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| *6-26-2020* |

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| **UAB Medicine and the CCTS** |
| OnCore Minimum Footprint V3.1 26JUN2020 |
| *Required fields that will ensure the flow of OnCore functionality such as Visit Tracking, Searches, Reports, and Invoices.* |

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[Protocols Module](#_PROTOCOLS_Module_>)

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[Medical Center Protocol Naming Convention](#_Medical_Center_Protocol)

|  |  |  |
| --- | --- | --- |
| Location | Team Responsible  | Required Fields |
| PROTOCOLS Module > PC Console |
| MAIN Tab (vertical) |  | CCC  *additional fields required for Cancer Center trials* |
| **DETAILSCCC**  (horizontal) | MC- OCSCC- PRMS | * Protocol No.
* NCT Number (If not applicable, “NA” will be entered.  If pending, OCS will enter “NCT99999999” and the Medical Center study team is expected to update this field as soon as the number is assigned.)NEW
* Library
* Department
* Organizational Unit
* Title
* Short Title (used for CTBN and PowerTrials interface)
* Phase
* Age
* Investigator Initiated (UAB IIT only)
* Protocol Type
* Investigational Drug
* Investigational Device

**Additional fields for ccc*** + Scope (Local or national)
	+ Data Table 4 Report Type
	+ Pilot Flag (Yes or No )
 |
| Accrual Information | MC – OCSCC- PRMS  | * Protocol Target Accrual (Sponsor’s Target Accrual)
* RC Total Accrual Goal (Upper)(UAB’s Target Accrual)
* Accrual Duration (Months)
 |
| Completion Dates | MC - OCSCC- PRMS  | * Primary Completion Date

 *(OCS completes initial entry. Study Team should update as needed.)*  |
| **Management** (horizontal) | MC – OCSCC-REG Team  | * IRB No. (Will begin with “I” followed by nine digits

 e.g. I123456789) |
| CCTS Staff | *The following will be entered by CCTS Staff Only when applicable:* |
| * CCTS Participation
* CCTS No.
* Automated Subject MRN *must be set to “No”*
 | * CCTS Approval Date
* CCTS Category
 |
| Study FIN Teams | *Important Financial Information but Not Mandatory:* * Internal Account No.

*Oracle Accounting String can be entered here if protocol has only one sponsor.* |
| Location | Team Responsible  | Required Fields |
| Administrative GroupsCCC | MC – OCSCC- PRMS  | * Management Group
* “Primary” check box

**Additional fields for ccc*** Program Area
* Disease Oriented Work Group

Mark one as Primary (Mngmt Grp; Prog Area; or Dis. Oriented Wk Grp  |
| **STAFF** (horizontal)  | MC - OCSANDMC-Study TeamCC- REG Team | **PI, Study Coordinator, and Billing Contact**, at minimum for CTBN/billing and PowerTrials (IMPACT) purposes* Role
	+ **Note:** choose one staff member for “Study Coordinator” role; other coordinator staff should be marked as “Study Coordinator-Secondary”
* Staff Name
* Start Date *(Click “Edit” to review Start and Stop Dates.)*
* Stop Date (*Required when staff changes.)*
 |
| **SPONSOR** (horizontal) | MC – OCSCC- PRMS  | * Sponsor Name
* Sponsor Protocol No. (*if one is provided by sponsor)*
* “Principal Sponsor” box checked for one sponsor

Click Grant/Contract hyperlink* Fund Acct. No. Enter the Protocol’s Award Number in this field. *(for Greenphire payment and will appear on the OnCore invoice)*
* Grant No. Enter PO number

*Both the Award and PO numbers will appear on the OnCore invoice.* |
| Financial Team |
| **IND/IDE** (horizontal) (Enter for whichever is applicable) | MC – OCSCC- PRMS  | * ID #
* Holder Type
* Holder name
* Click “Save”
 |

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| Location | Team Responsible  | Required Fields |
| TREATMENT TAB (vertical) |  |
| **DETAILS** (horizontal)  | Calendar Builders | *(Protocols must have at least one Arm.)** Step Code
* Step Type
* Click on “Arms” hyperlink to see:
* Arm Code
* Arm Description

Click Modalities/Drugs/Devices* Appropriate modality/drug/device information should be entered
 |
| **Disease/Diagnosis** (horizontal) | MC -Study TeamCC- Cal. Bldrs. | * Diagnosis (grouping)
 |
| INSTITUTION TAB(vertical) |
|  | MC – OCSCC- PRMS  | * Institution

*(“The University of Alabama At Birmingham” and participating institutions, if applicable.)* |
| STATUS TAB (vertical) | CCC  *additional fields required for Cancer Center trials* |
| **STATUS** (horizontal) | Appropriate Teams | * Click on appropriate signoffs when appropriate
* Signoff date
* Initiator
* Reason
 |
| NOTE: UAB will be depending on OnCore Research Insights reporting tool for overall protocol metrics. Therefore, it will be imperative to update protocol statuses, especially Closed to Accrual AND IRB Study Closure at the appropriate time.  |
| **TASK LISTSCCC Only** (horizontal) | CC Activation Staff | The ***Time to Activation*** task list is used by the CCC protocol activation staff to record and track protocol activation milestones and activities.* “Actual Date” fields are mandatory. “Planned Date” fields are not.
* Comments detailing activation activity, as applicable

Initiate ***Metrics*** task list if Management Group is “CTO-CC.”  |

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| Location | Team Responsible  | Required Fields |
| REVIEWS TAB (vertical)  |
| **IRB** (horizontal)Review Information | MC-Study TeamCC - REG Team | * Review Date
* Submit Date
* Committee
* Review Reason

(NOTE: *Initial entry must be* *“Initial Review” option.)** Review Type
* Action
* Action Date
* Expiration Date
* Click SUBMIT
* Then go to DETAILS
 |
| Details | MC-Study TeamCC - REG Team | * Type: MUST ENTER SOME TYPE OF CONSENT – THIS FLOWS TO SUBJECT CONSENT TAB.
* Amendment No. *(if applicable)*
* Version Date
* Description

*(This is helpful as items are added annually in this area.)** Global? *(if applicable)*
* Re-consent Required?

*(if applicable for participating institutions)* |

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| Location | Team Responsible  | Required Fields |
| ePRMS Module (Cancer Center Only) |
| SUBMISSION CONSOLE |
| Competing Protocols | CC- PRMS  | * If Yes, UAB #
* Attach: Protocol, ICF, IB (required for Phase I)
 |
| Documents  |  | Competing Protocols? Yes / No |
| COORDINATOR CONSOLE |
| Review Detail | CC- PRMS  | * Meeting Date
* Review Name
* Role
* Attach review document (2 primary reviewers, 2 biostats review, 1 radiology, 1 nursing)
 |
| Decision Detail |  | * Decision
* Priority score
* Action date
* Renewal date
* Attached review summary document
 |

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| Location | Team Responsible  | Required Fields |
| **SUBJECTS Module** > CRA Console |  |
| NEW SUBJECT REGISTRATION (vertical) |  |
| Subjects enrolled in trials with Hospital clinical billables as determined by the Office of Clinical Billing Review must have a UAB MRN assigned. If subject has no UAB MRN obtain one by emailing theses details to the following HIM personnel using the MRN Request Form found *by clicking “Additional Forms” on the OnCore Website*: [*https://www.uab.edu/CCTS/Research-Commons/OnCore/Resources*](https://www.uab.edu/CCTS/Research-Commons/OnCore/Resources)SUBJECT DETAILS: Name; DOB; SSN; Address; and Gender is helpful. SEND TO: John Rooney – jrooney@uabmc.edu and Latonia Todd  - lrtodd@uabmc.edu; CC the HIM Manager, Jean Griffith - jagriffith@uabmc.edu  |
| **FIND Subject***The search is conducted in OnCore first. If not found, then an EMMI search will be conducted.*  | MC - Study TeamCC- CTO-OVO | * SITE
* MRN
 |
|  | MC- Study Team CC- CTO - OVO | * Enter Ethnicity (*Does not flow from EMMI*)
* Enter Race (*Does not flow from EMMI*)
* Ensure Social Security Number is entered

(*for Greenphire payment)** Click “Add”
 |
| From CRA Console click on MRN hyperlinkSUBJECTS Console |
| DEMOGRAPHICS**CCC**  (vertical) | CCC  *additional fields required for Cancer Center trials* |
|  | MC- Study TeamCC- CTO-OVO | * Please do not change information in Subject Demographics Section
* Review Subject Demographics Update page
* Can enter Emergency Contact

*(if desired by your management group but not mandatory)***Additional fields for ccc*** Identifier Type (Enrolling Physician)
 |

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| Location | Team Responsible  | Required Fields |
| **CONSENT** | MC- Study TeamCC- CTO-OVO | * Select Consent(s) signed
* Signed Date
 |
| **ELIGIBILITYCCC** | MC- Study TeamCC-CTO-OVO | * Eligibility Status
* If “Not Eligible”, complete Reason Not Eligible fieldNEW
* Status Date

**Additional fields for ccc*** + Verified By
 |
| **ON STUDYCCC** | MC- Study TeamCC- CTO -OVO | * Sequence No.

*(unique identifier for this subject on this protocol)** On Study Date

**Additional fields for ccc*** Zip at Registration
* Disease Site
* Histology
* Study site
* Subject staff (Add SC, DM, PI, and Enrolling Physician)
 |
| **TREATMENT** (*All Subjects should be on an arm even if only one arm exists.)* | MC- Study TeamCC- CTO-OVO | * Choose Arm
* On Arm Date
* On Treatment Date
 |
| **FOLLOW UP** (*when appropriate for the subject*) | MC- Study TeamCC- CTO-OVO | * Off Treatment
	+ Off Treatment Date
	+ Off Treatment Reason
* Off Study
	+ Off Study Date
	+ Off Study Reason
* Follow-Up Update *(if applicable)*
	+ Follow-Up Start Date
	+ Follow-Up Stop Date
	+ Expired Date (if applicable)
 |
| **SAEs** | MC- Study TeamCC- Study Coordinator | * Event Date
* Date Reported
* Outcome

**Additional fields for ccc*** + Narrative: Enter event and grade details
 |

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| Location | Team Responsible  | Required Fields |
| **FINANCIALS Module** > Financials CONSOLE *Additional fields may be required to fulfill the stipulations of the contract. Refer to financials Reference Guides for more information.* |
| **PARAMETERS** |  |  |
| Budget Related | MC – OCSCC-Budget Team  | * Rate Base
* Default Sponsor
 |
| Invoice Related | MC – FIN TeamCC-Budget Team  | * Maximum Screen Failures
* No. of SAEs After Which Sponsor Will Be Invoiced
* Milestone Invoiceable Visit Prerequisite

*(will default to Occurred and should* ***not*** *be changed)* |
| Remit To | MC – FIN TeamCC-Budget Team  | * Organizational name
* Contact
 |
| Bill To | MC – FIN TeamCC-Budget Team  | * Organizational name
* Contact
 |
| **PROTOCOL RELATED** |
|  | MC – FIN TeamCC-Budget Team  | * Protocol Related Events

*(UAB Financial Recommendations entered by OCS, events may be removed or added as needed)** Negotiated

*(Negotiated amounts should be entered for all events with negotiated costs.)** “Variable?” check box, if applicable
 |
| **SUBJECT RELATED** |
|  | MC – FIN TeamCC-Budget Team  | * Negotiated

*(Negotiated amount should be entered for applicable procedures with a Charge Type set to Milestone or Pass Thru.)* **NOTE:** Charge Type should never be changed to or from the SOC designation. |

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| Location | Team Responsible  | Required Fields |
| **MILESTONES** |
|  | MC – FIN TeamCC-Budget Team  | * SAE

*(may be updated by study team as needed)** Screen Failed
* Subject Visits that are invoiceable should be selected
* Total Negotiated Amount

*(should be entered for all applicable milestones)***REMINDER: Confirm the entry of the Fund Acct Number and PO Number described in the SPONSOR Tab section as these have invoice template implications.** |

# Medical Center Protocol Number Nomenclature

*THIS WILL NOT AFFECT ANY PROTOCOL NUMBERS THAT WERE MIGRATED FROM SITEMINDER. THE NEW NOMENCLATURE APPLIES TO MEDICAL CENTER PROTOCOLS THAT WILL BE ENTERED IN ONCORE BY INTERNAL STAFF GOING FORWARD FROM GO-LIVE DATES.*

*NEW OnCore Protocol Numbers for the Medical Library will be comprised of three parts:*

1. *Management Group abbreviation*
2. *“I, F, W, X” then IRB Number*
3. *Study Acronym/Sponsor Number (study team’s choice).*

*For example, a Pulmonology protocol with an acronym of LIBERATE will be*

PUL-I123456789-LIBERATE*.*

*The following Department/Division management group abbreviations will be used when adding new, Medical Library protocols to OnCore.*

|  |  |  |
| --- | --- | --- |
| **Department Name** | **OnCore Management Group** | **3 letter naming convention** |
| Anesthesiology | Anesthesiology | ANE |
| Clinical Nutrition | Clinical Nutrition | CLN |
| Dermatology | Dermatology-Clinical Research | DCR |
| Dermatology | Dermatology-Grants | DGR |
| Emergency Medicine | Emergency Medicine | ERM |
| Genetics | Genetics - MC | GEN |
| Health Behavior | Public Health-Addiction | PHA |
| Medicine | Cardiology | CAR |
| Medicine | Endocrinology | END |
| Medicine | Gastroenterology and Hepatology (GI/Hep) | GIH |
| Medicine | General and Internal Medicine | GIM |
| Medicine | Gerontology | GER |
| Medicine | ID-HIV | IDH |
| Medicine | ID-STI | IDS |
| Medicine | ID-CTG | IDC |
| Medicine | Nephrology CTG | NEC |
| **Department Name** | **OnCore Management Group** | **3 letter naming convention** |
| Medicine | Nephrology Trans | NET |
| Medicine | Preventive Med - MC | PRM |
| Medicine | Pulmonology - MC | PUL |
| Medicine | Rheumatology | RHU |
| Neurology | Neuro-Muscular | NMU |
| Neurology | Multiple Sclerosis | NMS |
| Neurology | Stroke | NST |
| Neurology | Movement Disorder | NMD |
| Neurology | Epilepsy | NEP |
| Neurology | Memory Disorders | NME |
| Neurology | Neuropsychology | NPS |
| Neurology | Neuropathology | NPA |
| Neurology | Sleep/Wake Disorders | NSD |
| Neurosurgery | Neurosurgery - MC | NSU |
| OB/GYN | OB/GYN - MFM | MFM |
| OB/GYN | URO/GYN | URG |
| Optometry | Optometry | OPT |
| Oral and Maxillofacial Surgery (OMFS) | Oral & Maxillofacial Surgery  | OMS |
| Orthopedic Surgery | Orthopedic Surgery | OSU |
| Otolaryngology (OTOL) | Otolaryngology | OTO |
| Pathology | Laboratory Medicine | PLM |
| Pediatrics | PEDS: Adolescent Medicine | PAM |
| Pediatrics | PEDS: Allergy & Immunology | PAI |
| Pediatrics | PEDS: Cardiology | PCA |
| Pediatrics | PEDS Child Abuse | PCH |
| Pediatrics | PEDS: Critical Care | PCC |
|  | PEDS: Developmental and Behavioral  | PDB |
| Pediatrics | PEDS: Emergency Medicine | PEM |
| Pediatrics | PEDS: Endocrinology | PEN |
| Pediatrics | PEDS: Gastroenterology, Hepatology, & Nutrition | PGA |
| Pediatrics | PEDS: General Pediatrics | PGP |

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| **Department Name** | **OnCore Management Group** | **3 letter naming convention** |
| Pediatrics | PEDS: Hem/Onc | PHO |
| Pediatrics | PEDS Hospital Medicine | PHM |
| Pediatrics | PEDS: ID | PID |
| Pediatrics | PEDS: Neo | PNE |
| Pediatrics | PEDS: Nephrology | PNP |
| Pediatrics | PEDS: Neurology | PNU |
| Pediatrics | PEDS: Pulmonary | PPU |
| Pediatrics | PEDS: Rehabilitation Medicine | PRE |
| Pediatrics | PEDS: Rheumatology | PRH |
| Physical Medicine and Rehabilitation (PM&R) | Physical Medicine and Rehabilitation | PMR |
| Psychiatry | Psychiatry | PHI |
| Psychology | Psychology-Pain | PSP |
| Psychology | Psychology-Therapy | PST |
|  Psychology | Psychology-HIV | PSH |
| Radiology | Molecular Imaging, Therapeutics, and Advanced Medical Imaging Research | RIT |
| Radiology | Interventional Radiology | RIN |
| Radiology | Breast Imaging | RBI |
| Radiology | Diagnostic Radiology | RDI |
| Surgery | Cardiothoracic Surgery | SCT |
| Surgery | Gastrointestinal Surgery | SGI |
| Surgery | Vascular & Endovascular Surgery | SVE |
| Surgery | Acute Care Surgery | SAC |
| Surgery | Pediatric Surgery | SPE |
| Surgery | Plastic Surgery | SPL |
| Surgery | Transplantation Surgery | STR |
| Urology | Urology | URO |

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| DATE | TAB Location | CHANGES |
| 11.3.217 | STAFF | Added specific roles to add for CTBN purposes |
|  | SPONSOR | Add Oracle account string to Contract/Grant> Fund Acct No. field |
|  | STATUS | Added information about necessity of using Close to Accrual and IRB study Closure buttons.Enter date fields |
|  | REVIEWS | Added “IRB” to heading |
|  | SUBJECTS | Demographics – Added Enter Identifier owner as protocol number. This allows tracking of multiple, unique referring physicians |
|  | FINANCIALS | Added Rate Base |
| 11.28.217 | SUBJECTS | Removed reference to physician referral documentation |
|  | TASK LISTS | Added comment |
|  | MAIN/Details | Added short title |
|  | MAIN/Mang’t | Added IRB example |
|  | MAIN/Mang’t | Changed response to CCTS Participation field by MGs |
|  | Subject Search | Added MRN information |
| 12.7.2017 | Final page | Added Protocol Number Nomenclature |
| 4/3/2018 | Final page | Added Wave 2 MG abbreviations |
| 6.28.2018 | All | Reworded to show only mandatory field names as much as possible. Removed instructions explaining how to enter data. Updated instructions for obtaining MRN. |
| 8/24/18 | MAIN/Det’ls | Removed reference to Medical (Library) and Medical Center (OU) |
|  | MAIN/Mang’t  | Added CCTS fields and owner of those fields |
|  | MAIN/Mang’t  | Identified proper response to Automated Subject MR field |
|  | MAIN/Mang’t  | Added description of Internal Account No. field |
|  | MAIN/Sponsor  | Changed information that will be entered in Fund Acc’t No. field |
|  | N/A | Changed name and email addresses of HIM staff who are to receive MRN request form |
|  | N/A | Added table of all Management Groups for Medical Center OU |
|  | N/A | Changed Versioning nomenclature |
|  | Subject Console | Added Cancer Center field requirements |
| 9/21/2018 | Protocol Naming | Added PEDS: Cardiology, PCA |
| 3/24/2020 | Financials Modules | Added required fields |
|  | Protocol Console | Updated CCC required fields  |
|  | Subject Console | Updated CCC required fields  |
|  | Management Groups | Added Pathology – Laboratory Medicine – PLM |
|  | Protocol Naming | Added various PEDS management groups |
| 4/15/2020 | ALL | Formatting changes |
| 6/24/2020 | Subjects/Eligibility tab | Added a required field to assist with reporting values: * If “Not Eligible”, complete Reason Not Eligible field
 |
|  | NCT Number | Field configuration changed to allow “NA” when no NCT number is assigned. OCS will not use NCT99999999 to identify a pending NCT number. |
|  | CC Team name change | From PRC-WG Nav team to PRMS |