at a later time by clicking Undo Withdraw.

Submissions in an Assigned or On Agenda status need to be unassigned or removed from the agenda by the PRMC Coordinator before they can be withdrawn. When a submission is withdrawn, the protocol status will be changed to Abandoned if it is currently in New status.

Submission is put on the PRMC Agenda

When the submission has been put on the agenda for a PRMC meeting, an email notification will go to the Principal Investigator and the Study Coordinator. At any time, you can view whether the submission has been scheduled for review in the Pending tab of the Submission Console. The Review Date field shows the scheduled meeting date for a submission with a status of On Agenda.

PRMC Meeting Results

After the PRMC meeting has occurred, the PRMC Coordinator records the meeting outcomes in the Decision Detail section of the submission. You can view these results in the Completed tab of the Submission Console. An email notification is sent to the PI and Study Coordinator informing them of the committee's decision.

Below is the decision term and what that term's definition is:

Decision	Definition
Acknowledged	Approved
Approved	Approved
Approved with recommendations	Approved
Approved with stipulations	Provisionally Approved
Close	Closed
Disapproved	Disapproved
Exempt	Approved
Recommend closure	Closed
Tabled	Provisionally Approved

Approved submissions will become PRMC Approved in the protocol status.

Provisionally Approved means additional steps must be taken to complete the review process. (I.e. additional documentation needed, a query answered, etc.)

OnCore® Clinical Research Management		
PA-102	Title: **Additional Protocol Details**	
Revision:	Effective Date:	OnCore Version
1	07/16/2012	12.0
2	10/21/2014	13.5
3	03/19/2015	13.5 Enterprise
4	03/17/2016	14.1 Enterprise
5	02/20/2017	14.1 Enterprise
6	11/12/2019	14.2 Enterprise
7	11/24/2020	16.0.8

PA-102 Additional Protocol Details

Purpose

This document describes the procedure to enter additional protocol details via the PC Console after submitting a protocol via the ePRMS Submission Console and prior to the Open to Accrual status in OnCore.

Scope

This procedure should be used for Cancer Center protocols that are being submitted through ePRMS. This includes an Affiliate's cancer protocol that will be recorded in OnCore.

Responsibility

Study Coordinators or designated protocol coordinators are responsible for entering and submitting the additional details to the protocol via the PC Console.

Procedures

1. Go to the PC Console under the Protocols tab across the top.

2. Make sure you are in the correct protocol or search for your protocol in the Select Protocol search box.

Management Tab

3. Click on the Management tab across the top in the Main PC Console window.

4. Click the Update button at the bottom right of the screen.

5. In the PRMC/CTWG No. box you may enter a nickname that the protocol may be known by. This is a searchable field when searching for a protocol.

6. *GCRC Participation box – Should be NO, WVU does not have a General Clinical Research Center

7. Make sure the correct Coding Scheme is listed, and update as needed.

8. If you want the Off Treatment Date to automatically populate the On Follow-Up date, you should change this box to Yes.

9. Click Submit to save your changes.

Staff Tab

Treatment Tab - records information related to the protocol treatment and disease.

10. Click the Treatment Tab on the left-hand menu.

11. The Details tab will be completed by the staff creating the Calendar for the protocol. This tab is used to indicate the steps, arms and drugs for the protocol.

Disease/Diagnosis Tab

12. Choose the Disease tab across the top. (The disease site chosen when submitting via ePRMS should be here, if not do the following)

13. Click the Select button to choose the disease sites for the protocol from the popup window by checking the appropriate checkboxes and clicking the Add button.

More than one disease may be selected for the protocol.

14. Click Submit to save your changes.

Institution Tab -The Institution tab is used to identify the Institutions and Study Sites that will be participating in the protocol.

15. Choose the **Institution tab** from the left-hand menu.

16. Click Update to make sure you are in update mode.

17. West Virginia University should be listed.

Additional institutions or study sites that will be participating can also be added by clicking the Add button in the upper right. Start typing the name of the Institution and click on the magnifying glass to search for the correct Institution.

18. If the Institution will use WVU IRB, check the box that says, “Uses Research Center IRB?”

19. Then click Save on the right.

20. Staff tab- Staff names and roles for this Institution can be added or modified in the Staff Tab.

21. Click on Update to add the staff that will be participating on this protocol at this Institution.

22. Click Add after each addition.

Click on PC Console on the left-hand menu to get back to the main PC Console page.

OnCore® Clinical Research Management		
PA-103	Title: **New Protocol Entry via PC Console**	
Revision:	Effective Date:	OnCore Version
1	07/16/2012	12.0
2	10/21/2014	13.5
3	03/19/2015	13.5 Enterprise
4	03/17/2016	14.1 Enterprise
5	02/20/2017	14.1 Enterprise
6	10/27/2017	14.1 Enterprise
7	10/22/2018	14.2 Enterprise
8	05/12/2020	16.0
9	02/16/2021	16.0.8

PA-103 New Protocol Entry via PC Console

Purpose

This document describes the procedure to enter a new protocol into OnCore via the PC Console.

Scope

This procedure should be used for Non-Oncology protocols or those protocols that do not require PRMC approval.

Responsibility

Study Coordinators or designated protocol coordinators are responsible for entering new protocols into the PC Console.

Procedures

Fields with an * are required fields.

1. Choose Protocols, PC Console from the OnCore menu across the top of the screen.
2. On the left-hand menu, at the bottom of the list, choose New Protocol.
3. Enter the protocol information as follows:

***Protocol No.**	The sponsor protocol number
***NCT Number**	Enter the NCT number from ClinicalTrials.gov. If this study is not required to be registered with CT.gov enter NA.
***Library**	Choose Non-Oncology for HSC, RNI or other Non-Oncology trials. Choose HVI for Heart and Vascular Institute trials.
***Department**	The Department the Principal Investigator is associated with. Refer to the HSC Directory http://directory.hsc.wvu.edu/ and http://home.hsc.wvu.edu/ ; choose the appropriate School's website and Department list for clarification.
***Organizational Unit**	This should be the School the Principal Investigator is associated with. Refer to the HSC Directory http://directory.hsc.wvu.edu/ to look up the Principal Investigator.
***Title**	Title of the protocol, copy and paste from the protocol if possible
***Short Title**	Include the phase, drug or treatment and disease
Objectives	Copy and paste the main objective from the protocol to this field. (Review the paste for spacing and extra lines and correct as needed)
Phase	Select the phase of the protocol from the drop-down list
Scope	National is nationwide or international. Local is only at this institution or its affiliates, usually an investigator initiated protocol
***Age**	Select the age group for eligible subjects
Consent at Age of Majority	If Adults are chosen in the Age field, this field is grayed out and cannot be changed. If Children or Both are selected in the Age field, the default changes to Yes. Yes means, children should be re-consented near their 18th birthday. No = no re-consent will be required for children when they reach 18.
Drug Accountability	Yes - the sponsor will supply the drugs No - the drugs are standard of care/commercially available N/A - no drugs are involved in the protocol
***Investigator Initiated Protocol**	No - if it is an industry or cooperative group protocol exclusively. Yes - if a WVU Investigator has written the protocol, even if it is sponsored by industry or cooperative group

Involves Therapy	Yes - Therapeutic, Prevention, Supportive Care trials No - Registries, Screening, Early detection, Lab correlate trials N/A - Chart reviews, Surveys
Exclude Protocol on Web	Check the checkbox if the protocol should not show on the CRU website. This should be checked for chart reviews, surveys and secondary companion studies.
Open for Affiliates Only	No – until all necessary signoffs have been completed, after the initial IRB Review is entered. Then YES, if an Affiliate will be the only participant in the study when the study is ready to Open.
Summary Accrual Info. Only	Choose No, unless only the number of subjects accrued is going to be recorded, such as chart reviews or survey type protocols.
***Protocol Type**	Select the appropriate protocol type as described in Appendix 1
Registration Center	External for Industry/Cooperative Group registrations; Study Site for Investigator Initiated / local only protocols.
Involves Correlates or Companions	Select Yes if another protocol is directly related to this protocol and subjects must be registered to both protocols. Otherwise choose No.
Data Monitoring	External for a CRO or Sponsor Internal is for Investigator Initiated protocols.
Adjuvant	Select whether this protocol is adjuvant from the dropdown list. N/A should be selected for chart reviews, surveys, etc.
Includes Specimen Banking?	Check the checkbox if the protocol collects specimens for banking.
Companion Study?	If subjects are required to be enrolled to this study, prior to being eligible for another study, check this box. (Contact the OnCore Administrator if this is required.)
Multi-Site Trial	Does this trial recruit form two or more study sites? Yes or No
***Investigational Drug**	Select whether this study utilizes investigational drugs from the dropdown list.
Precision Trial	Yes, if this is classified as a precision trial No, if not a precision trial

Precision Trial Classification	**Basket** - for trials that allow the study of multiple molecular subpopulations of different tumor or histologic types all within one study. **Umbrella** - for trials using a design that focuses on a single tumor type or histology. **Targeted** - for trials designed to evaluate treatments targeted at one or two molecular populations in single or multiple disease type. **Other Adaptive Trials** - for other studies believed to be precision medicine trials based on non-traditional study design not identified above, limited inclusion criteria, and emphasis on patient-centric treatment.
Pilot	Yes or No, to indicate if this is a Pilot study
***Investigation Device**	Select whether this study utilizes investigational devices from the dropdown list.
Rare Disease	Yes or No, to indicate whether the protocol relates to a rare disease
Accrual Information	
***Protocol Target Accrual**	Enter the total number of subjects needed for the entire study.
***RC Total Accrual Goal (Lower)**	The lower total accrual goal for WVU
***RC Total Accrual Goal (Upper)**	The upper total accrual goal for WVU
***RC Annual Accrual Goal**	The prospective number of accruals per year
Affiliate Accrual Goal	The prospective number of accruals for all affiliate institutions. **Note**: If this is an Affiliate Only protocol the above accrual information also needs to be filled in based on the affiliate's accrual goals.
***Accrual Duration (Months)**	The estimated length of time that the study will be open to accrual
***Primary Completion Date**	Select Anticipated and specify the expected completion date. The date that the Sponsor expects to complete the primary objective of the study.
Study Completion Date	Not necessary to be completed at initial protocol entry.

4. Click Submit to save your entries to this point.

Additional tabs will appear next to the Details tab across the top after you submit. They are Management, Staff, Sponsor, IND/IDE.

5. Click on the **Management tab** across the top.

6. The IRB No. may be filled in if you have started an IRB submission in WVU KC IRB system. Otherwise it can be entered at a later date.

7. In the PRMC/CTWG No. box you may enter a nickname that the protocol may be known by. This is a searchable field when searching for a protocol.

8. *GCRC Participation box. Select No, WVU does not have a General Clinical Research Center

9. Make sure the correct Coding Scheme is listed, and update as needed.

10. If you want the Off Treatment Date to automatically populate the On Follow-Up date, you should change this box to Yes.

11. Fill in the **Administrative Groups section** of the form as defined below:

Management Group **This is the management group you have been assigned to, based on the type of trials you manage and your OnCore access.** For example: CTSI-CT PEDS-CT HVI-CT RNI-CT	Click Select and choose the Management Group(s) from the popup window by checking the appropriate checkboxes and clicking the Add button. Check the **Primary** checkbox for the one that will be primarily responsible. Choose any other dept. specialty that may need to access the protocol. This is also used for reporting on those specialties. (i.e. Neonatology, Cystic Fibrosis, Lung, Radiation Oncology, etc.)

12. Click Submit to save your entries.

13. Click on the **Staff tab** across the top.

14. **Protocol Staff section** of the form, choose the following staff involved in the protocol using the Add button after each selection:

Principal Investigator	The Principal Investigator of the protocol
Co-Investigator	All Co-Investigators listed on the protocol
Study Coordinator-Primary	The Research Nurse or Coordinator of the protocol
Study Coordinator-Backup	Backup Coordinator(s) on your disease team

Data Manager	The Data Manager assigned to the protocol
Lab Staff	Bio-specimen Processing Core staff, etc.
Pharmacist	Investigational Pharmacist(s) and team
Pharmacy Staff	Pharmacy administrative staff
Regulatory-Primary	The Regulatory person assigned to the protocol
Regulatory-Backup	Any additional Regulatory staff that will be trained on the protocol
Accountant	Financials person that should receive notifications
Manager	Manager that should receive notifications
Other Staff	Any other staff that should be listed on the Delegation Log for this protocol.
Affiliate Sites add from the following	
Affiliate Principal Investigator	The Principal Investigator of the protocol
Affiliate Co-Investigator	All Co-Investigators listed on the protocol
Affiliate Coordinator	The Research Nurse or Coordinator of the protocol

Notice that you, as the person creating the protocol, are automatically added to the staff list as Protocol Creator. **You must add yourself** to the staff with the appropriate role (i.e. Study Coordinator/Research Nurse, etc.)

15. Click on the **Sponsor tab** across the top.

16. In the Sponsor Details click the Add Sponsor button to choose the sponsor. You can start typing the name of the sponsor to find the sponsor in the drop-down list. Click on the name of the sponsor once you find it, and then click the Add hyperlink to add the sponsor.

If the Sponsor is not in the list, contact the OnCore Administrator to add the sponsor to the list.

17. Enter the Sponsor Protocol Number.

18. Check the box for the **Principal** sponsor and click Submit to save.

Treatment Tab - records information related to the protocol treatment and disease.

19. Click the Treatment Tab on the left-hand menu.

20. The Details tab will be completed by the staff creating the Calendar for the protocol. This tab is used to indicate the steps, arms and drugs for the protocol.

Disease/Diagnosis Tab

21. Choose the Disease/Diagnosis tab across the top.

22. Click the Select button to choose the Diagnosis Group for the protocol from the popup window by checking the appropriate checkboxes and clicking the Add button.

For Non-Oncology protocols these are based on the ICD-10 Chapters of Diseases – Find the chapter the main diagnosis of eligibility of the protocol relates to.

More than one Diagnosis Group can be selected for the protocol.

23. Click Submit to save your changes.

Institution Tab -The Institution tab is used to identify the Institutions and Study Sites that will be participating in the protocol.

24. Click on the **Institution Tab** on the left-hand menu.

25. Click on the **Add** button in the upper right corner of the window.

26. Click the search icon to find the Institution that is participating in the protocol.

27. Choose West Virginia University.

28. Click on Save on the right.

29. Click on the hyperlink of West Virginia University.

30. Click on Study Sites on the left menu.

31. Click Update and uncheck the Study Sites that will NOT be participating in this protocol.

32. Click Submit.

33. If the Affiliate Institution uses the WVU IRB check the box that says, “Uses Research Center IRB?” Click Save to save your entry.

34. Click Submit to save your changes.

PA-103.5 Task Lists

Purpose

This document describes the procedure to activate Task Lists on a protocol and complete tasks assigned via the PC Console.

Scope

This procedure should be used for most protocols managed by the CRU and any other clinical trial units that utilize the Task Lists.

Responsibility

Study Coordinators, Regulatory Associates, Accountants, Data Managers, or designated protocols staff are responsible for activating the Task List in the PC Console and completing assigned tasks.

Procedures

The Protocol Activation, Budget & Contract and Regulatory Initial IRB Review Task List should be activated as soon as the Institution is Site Selected.

To Release a Task List Template

23. Go to the PC Console under the Protocols tab across the top.

24. Make sure you are in the correct protocol or search for your protocol in the Select Protocol search box.

25. Click on the Status tab on left menu in the Main PC Console window.

26. Click on the Task List tab across the top.

27. In the Task List Template section at the top will be a list of the protocol templates listed in NEW status.

28. Click on the hyperlink for the template to open it up.

29. In the upper right corner click on the Update Status button and choose “Move to Complete Status”

30. In the upper right corner click on the Update Status button and choose “Move to Released Status”

31. Do this for each of the protocol templates that needs to be activated.

Releasing the template moves it down to the Task List section which can now be used to enter completed dates as tasks are completed.

To Activate the Protocol Activation Task List

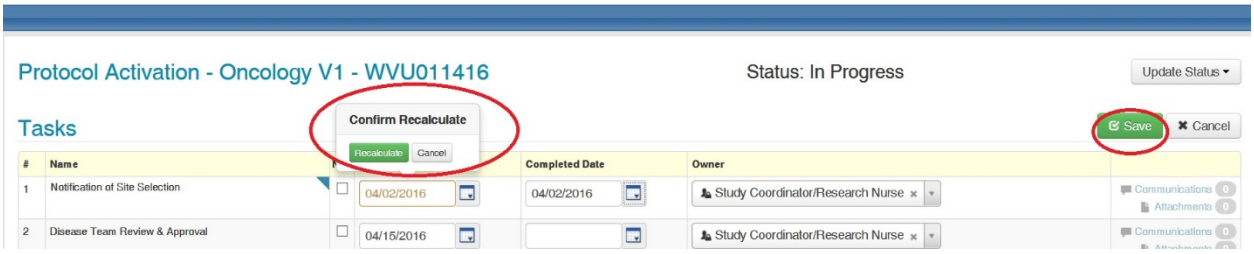
The first Task List that should be activated is the Protocol Activation Task List.

The Notification of Site Selection Task should be the first task to be completed. This will activate the other target dates for the other tasks on this list as well as other linked task lists.

1. Click on the Protocol Activation Task List in the Task List section.

2. Enter the date of Site Selection in the Target Date field. A box will pop up “Confirm Recalculate”.

3. Click on the **Recalculate** button. This will be the trigger to populate the Target Dates for the rest of the Task List.



4. Enter the same date in the Completed Date field for Notification of Site Selection.

5. Click on Save at the upper right.

6. Click Close to exit from the Task List.

Tasks that are Not Applicable or can be checked NA, then click Save so they are not available to be completed.

Completing tasks in an Active Task List

1. To complete a task on a Task List either go to the protocol via the PC Console-Status-Task List or Click on the Task you wish to complete via the Home Screen Task List Widget Box.

2. Once you are in the Task List you can enter a Complete Date for the tasks you are assigned to.

3. Once you have updated the tasks with the Completed Dates. Click SAVE at the top right of the screen.

4. Click Close to exit from the Task List.

Adding Communications and Attachments

Clicking the **Communications** link opens a window where you can add communications to the task. The task owner can add or remove communications, and those with the permission to view the task list can view the communications.

1. Enter the Date of the communication
2. Enter the specific details of the communication.

3. Click Add

4. Click Done when finished to close the window.

Clicking the **Attachment** link opens a window where task owners can add attachments to a specific task.

1. Description - Enter the document description. This is a required field.

2. Version Date - Type or use the date widget to enter the version date for the document. This is a required field.

3. Click on File or URL
    - If File, click on 'Browser' to select your file and click on Accept
    - If URL, type in the URL and click on Accept

4. Click the Add button to attach to the task.

5. Click Done when finished to close the window.

Adding additional Tasks in a Task List

1. A protocol specific Task can be added by typing the new Task in the Name field.

2. Click on the Add button in the bottom right of the screen.

3. Target date can be entered. **NOTE:** A task must have a target date in order for it to show up in a person's Active Task Widget

4. Owner can be a specific person or a protocol Staff Role.

5. Click SAVE to save the new task.

6. Click Close to exit from the Task List.

Activating the Study Close-Out Task List

Regulatory staff will release the Study Close-out task list when they are notified of study closure from the Sponsor/CRO.

See **Release a Task List Template** above.

OnCore® Clinical Research Management		
PA-104	Title: **IRB Reviews**	
Revision:	Effective Date:	OnCore Version
1	07/16/2012	12.0
2	10/21/2014	13.5
3	03/19/2015	13.5 Enterprise
4	03/17/2016	14.1 Enterprise
5	10/22/2018	14.2 Enterprise
6	11/12/2019	14.2 Enterprise
7	05/12/2020	16.0

PA-104 IRB Reviews

Purpose

This document describes the procedure to enter IRB Reviews into OnCore via the PC Console.

Scope

This procedure is used for entering Initial IRB reviews as well as Amendments and Continuing Reviews.

Responsibility

Regulatory or designated protocol coordinators that are responsible for entering IRB review information into the PC Console.

Procedures

1. Choose Protocols, PC Console from the OnCore menu across the top of the screen.
2. Make sure you are in the correct protocol or search for your protocol in the Select Protocol search box.

If this is the Initial Review enter the following information to the PC Console Main page:

- Enter the NCT number from ClinicalTrials.gov or NA (if not already entered)
- Enter the WVU IRB number on the Management tab IRB No. field
- Enter the central IRB number in the Pharmacy No. field (i.e. Advarra IRB, etc.)

3. Choose Reviews from the left-hand menu.
4. Choose the IRB tab across the top.

5. Click Edit on the previous review (unless this is the first IRB Review to enter) and **Uncheck the Released box for any documents that are no longer valid.**

6. Click Submit, and then Close.

To Add the new review

7. Click the Add button and fill in the following fields defined below.

8. Review Date: The date the protocol was reviewed at the IRB.

9. Submit Date: The date the PI submitted the protocol in the IRB system.

10. Committee: Enter the WVU IRB, Advarra IRB or CIRB (for NCI central IRB cancer trials), etc., from the drop-down list

11. Review Reason: Choose from the drop down list the type of review, Continuing Review, Initial, Major Amendment, Minor Amendment or Other

12. Review Type: Choose from the drop-down list, Full or Expedited.

13. Action: Choose from the drop-down list, Acknowledged, Approved, Disapproved, Exempted, or Other.

Note: Only Approved, Acknowledged and Exempted will move the protocol forward. If the review is deferred do not enter the review until it is approved.

The overall protocol status will display 'IRB Initial Approval' when a review with the following conditions is submitted:

Review Reason = Initial Review, Action = Approved, Acknowledged, Exempted and Action Date is entered.

14. Action Date: The date on the letter from the IRB. This may be different than the Review Date.

15. Expiration Date: This date is on the letter from the IRB.

16. Review No. field can be used to identify a specific review number or left blank

17. Summary: Enter a description of relevant information about the review.

18. Click Submit on the bottom of the page.

19. Make sure the Institution populated and click on Edit and add any other Institutions this review applies to.

In the **Details** section you will add the IRB approved documents for this review.

Protocol, IB, Questionnaires, IRB Approval letters, etc. follow either of the steps below

If there are documents from a previous review that apply to this review:

Click the **Select Previous Details/Docs**

20. Click on the + to expand the review you would like to copy documents from or Expand All at the top to expand all the previous reviews.

21. Check the appropriate boxes for each document type.

Include will include the document details, (Type, Amend.#, Received Date, Version Date, Description, Comments) Details can be edited once included.

Copy Doc? This will copy the uploaded document to this review.

22. Click on Save at the bottom of the page to save the information to the current review.

23. Click OK.

24. Verify information copied from previous review is relevant and edit as needed.

25. The Release checkbox for the documents will automatically be checked.

26. Click Submit to save the review.

To manually add documents to the review:

27. Click Add to enter the relevant document information approved with this review. (Protocol, Consents, IB, Patient Questionnaires, etc.)

28. Type: Choose the type of document from the list.

29. Amendment No. from the IRB.

30. Version Date: For protocols, the protocol version date approved by the IRB.

31. Comments can be added in the comments box.

32. Click the Save hyperlink to save your changes.

33. Click on the Attach a File hyperlink to attach the document. Browse to your document to attach.

34. Repeat steps 21-27 for each document that was approved with this review.

35. Click on the Release checkbox for the documents to be released for users to access.

36. Click **Submit** to save your additions.

Consent Forms

37. Click Add to enter the relevant consent form information approved with this review.

38. Type: Choose the type of Consent approved by the IRB. This should remain consistent through the life of the protocol. (i.e. Treatment consent)

39. Version Date: For Consent forms, enter the approved version date on the consent

40. Description: For Consents, enter the version date and last amended date from the approved consent form. **Note:** This information will show on the Consent Tab in the CRA Console

41. Next under Type: choose the consent labeled **CONSENT** from the drop-down list and copy the same information you entered for the previous consent form.

42. Click on the Attach a File hyperlink to attach the consent form to this one labeled **CONSENT**.

43. Browse to your document to attach.

Attaching to the one labeled **CONSENT** releases the document to the Documents and Info tab in PC Console rather than to the Institution tab.

44. Click on the Release checkbox for the documents to be released for users to access.

45. Click **Submit and Close** to exit from the review and the standard IRB approval notice will go out.

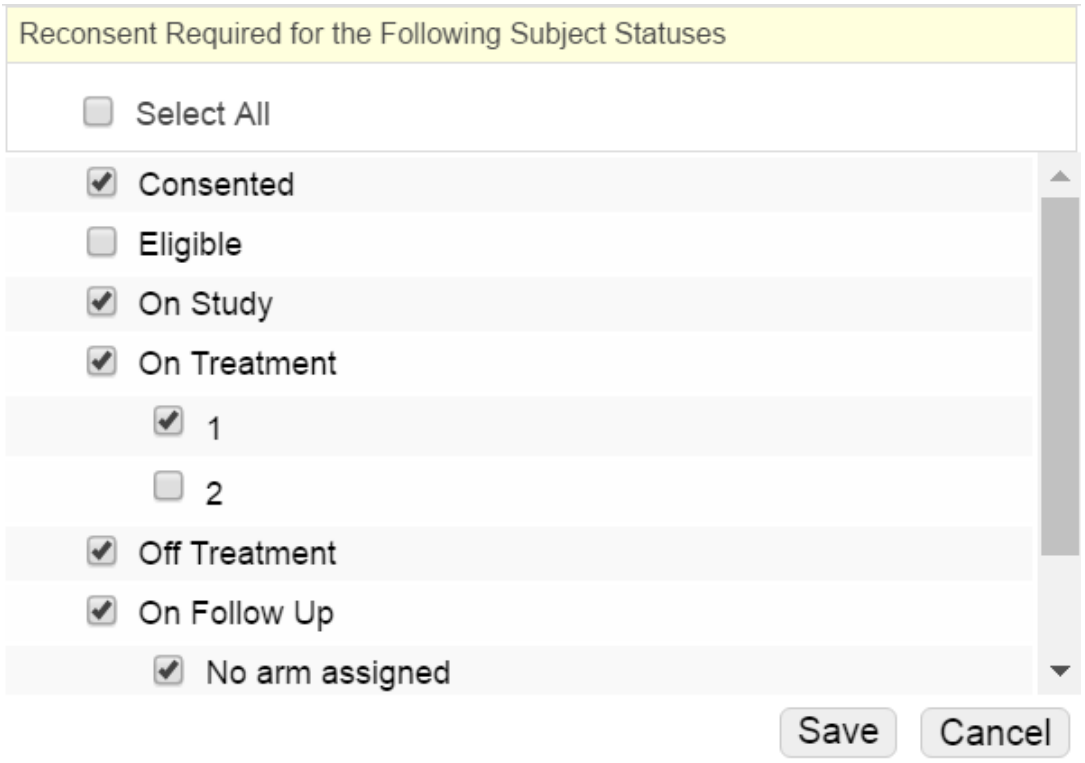
Reconsent Required

When an amendment has an updated consent form, this checkbox can be used to indicate reconsent requirements for subjects.

Note this checkbox can only be successfully selected when the Type of update consent form matches the Type of the original consent form. (i.e. Treatment Consent must be used if the original consent type was Treatment Consent)

Selecting Reconsent Required? causes a **»** link to appear.

Click the link to indicate which subject status the reconsent should apply to. (see picture below) This will cause an 'RR' superscript to appear next to each subject's name in the CRA Console until the subject has been reconsented.



IRB Approval Notice

This overrides the standard IRB approval notification and allows you to add details of the review and attach the IRB approved documents. This notification will go out to the PI and most staff associated with the protocol as well as other key personnel.

46. Clicking the IRB Approval Notice hyperlink under the review that was just entered will display the IRB Approval Notification page.

47. To include the any documents that were released with this review in the notification, click on the check box of at the bottom of the page next to the document.

48. Click Override to open up the notification and add more detailed information about the review.

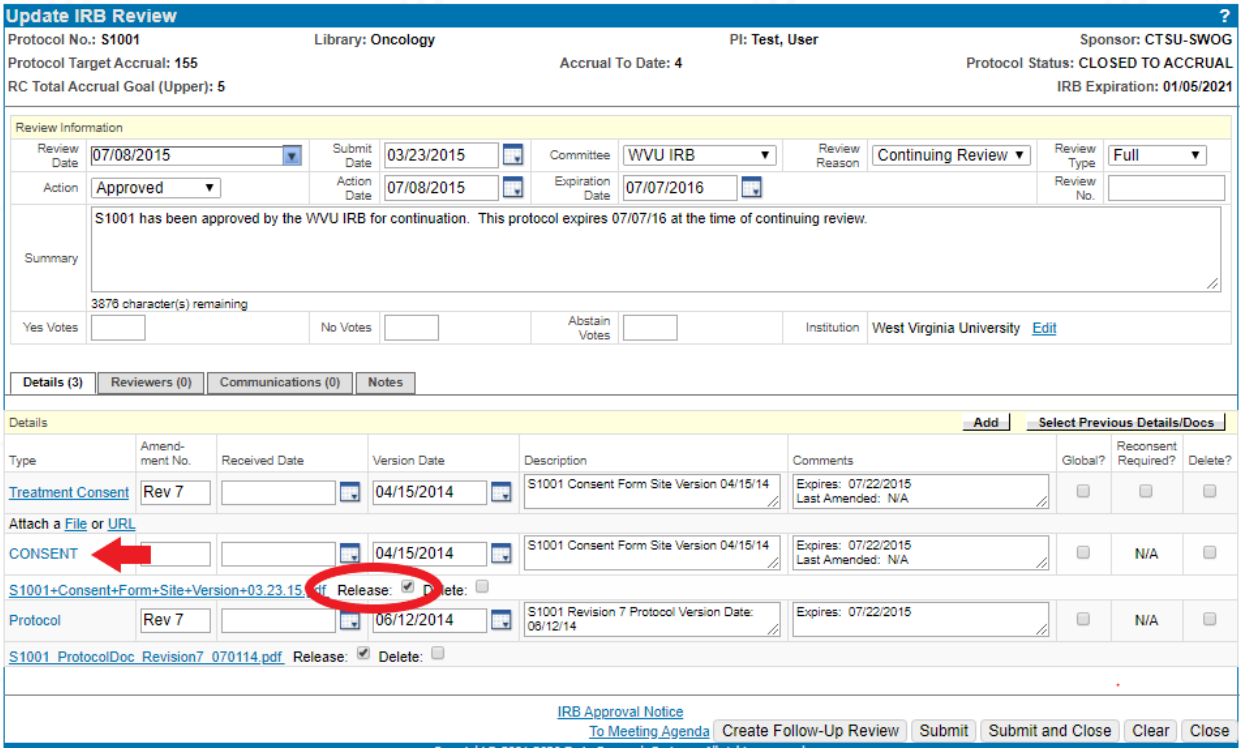
49. Place the cursor at the beginning of the notification and hit return to add any additional details about the review.

50. This notification will be sent to those listed on the IRB Notification. Additional email address can be added to the notification before sending.

51. Click Send to send out the notification.

52. Click the To Review hyperlink to get back to the review.

53. Click **Submit and Close** to exit from the review.



Documents released from an IRB Review.

Protocols, IBs etc. Consents, are released to PC Console, Documents/Info tab on the left.

OnCore® Clinical Research Management		
PA-105	Title: **Protocol Status**	
Revision:	Effective Date:	OnCore Version
1	07/16/2012	12.0
2	10/28/2014	13.5
3	03/19/2015	13.5 Enterprise
4	03/17/2016	14.1 Enterprise
5	02/20/2017	14.1 Enterprise

PA-105 Protocol Status

See **Appendix 3** for OnCore Protocol Status Definitions

Purpose

This document describes the procedure to update the statuses of a protocol in OnCore via the PC Console.

Scope

This procedure is used to update the status of a protocol.

Responsibility

Regulatory or designated protocol coordinators, Accountant and Study Coordinators assigned to the protocol are responsible for signing off and updating the various statuses of the protocol via the PC Console.

Procedures

Protocol Signoffs – After the 'IRB Initial Approval' status is completed, organization specific Protocol Signoff buttons will become available. The following sign offs and status changes are done at PC Console, Status tab on the left hand menu, excepted where noted differently.

1. **Accountant Signoff** - The Accountant signs off when the contract has been signed by WVU's Office of Sponsored Programs and the Sponsor. OSP sends a copy of the contract to the Accountant to notify when this has happened.

2. The Accountant clicks the Accountant Signoff button in the Status tab in the PC Console and enters the date the contract was signed.

3. **Clinical Signoff** – The Study Coordinator signs off when all protocol related training, site visits, lab preparation, etc. are completed and Investigational drug is available at the site.
4. The Coordinator clicks the Clinical Signoff button in the Status tab in the PC Console and enters the date.

5. **Regulatory Signoff** - The Regulatory department signs off when no IRB or regulatory documentation is pending and the protocol is ready to be opened.

6. The Regulatory staff clicks the Regulatory Signoff button in the Status tab in the PC Console and enters the date.

7. **Open to Accrual** – The Clinical Manager or Coordinator (depending on the Department's workflow) reviews the protocol in OnCore for all completed tasks and verifies the protocol is ready to Open to Accrual.

8. Click the Open button in the Status tab in the PC Console and enters the date.

Note: The Regulatory staff is responsible for any other status updates such as, On Hold, Closed to Accrual, Abandoned, Suspended, or IRB Study Closure.

Affiliate Sites

9. An Affiliate Site's status must be updated through the Institution Tab on the PC Console.

10. Click on the hyperlink for the Institution to be updated.

11. Click on the Status tab on the left hand menu.

12. Click on Update to enter update mode.

13. Choose the status from the drop down list.

14. Enter the date the status changed.

15. Choose from the drop down list the Initiator of the change in status. (Not required for Open to Accrual)

16. Choose a Change Reason from the Search icon. (Not required for Open to Accrual)

17. Click the Add button to save your changes.

For Affiliates Only status (This is for protocols ONLY open at Affiliates not at WVU)

When the Open for Affiliates only field is marked Yes in the Protocol > PC Console > Main > Details page, the Status tab will display a For Affiliates Only button.

Selecting this button will allow you to change the protocol status for the Research Center from New to For Affiliates Only. This assumes the research center will not open the protocol, but allows the research center to track and monitor the protocol.

Once a protocol's status is For Affiliates Only, the next available status is IRB Study Closure. If the research center decides to open the protocol, an undo button is available.

OnCore® Clinical Research Management		
PA-106	Title: **Protocol Deviation**	
Revision:	Effective Date:	OnCore Version
1	07/16/2012	12.0
2	10/28/2014	13.5
3	03/19/2015	13.5 Enterprise
4	03/17/2016	14.1 Enterprise
5	05/12/2020	16.0

PA-106 Protocol Deviation

Purpose

This document describes the procedure to enter a deviation related to the protocol into OnCore via the PC Console.

Scope

A protocol deviation must be entered in OnCore when a variance from the approved protocol occurs that affects study conduct and/or all subjects enrolled.

Responsibility

Study Coordinators or designated protocol coordinators who are responsible for entering protocol deviations into the PC Console.

Procedures

1. Choose Protocol, PC Console from the OnCore menu across the top of the screen.

2. Enter the protocol number in the Select Protocol box on the left-hand side of the screen.

3. Click the hyperlink to choose the protocol. Verify you are in the correct protocol by viewing the protocol information at the top of the screen.

4. Choose Deviations from the left-hand menu.

5. Click on the New Protocol Deviation button at the top right of the screen.

6. Enter the following applicable fields, those with * are required:

*Date Discovered	Date being entered in OnCore
Reported by	Automatically populates the person that is entering the deviation in OnCore.
*Information Source	Where did the information about the deviation come from? How was it reported? (Lab staff, Monitor, etc.)
*Deviation Date	The date the deviation occurred.
*Category	Choose from the drop down list the category the deviation relates to. (Consent, Eligibility, Response/Outcome, Scheduled Test, Treatment, Other) Whether it is a Minor or Major deviation in the respective category. See Appendix 5 for examples.
*Description of Deviation	Enter a detailed description of the deviation.
Effect on Patient Safety	Enter any effects this deviation may have on the patient's safety or none if not applicable.
*Action Taken	Enter the corrective action that will be taken for this subject and any process that will prevent this deviation from occurring again.
Role Responsible for Action Taken	What staff role is responsible for the corrective action plan.
*Did the deviation put the participant or others at increased risk and/or negatively affect the primary study aims?	Choose YES or NO to the answer to this question.
Has the integrity or validity of the data been compromised?	Choose YES or NO to the answer to this question.
Was an IRB waiver granted?	Choose YES, NO or N/A to the answer to this question.
Report to the IRB?	If the answer to the previous question is **YES, choose Immediately** in the drop-down box and notify the Regulatory department that the deviation needs to be reported to the IRB. If the question in answered **NO, choose Next Continuing Review** or Not Applicable.

Date Reported to the IRB	Enter the date the deviation was submitted to the IRB. (This will be entered by the Regulatory department)
*Report to Sponsor?	Choose Yes or No if this deviation was reported to the Sponsor or not.
Date Reported to Sponsor	Enter the date the deviation was reported to the Sponsor.
Team Reviewed Date	Date reviewed by the disease team.
DSTC Reviewed Date	This will be entered by the DSTC Coordinator when the DSTC reviews the deviation.

7. Click the Submit button.

8. Click the Close button.

9. **You must notify the Regulatory staff of a Protocol Deviation.**

   There is no automatic notification when a Protocol Deviation is entered.

OnCore® Clinical Research Management		
SA-101	Title: **Subject Registration and Administration**	
Revision:	Effective Date:	OnCore Version
1	07/16/2012	12.0
2	10/28/2014	13.5
3	03/19/2015	13.5 Enterprise
4	03/17/2016	14.1 Enterprise
5	02/20/2017	14.1 Enterprise
6	11/12/2019	14.2 Enterprise
7	05/12/2020	16.0
8	2/16/2021	16.08

SA-101 Subject Registration and Administration

See Appendix 4 for OnCore Subject Status Definitions.

Purpose

This document describes the procedure to enter a new subject into OnCore via the CRA Console.

Scope

This procedure is used to enter all subjects who have signed a consent form into the OnCore database. The CRA console has the capabilities to register subjects, enter consent information, verify eligibility, track subject visits, capture key dates (On Study, On Treatment, etc.) and record follow-up details.

Responsibility

Study Coordinators, Data Managers or designated protocol coordinators who are responsible for entering new subjects into the CRA Console.

Procedures

Enter a Subject Registration

1. Choose Subjects, CRA Console from the OnCore menu across the top of the screen.

2. Enter the protocol number in the Select Protocol box on the left-hand side of the screen.

3. Click the hyperlink to choose the protocol. Verify you are in the correct protocol by viewing the protocol information at the top of the screen.

4. Choose Register Subject at the bottom of the list of tabs on the left-hand menu.

5. Choose the Study Site that the subject is to be registered to from the drop-down list.

6. Enter the MRN, or Last Name and Birth Date fields in the Find Fields area. Click Find. Any subjects that are found in OnCore or the demographics interface with EPIC that match any of the information entered will appear at the bottom of the screen.

7. **If your subject is found**, click on the MRN hyperlink for your subject. The demographics information will populate.

8. Complete the Subject Details section by filling in the Ethnicity and Race fields

9. Click Add.

10. The subject Demographics tab will open up. Verify the Subject Demographics and Contact Information is correct. Add any additional information needed.

11. Click Submit at the bottom of the page.

12. Continue to step 15.

13. **If your subject was not found**, verify the data you have entered is correct because any patient seen within WVUMedicine that has recently been checked into EPIC should be found. If not, such as an Affiliate registration, Click on Create New button and complete the fields in the Subject Details section and click Add.

14. The subject Demographics tab will open up. Enter the Contact Information and click Submit at the bottom right.

15. Subject Emergency Contact information is not required but can be entered. Make sure to click Add in the bottom right of this section if you enter Emergency Contact information.

Consent

16. Click on the Consent Tab on the left-hand menu.

17. Enter the date the subject signed consent in the Available Consents box.

18. Click on the Select Consents button next to the date field.

19. The most recent IRB approved consents with a version date prior to the date signed will appear.

Clicking the + symbol to the left of the Consent Type displays all previous versions of that consent type.

20. Choose Accepted or Refused for the appropriate IRB-approved consent record from the list. Signed date may be edited in this window.

**Verify the Version date and Approved date on the Consent form against what shows in the drop-down box.

Contact the Regulatory Associate assigned to the protocol ASAP if a discrepancy is noted.

21. Click on the Submit button in the lower right.

22. Then click the Close button.

If the subject has a New status, the first consent will change the subject's status to Consented.

In addition to recording the consent form signature information, the Consent tab can be used to record other consent information and types of consent status. The options available in the Status dropdown box are:

Consent Refused: Subject has refused consent. Subject status is Consent Refused.
Consent Waived: Subject has waived consent. Subject status is Consent Waived.
Withdrawn: Subject has withdrawn consent. Subject status is Withdrawn. This choice is available only after a consent signature is entered.

23. Click on the Eligibility Tab on the left-hand menu.

24. Make sure you are in Update mode.

25. In the Version Date field, enter the Version of the Eligibility Checklist, (this should be the same date as the latest approved protocol date)

26. Choose the appropriate Eligibility Status from the drop-down list. (Eligible (O) means Eligibility Override, special permission was given from the sponsor to allow the subject to be enrolled if they do not meet all the eligibility criteria)

27. Verified By field: Enter the initials of two persons that reviewed the eligibility for this subject. (i.e. AS/LW)

28. Status Date: Enter the date the subject was eligible. (**Note:** This date should be the same date or after, the subject was consented and after all screening procedures are completed)
29. Comments can be added as needed.

30. Click Submit to save.

Not Eligible subjects should also be entered and the Reason Not Eligible recorded.

On Study

The On Study tab is used to record the Sequence No., On Study Date, Disease/Diagnosis and Histology for patients as well as the Diagnosis Date, additional protocol subject identifiers, and subject staff, as well as additional details about the subject's insurance and ZIP code at time of registration.

31. Choose the On Study Tab from the left hand menu.

32. Sequence No. - For most studies the Sequence number will be given to you by the Sponsor. This is the Subject number the sponsor issues for the subject.

Enter the following fields in the Subject OnStudy Updates section.

On Study Date	This is the date the Sponsor considers the subject registered to the protocol. **When this date is entered the subject counts as an accrual to the protocol**
Disease Site (oncology studies only) Required for NCI reporting	The Disease Site browse allows you to select the disease site codes. The initial choices that show when the Browse button is clicked are restricted to those that correspond to the disease site(s) entered in the protocol
Histology (oncology studies only) Required for NCI reporting	The Histology browse allows you to select the histology codes. The initial choices that show when the Browse button is clicked will be restricted to those that correspond to the disease site(s) entered in the protocol.

Primary Diagnosis (non-oncology studies only)	The Primary Diagnosis browse allows you to select the primary diagnosis. This is based on ICD-10 codes. If your diagnosis does not appear, contact the OnCore Administrator to add the code needed.
Secondary Diagnosis (non-oncology studies only)	The Secondary Diagnosis browse allows you to select a second diagnosis if applicable.
Diagnosis Date	The initial date this subject was diagnosed. Choose Actual, Approximate or Not Available from the drop- down list next to the date field.
Disease Team (oncology studies only)	Populates automatically from what was entered at the PC Console.
Zip at Registration	Enter the zip code that the subject lives in at the time of initial registration to the study
Study Site	Populates from the study site that was chosen at registration.
Transferred Date	Can be used to indicate the date that a subject, **who was enrolled on the protocol at another institution,** was transferred to this institution.
Comments	May be used to record any study specific comments.

33. Additional Protocol Subject Identifiers section holds a table of identifiers for the subject that applies to this protocol, similar to the sequence number. The Identifier Type can be selected from a pre-defined list and free-text can then be entered for the Identifier.

34. Subject Staff: Identifies the subject related staff for the subject.

If you choose the Team button a list of all staff on the protocol will be listed and you can choose those you want to add.

If you choose the PI or a Co-Investigator and he/she is the Treating Physician **you must change the Role to Treating Physician**. This is critical data for reporting.

To change to Treating Physician click on the hyperlink of the person's name, when the pop-up window opens, change the role to Treating Physician.

Treating Physician, Data Manager and Study Coordinator are key staff that must be added to each subject.

35. Click Submit to save the changes.

Treatment

36. Click on the Treatment Tab on the left-hand menu.

37. Click the Add button on the right side of the screen.

38. Choose the Arm the subject is assigned to from the drop-down list.

39. Enter the date the subject was assigned to that arm in the On Arm Date field.

40. Enter the date the subject started Treatment in the On Treatment Date field.

41. Click Save to save your changes.

Off Treatment/Off Study/On Follow-Up

42. Click the Follow-Up Tab from the left-hand menu.

43. Click Update in the bottom right to enter update mode.

44. Enter the **Off Treatment Date**.

45. Choose the **Off Treatment Reason** from the drop down list.

46. If the subject will begin Follow-Up activities enter the **Follow-Up Start Date**.

(This date will automatically be populated based on the Off Treatment Date **if this option was activated at the PC Console Management page**)

47. Last Follow-Up Date: The last time the subject had a Follow-Up visit.

48. Next Follow-Up Date: The next scheduled Follow-Up visit.

49. Last Known Survival Status: Survival status of the subject after one of the institution personnel spoke to or had contact with the subject.

50. Expired Date: The date of death reported to institution personnel. The Approx.? checkbox can be used if the reported date is not exact. If the Expired Date is entered here, it will also populate the Expired Date field on Subject Console > Demographics.

51. Off Study Date: Subject has completed entire study and is no longer in Follow-up.

52. Off Study Reason: The reason the subject went off study can be selected using the drop-down menu.

53. <u>Best Response Section</u> Oncology only:

54. <u>Date of Progression</u> field should be entered when the subject progresses on study. (Bottom right of screen) This is a key anchor date for calendars with an additional follow up sequence of events after progression.

SA-101.5 Subject Visit Tracking and Forms

Purpose

This document describes the procedure to check in visits and complete forms for subjects on a protocol with a calendar and/or electronic data capture forms. (eCRFs)

Scope

A protocol calendar is used to manage subject visits in the study: planned visits, confirming their occurrence, and recording clinical data during a visit. The calendar is also the basis to manage the financial aspects of the protocol. (invoicing, receipts, milestones and coverage analysis)

Forms are used to capture study data generated by subject events and to support a protocol's data collection requirements for Investigator Initiated protocols.

Responsibility

Study Coordinators, Data Managers or designated protocol coordinators who are responsible for checking in visits on the calendar and verifying which procedures occurred at that visit and entering data on the visits' respective form.

Procedures

Subject Calendar Activation

In order to record subject visit information, the calendar segments containing the visit must be activated. Activation occurs when anchor dates for the subject are entered into OnCore. The anchor dates that can be used to define a calendar segment are 'Consent Signed', 'On Study', 'On Arm', 'On Treatment', 'Off Arm', 'Off Treatment', 'Off Study' and 'Date of Progression'.

When an anchor date is entered for a subject, the calendar segments based upon the date become active and a Planned Date will be calculated for the visits in the segment.

When a segment is active, the visit labels of the segment become links. Click a link to display the visit's Subject Visit Update page where you can verify the date the subject was seen and enter visit specific information.

Verifying Subject Visits

1. From the CRA Console, click on the MRN hyperlink of the subject whose visit you will verify.
2. Make sure the subject's statuses are up to date.
3. On the left-hand menu choose Calendar.
4. Click on the hyperlink of the visit you will be verifying. This will display the Subject Visit Update page.
5. Enter the Visit Date, (which defaults to the Planned Date shown on the subject calendar)
6. Select one of the 'Visit Status' radio buttons, Occurred, Missed or N/A.
7. You can enter any relevant information about the visit in the Visit Details section.

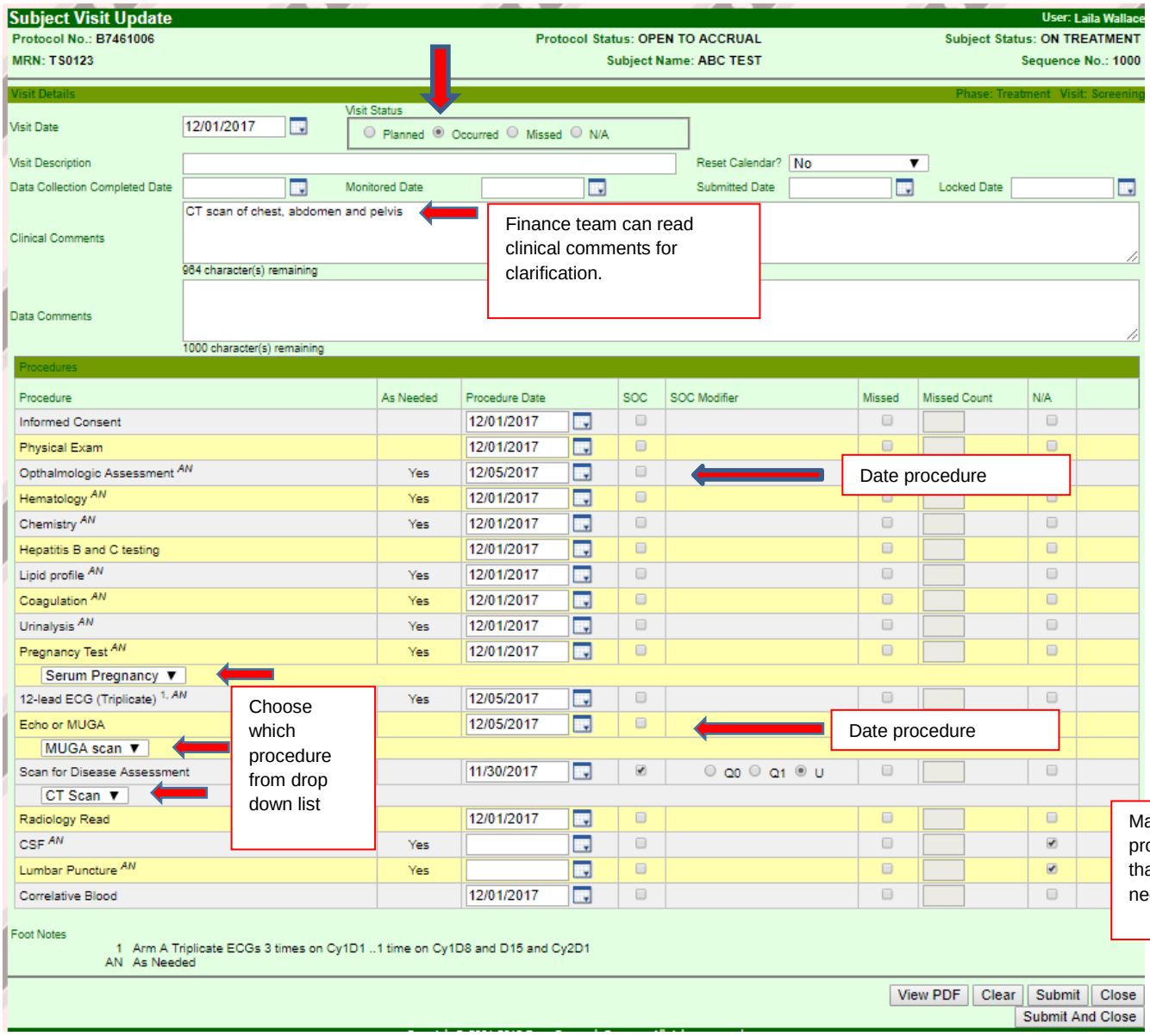
Procedures

The procedures that are associated with this visit will show up in the Procedures section.

1. Enter the date each procedure occurred.
2. When checking in visits verify all procedures listed occurred as designated (SOC vs. Research) and the date they occurred. (Screening usually has a 28 day window, so procedure dates will vary)
3. Mark any procedures that were missed or not needed with an explanation of why. (Financials will see these comments on the Financials tab)
4. If there is a drop-down box choose one from the list or mark N/A with a comment.

   Examples:

   - Pregnancy test – Serum or Urine
   - Echo/MUGA
   - Disease Assessment – CT Scan or MRI or PET/CT- add details of what type was done in the Clinical Comments section so the Financials can get the details for billing.
   - Tumor sample – Archive or Fresh



If a visit variation occurs (N/A or Missed), a window will appear to provide a free text field to record the variation's Reason for Change.

5. Click Submit at the bottom of the page.

Additional Procedures - If additional procedures occurred at this visit;

6. Click on the Additional Procedures button at the bottom of the page.

Protocol Procedures tab - Shows all procedures already assigned to the protocol.

Free-text Procedures tab - Allows you to enter a free-text procedure.

On each tab, use the checkboxes to select an additional procedure for the visit.

7. Click Submit for each addition.

8. Click Submit and Close to close out of the visit.

A window will appear to provide a free text field to record the Reason for Change.

Additional Visits

At times, subjects will be seen for visits that are not on the standard schedule. These visits can be recorded via the Additional Visits tab.

9. Click on the Additional Visits tab on the left menu in the Subject's record in the Subject Console.

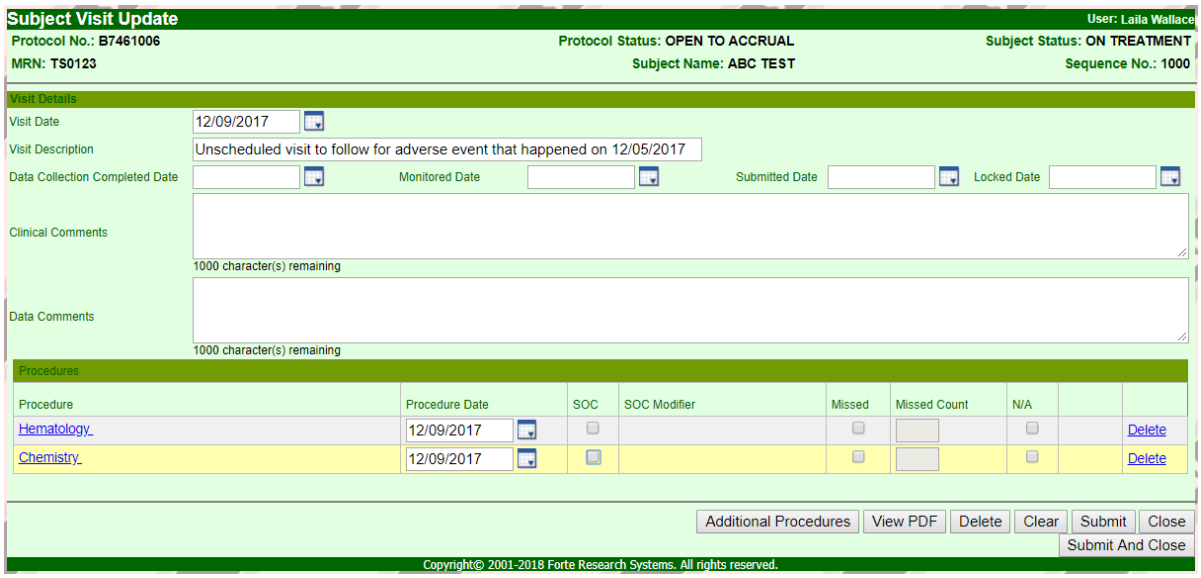
10. Click New in the Additional Visit page.

11. Enter the Visit Date, description and click Submit.

12. Click on the Additional Procedures button at the bottom of the page.

13. Add procedures as needed in the instruction above.

14. Click Submit and Close to close out of the visit.



OnCore® Clinical Research Management		
SA-102	Title: **Serious Adverse Events**	
Revision:	Effective Date:	OnCore Version
1	07/16/2012	12.0
2	10/21/2014	13.5
3	03/19/2015	13.5 Enterprise
4	03/17/2016	14.1 Enterprise
5	04/25/2019	14.2 Enterprise
6	05/13/2019	14.2 Enterprise

SA-102 Serious Adverse Events

Purpose

This document describes the procedure to enter a Serious Adverse Event related to a subject into OnCore via the CRA/Subject Console.

Scope

When a subject's adverse event meets the criteria for expedited reporting as defined in the protocol, an SAE must be recorded within OnCore. This data is needed for Regulatory review for IRB submission and the Data Safety and Toxicity Committee review or other internal review committee.

Responsibility

Study Coordinators, Data Managers or designated protocol /subject coordinators who are responsible for entering SAEs into the Subject Console.

Procedures

To Enter an Initial SAE for a subject, follow the steps below.

1. Choose Subjects, CRA Console from the OnCore menu across the top of the screen.

2. Enter the protocol number in the Select Protocol box on the left-hand side of the screen.

3. Click the hyperlink to choose the protocol. Verify you are in the correct protocol by viewing the protocol information at the top of the screen.

4. Click on the MRN hyperlink of the subject for which you need to enter an SAE.

5. Choose SAEs from the left-hand menu.

6. Click on the New button at the right of the screen.
7. Enter the following fields:

Note: Fields with an asterisk are required at initial submission of the SAE.

Field Name	Definition
***Event Date**	Date the SAE first occurred
Event End Date	Date the SAE was resolved or ended (may necessitate a follow-up report if not known at time of submission)
***Reported Date**	Date the SAE is being **entered OnCore** by the staff. Reports are run based on this date.
***Reported By**	Name of the staff entering the SAE
Death Date	If death occurred, date of death
Death Occurred	Choose from drop down list time frame from last treatment. For Transplant chose based on date of transplant.
Did the SAE occur at your site or at a site for which the PI is responsible?	Since we only enter SAEs that occur at our site, chose YES.
***Event Narrative**	• Enter any other pertinent information not found in any other section of the SAE form such as why and/or what caused the event to happen. • May state, "Refer to attached SAE document" and attach detailed SAE report for DSTC to review.
***Treating Physician Comments**	Enter a note that you reviewed the SAE with the name of the responsible Treating Physician.
PI Comments	Any PI comments may be entered (completely optional and used generally when there is a difference of opinion from the treating physician upon review).
***Protocol Attribution**	Can the SAE be attributed to the fact that the subject is on the protocol in anyway? This would include relationship to the Investigational product, standard product listed on the protocol, protocol procedures, or disease under study.

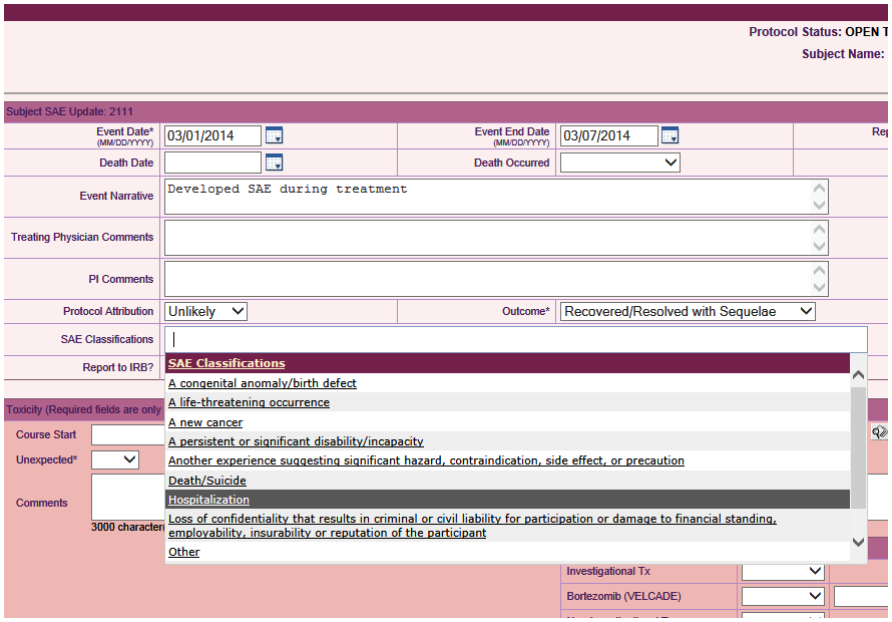
***Outcome**	Choose the outcome at the time the SAE is being entered (will necessitate follow-up if not resolved at time of reporting).
Consent Form Change Required?	Choose YES if a consent form will need revised per the IRB policy or deemed necessary by the PI. This is generally required when the subjects are at a greater risk of harm than previously known or recognized. For example: the event is a new, unexpected event **OR** if the event occurred at a higher toxicity than previously reported.

SAE Classification section

In the SAE Classification section, choose the classification(s) from the drop-down list.

Note: This must be completed when the SAE is being created.

If other is selected, define in the Event Narrative section.



Report to the IRB? Choose one of the following based on the criteria:

Immediately	If any event is marked as **Unexpected** **AND** The protocol attribution is Possible, Probable or Definite **AND**

	The consent form needs to be changed because the subjects are at a greater risk of harm than previously known or recognized.
Next Continuing Review	Choose this by default unless it meets the criteria above and needs to be reported immediately.

Adverse Event Details Toxicity Section

At least one toxicity must be identified, for an SAE notification to be released.

8. **All fields are required in the Adverse Event Details section,** enter the following based on the definition.

Course Start	The start date of the cycle or course of treatment that this SAE occurred in.
Category	This is the SOC (System Organ Class) from the CTCAE version that is assigned to the protocol.
AE Detail	This is the CTACE term describing the adverse event– the choices are narrowed down based on the Category chosen in the previous field.
Grade	Grade of the severity of the AE based on the CTCAE version.
Select Detail (Optional way to choose)	This hyperlink can be used to choose the AE Description from the entire list of CTCAE toxicities. Once AE Description is chosen, click the SELECT button in the bottom right and it will populate the Category, Toxicity and Grade fields. (This is a large list and may take longer to use than entering each field individually)
Unexpected	Is the event unexpected for any of the treatments in this protocol?
DLT	For Phase I trials is this a Dose Limiting Toxicity? Answer Yes or No. If this is not a Phase I trial it may be left blank.
Action	Choose the action taken for this Toxicity.
Therapy	Choose from the drop-down list if any therapy is being given for this Toxicity.
Comments	Enter any specific comments for this toxicity.
Source Section	Choose the Attribution for each protocol drug, investigational therapy, disease etc. that applies to this Toxicity. (Unrelated, Unlikely, Possible, Probable, Definite) For any drugs listed or investigational therapy: enter the date of the last dose in the box next to that treatment.

9. Click the **ADD** button in the bottom right of the Toxicity section to save your entries.

10. Repeat steps 9 and 10, for each Toxicity related to this SAE as reported to the Sponsor.

11. In the Tracking Details section enter the date the Sponsor was notified. All other tracking dates will be entered by the DSTC or Regulatory department.

12. If submitting via CTEP AERS, enter the AERS number in the SAE Identifier section.

Supporting Documents section

Upload a copy of the SAE report submitted to the Sponsor and any other supporting document.

13. Click the Add button on the right to open the section.

14. Choose the type of document from the Document Type dropdown list.

15. Click on the File hyperlink to upload the document.

16. Enter the version date of the document.

17. Enter a brief description of the document and/or reason for uploading it to the SAE in the Description field.

18. Click the Add button in the bottom right of this section.

19. Additional documents can be added by following steps 13-18.

20. Click Submit at the bottom right of the screen to save the SAE.

*** An SAE notification will be sent out automatically each time you click Submit.**

21. Click Close to get out of Update mode and be able to print any reports that are available at the bottom of the screen.

Enter a Follow-up SAE for any changes or updates to a previously entered SAE.

Follow –Up to an SAE

1. Choose Subjects, CRA Console from the OnCore menu across the top of the screen.

2. Enter the protocol number in the Select Protocol box on the left-hand side of the screen.

3. Click the hyper link to choose the protocol. Verify you are in the correct protocol by viewing the protocol information at the top of the screen.

4. Click on the MRN hyperlink of the subject for which you need to enter a Follow-Up SAE.

5. Choose SAEs from the left-hand menu.

6. Select the Event number of the original SAE (for the 1st Follow-Up) or the most recent Follow-Up SAE to the original SAE.

7. Go to the bottom right of the page and choose Create Follow-Up button.

8. Reported Date: Date the Follow-Up SAE is being entered into OnCore by the staff

9. Choose the outcome at the time the Follow-up SAE is being entered.

10. Enter any additional follow-up data as reported to the Sponsor and attach all follow-up reports submitted.

11. Click Submit when finished.

12. Click Close to get out of Update mode and be able to print any reports that are available at the bottom of the screen.

OnCore® Clinical Research Management		
SA-103	Title: **Subject Deviation**	
Revision:	Effective Date:	OnCore Version
1	07/16/2012	12.0
2	10/28/2014	13.5
3	03/19/2015	13.5 Enterprise
4	03/17/2016	14.1 Enterprise
5	05/12/2020	16.0

SA-103 Subject Deviation

Purpose

This document describes the procedure to enter a deviation related to a subject into OnCore via the CRA/Subject Console.

Scope

A deviation must be entered in OnCore when a variance from the approved protocol procedures related to a subject occurs.

Responsibility

Study Coordinators, Data Managers or designated protocol/subject coordinators and/or regulatory staff who are responsible for entering deviations into the Subject Console.

Procedures

10. Choose Subjects, CRA Console from the OnCore menu across the top of the screen.

11. Enter the protocol number in the Select Protocol box on the left hand side of the screen.

12. Click the hyperlink to choose the protocol. Verify you are in the correct protocol by viewing the protocol information at the top of the screen.

13. Click on the MRN hyperlink of the subject for which you need to enter a deviation.

14. Choose Deviations from the left-hand menu.

15. Click on the **New** button at the right of the screen.

16. Enter the following fields: (the ones with * are required)

*Date Discovered	Automatically populates the date being entered in OnCore.
Reported by	Automatically populates the person that is entering the deviation in OnCore.
*Deviation Date	The date the deviation occurred.
Information Source	Where did the information about the deviation come from? How was it reported? (Subject reported, Medical record, Monitor, Coordinator etc.)
*Category	Choose from the drop down list the category the deviation relates to. (Consent, Eligibility, Response/Outcome, Scheduled Test, Treatment, Other) Whether it is a Minor or Major deviation in the respective category. See Appendix 5 for examples.
****Treating Physician** **(This is a required field)**	Choose the treating physician. Start typing the physicians name to narrow down the list.
Date Reviewed by the Treating Physician	Regulatory will enter the date after the Treating physician reviews the deviation.
*Description of Deviation	Enter a detailed description of the deviation.
*Effect on Patient Safety	Enter any effects this deviation may have on the patient's safety or enter None.
*Action Taken	Enter the corrective action that will be taken for this subject and any process that will prevent this deviation from occurring again.
Role Responsible for Action Taken	What staff role is responsible for the corrective action plan.
*Did the deviation put the participant or others at increased risk and/or negatively affect the primary study aims?	Choose YES or NO to the answer to this question.
Has the integrity or validity of the data been compromised?	Choose YES or NO to the answer to this question.
Was an IRB waiver granted?	Choose YES, NO or N/A to the answer to this question.

Report to the IRB?	If the answer to the previous question is **YES, choose Immediately** in the drop-down box and notify the Regulatory department that the deviation needs to be reported to the IRB. If the question in answered **NO, choose Next Continuing Review** or Not Applicable.
Date Reported to the IRB	Enter the date the deviation was submitted to the IRB.
*Report to Sponsor?	Choose YES or NO whether this deviation was reported to the Sponsor.
Date Reported to Sponsor	Enter the date the deviation was reported to the Sponsor.
Team Reviewed Date	Date reviewed by the disease team.
DSTC Reviewed Date	This will be entered by the DSTC Coordinator after it has been reviewed by the DSTC. (if applicable)

17. Click the Submit button.

A Deviation notification will be sent to those on the notification for Subject Deviations.

OnCore® Clinical Research Management		
FN-100	Title: **Financials Parameters**	
Revision:	Effective Date:	OnCore Version
1	04/30/2019	14.2 Enterprise
2	05/12/2020	16.0

FN-100 Financials Parameters

Purpose

This document describes the procedure to set the Financial Parameters for a protocol, based on the approved contract and budget.

Scope

The Parameters tab is used to define the rules and that will manage the financials activities for a protocol budget, invoicing and tracking payments.

Responsibility

Financial team member responsible for entering the data into OnCore based on the approved contract and budget.

Data entry fields

Budget Related

WVU's instance of OnCore does not use the Charge Master, so some fields don't apply.

Rate Base - A rate base is required for budgeting. Choose the rate based of the Sponsor type for both the Budget Related and Sponsor Settings. (Industry, Federal or Investigator Initiated)

Default Sponsor – Default Sponsor should be chosen if multiple sponsors are listed for this protocol.

Vendor Payables Enabled - If Yes is selected, payables will be created from this protocol for subject-related and protocol-related events. If No is selected, no payables will be created from this protocol.

Withholding % - The withholding percent affects the sponsor invoice "Total Due" amount. By entering the % withheld from the contract and indicating which events the withholding applies to (protocol related, milestones or pass-thru (invoiceable) items, it pertains to. The invoice will reflect the total amount of the item, the total amount after withholding and then the total amount due. ** Most contracts only keep the withholding amount from the Milestone payments****

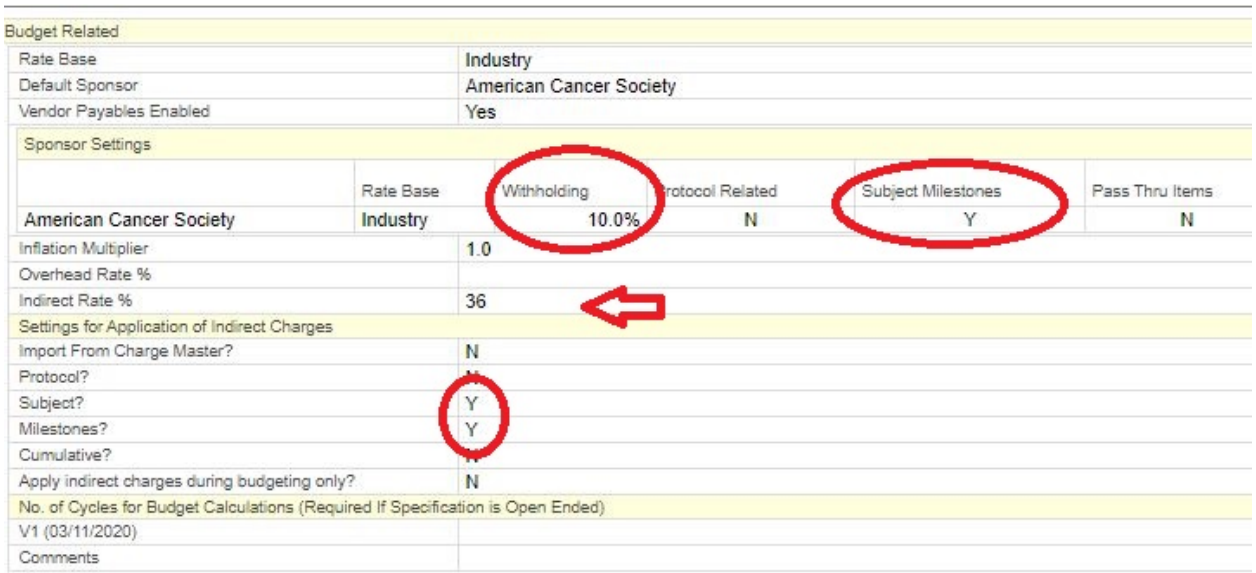
Indirect Rate % - The indirect rate is what WVU calls the Overhead rate. Enter the overhead rate % from the budget. Indirect rate = Overhead rate negotiated with the sponsor

Settings for Application of Indirect Charges

- Check the box "Use Protocol Specific Settings" for this section.
- Check the Subject and Milestones box.

This will apply indirect charges to subject related items and milestones automatically when they are invoiced.

If you don't want a subject related item to include overhead, at the subject procedure you will need to change the Indirect box to NO. (i.e. Travel Reimbursement)



Budget Related						
Rate Base	Industry					
Default Sponsor	American Cancer Society					
Vendor Payables Enabled	Yes					
Sponsor Settings						
	Rate Base	Withholding	Protocol Related	Subject Milestones	Pass Thru Items	
American Cancer Society	Industry	10.0%	N	Y	N	
Inflation Multiplier	1.0					
Overhead Rate %						
Indirect Rate %	36					
Settings for Application of Indirect Charges						
Import From Charge Master?	N					
Protocol?						
Subject?	Y					
Milestones?	Y					
Cumulative?						
Apply indirect charges during budgeting only?	N					
No. of Cycles for Budget Calculations (Required If Specification is Open Ended)						
V1 (03/11/2020)						
Comments						

Invoice Related

Screen Failures Invoice Ratio - The ratio x:y (*Not Eligible*:*Eligible*), indicates WVU can bill the sponsor *x* number of subjects deemed ineligible, for every *y* number of eligible subjects. This is found in the Contract.

- *Not Eligible*: The number entered in the first field indicates the number of screen failures.
- *Enrolled*: The second number indicates the number of subjects that must be considered enrolled in order for you to bill the sponsor for the number of screen failures indicated in the first number. Review the contract for what the Sponsor considers enrolled (Consented, Eligible, OnStudy)

Initial Invoiceable Screening Failures - Indicates the number of screening failures that must occur before the Screening Failures Invoice Ratio applies. When this field is left blank or set to 0, the Screening Failures Invoice Ratio applies immediately.

Maximum Screening Failures - Indicates the number of screen failures that will be available for invoicing. Check the contract, there may be a maximum number of screen failures.

No. of SAEs After Which Sponsor Will Be Invoiced - Indicates the number of serious adverse events (SAEs) that must occur on the protocol prior to the sponsor receiving an invoice for SAEs. The Invoiceable Items tab automatically begins listing the SAEs once the number meets and exceeds the limits indicated here, when SAEs are selected as milestones in the Milestones tab. Enter 0 so the first SAE that occurs will be available to be invoiced.

No. of OSRs After Which Sponsor Will Be Invoiced - Indicates the number of Outside Safety Reports/external SAEs that must occur on the protocol for the sponsor to receive an invoice for OSRs. The Invoiceable Items tab automatically begins listing the OSRs once the number meets and exceeds the limits indicated here, if OSRs are selected as milestones in the Milestones tab. Enter 0 if you want the first OSR that occurs to be invoiced.

Maximum Invoiceable OSRs - Indicates the last Outside Safety Report that will be available for invoicing. For example, when you enter 999 in this field, the 999th OSR is the last one that will be added to the Invoiceable Items tab.

Milestone Invoiceable Visit Prerequisite – This field determines what the prerequisite is for invoicing visits. This should be set to Occurred.

Invoice Related			
Screening Failures Invoice Ratio (Not Eligible : Enrolled)	1 : 1	Enrollment Status	ELIGIBLE
Initial Invoiceable Screening Failures	1	Maximum Screening Failures	5
No. of SAEs After Which Sponsor Will Be Invoiced	0		
No. of OSRs After Which Sponsor Will Be Invoiced	0	Maximum Invoiceable OSRs	100
Milestone Invoiceable Visit Prerequisite	Occurred		
Invoicing Reminder			
Notification Frequency in Months	2		
Number of Notifications after study closure	1		
Notification Start Date	12/03/2018		
Notification Comments			

Invoicing Reminder

Notification Frequency (Months) How often notifications are sent.

Number of Invoice reminders to send after study closure

Indicates the number of additional reminders that will be sent once the protocol has a completed status (Abandoned, Terminated, or IRB Study Closure).

Notification Start Date The date on which notifications begin.

Notification Comments Any other information regarding the notifications.

Remit To / Bill To

This section allows you to enter the Remit To and Bill To addresses that will be printed on the invoices.

Remit To = The address you want the checks to be sent to (i.e. WVU)

Bill To = The address and email address the invoice will be sent to (i.e. Sponsor or CRO)

APPENDIX

Appendix 1: Protocol Type

Based on the NCI-National Cancer Institute's CCSG Data Guide Data Table 4- Information on Clinical Research Studies

Protocol Type

Description	Definition
Treatment	Protocol designed to evaluate one or more interventions for treating a disease, syndrome, or condition.
Supportive Care	Protocol designed to evaluate one or more interventions where the primary intent is to maximize comfort, minimize side effects or mitigate against a decline in the participant's health or function. In general, supportive care interventions are not intended to cure a disease.
Prevention	Protocol designed to assess one or more interventions aimed at preventing the development of a specific disease or health condition.
Screening	Protocol designed to assess or examine methods of identifying a condition (or risk factor for a condition) in people who are not yet known to have the condition (or risk factor)
Diagnostic	Protocol designed to evaluate one or more interventions aimed at identifying a disease or health condition.
Other	Observational, Registries, Chart reviews, Survey and types that are not in other categories
Health Services Research	Protocol designed to evaluate the delivery, processes, management, organization, or financing of health care.
Basic Science	Protocol designed to examine the basic mechanisms of action (e.g., physiology, biomechanics) of an intervention.

Appendix 2: Summary 4 Report Type

Based on the NCI-National Cancer Institute's CCSG Data Guide Data Table 4- Information on Clinical Research Studies

Summary 4 Report Type

Description	Definition
Interventional	Participants may receive diagnostic, therapeutic, behavioral or other types of interventions. The participants are followed and biomedical and/or health outcomes are assessed.
Observational	Cancer patients and healthy populations that involve no intervention or alteration in the status of the participants.
Ancillary or Correlative	Correlative- Laboratory based studies using specimens to assess cancer risk, clinical outcomes, response to therapies, etc. Ancillary - Must be linked to an active clinical trial and should include only patients accrued to that clinical trial.
Not Applicable	Chart review and survey protocols are not applicable to Data Table 4 reporting. Make sure Summary Only box is Yes for these protocols.

Appendix 3: OnCore Protocol Status Definitions

OnCore Protocol Status Definitions

Protocol Status	Definition
New	Protocol has been created in PC Console or ePRMS Submission Console
PRMC Initial Approval	Protocol has been approved by the PRMC
On Hold	Sponsor puts the protocol on hold for any reason prior to opening to accrual.
IRB Initial Approval	Protocol has been approved by the IRB for the initial submission
Accounting Signoff	Accounting has signed off – the contract is fully executed
Clinical Signoff	Study Coordinator has signed off - all protocol related training, site visits, lab preparation, etc. are completed and Investigational drug is available at the site.
Regulatory Signoff	Regulatory has signed off – no outstanding Regulatory items
Open to Accrual	The protocol has been Opened to Accrual by the Study Coordinator – (site initiation is done, drug is here, laboratory is ready, etc.) Subject can be enrolled to the protocol
Closed to Accrual	Regulatory has closed the protocol to accrual – No new subject may be enrolled – Subjects may be in treatment or follow-up status
IRB Study Closure	Protocol is completed and has been closed by the IRB
Abandoned	Protocol is ended prior to Open to Accrual status
Suspended	Protocol has been Open to Accrual but subject registrations are temporarily suspended. Protocols can re-open after issues causing suspension are resolved.
Terminated	Study storage requirements have been met and records have been destroyed.

On various reports, these protocol statuses are broken out into Pending, Active and Completed categories. The statuses for each category are as follows:

- **Pending**: New, PRMC Approval, IRB Initial Approval, On Hold, Protocol Signoff(s)
- **Active:** Open to Accrual, Suspended, Closed to Accrual

Appendix 4: OnCore Subject Status Definitions

OnCore Subject Status Definitions

Subject Status	Definition
New	Subject is registered/enrolled to a protocol.
Consented	Subject has a signed consent form entered in OnCore
Eligible	Subject has been verified to be eligible for the protocol. Eligible status has been entered into OnCore.
Ineligible	Subject is ineligible for the protocol.
Eligible (O)	Subject has exceptions in the eligibility checklist; Sponsor has approved the subject's eligibility to the protocol.
On Study	Subject is considered accrued to the protocol per the Sponsor's criteria, when the On Study date is entered.
On Treatment	Subject is considered on Treatment when a treatment Arm and On Treatment date is entered in OnCore.
Off Treatment	Subject is no longer receiving treatment.
On Follow-up	Subject is beginning Follow-up activities for the protocol.
Off Study	Subject has completed entire study and is no longer in Follow-up.
Expired	An Expired date is entered for the subject.

Appendix 5: Deviation Category Examples

Major Eligibility
A research subject was enrolled, but does not meet the protocol's eligibility inclusion/exclusion criteria
Documentation missing to confirm eligibility (actual testing results)

NO Minor Eligibility Allowed

Major Consent
Inadequate or improper informed consent procedures
Failure to obtain informed consent prior to initiation of study-related procedures
Use of an incorrect version of the document when new information was not provided which may impact their willingness to continue
Failure to re-consent with revised document when appropriate
Consenting performed by person not delegated/trained as study team member
Translated consent or short form not signed and dated by a non-English subject

Minor Consent
Missing original signed and dated consent form (copy available)
Missing pages from an executed consent form
Consent signature is dated by someone other than subject
Subject not informed of new information when signing of a consent is not required
Consenting performed by persons not IRB approved, but has sufficient documentation they have the knowledge of protocol and drug (i.e., person delegated and trained on protocol but not IRB approved)

Major Scheduled Test
Failure to obtain a protocol specific research activity, test or procedure on a protocol that, in opinion of the PI, **CAN or DOES affect subject safety or data integrity** including lack of review of dose dependent activity, test or procedures

Minor Scheduled Test
Failure to obtain a protocol specific research activity, test or procedure on a protocol that, in opinion of the PI, **does not affect subject safety or data integrity**
Missing lab results, tests and/or procedure documentation
Study procedure conducted out of sequence
Study visit conducted outside of required study specific timeframe

Major Treatment
Subject received wrong treatment or incorrect dose great than 10%
Repetitive or serious error in dosing, timing or schedule. This includes wrong route, incorrectly prepared, timing/sequencing.
Dose modifications not in agreement with protocol
Lack of documentation of treatment, dose mods or non-protocol treatment
Continuing treatment when protocol-defined event requires cessation of treatment
Subject received commercial supply (or other study supply) rather than sponsor-supplied agent
Subject received an excluded concomitant medication or other treatment

Minor Treatment
Missed oral medications, not relating to treatment of toxicities, or a missed day of treatment with continuous therapy
Dosage errors within 10% (or may be different per sponsor)
Failure to return study medications

Major Response/Outcome
Failure to obtain response assessment according to protocol
Inaccurate response assessment which lead to incorrect continuation or cessation of therapy
Incorrect method of response assessment

Minor Response/Outcome
Inaccurate documentation of initial sites of involvement

Major Other
Performance of study procedure not approved by IRB
Delay in data submission greater than 6 months
Failure to report SAEs on interventional trials within required timeframe to IRB, sponsor, FDA
Failure to report AEs that might affect subject safety or data integrity
Research procedures performed by persons not delegated/trained OR not in their professional scope (licensure)
Pharmacy records not properly maintained (DARFs)
Investigational agent not stored properly

Minor Other
Delay in data submission by 3-6 months
Frequent data inaccuracies, errors in submitted data
Failure to report SAEs on non-interventional trials within required timeframe to IRB, sponsor, FDA