OnCore Annotated Cheat Sheet

ePRMS Submission

	OnCore Field	Rutgers-Specific Instruction	OnCore Definition/Functionality
1	Library	Select either "Oncology" or "RBHS" (all non-oncology) as appropriate. This field is not edit-able after initial submission.	Determines the Reference Lists, Forms, Protocol Annotations, Notifications, and Signoffs available for the protocol. This field cannot be changed once the status of the protocol has changed from New.
2	Review Type	Select "Admin" for all studies that are externally initiated, such as pharmaceutical, industry, NIH, or consortium sponsored studies. OR Select "Full" for trials that are locally initiated by a Rutgers investigator.	Determines whether an abbreviated administrative review will be performed or a full scientific review board approval is required (only necessary for IITs).
3	Protocol No.	Enter the unique Rutgers protocol identifier using the following formula, e.g., **NK21-SMITH**: • a trial conducted in Newark that was first identified in 2019 whose principal investigator is Dr. Smith • NK21 = Two-letter abbreviation for study campus location + two-digit year of study initiation • SMITH = Last name of PI • CTO staff will later add additional identifiers to this formula after your initial ePRMS submission based on how many trials the PI has initiated each year.	Indicates the main identifier for a protocol. The protocol number displays in the Protocol Header and is used in most reports. The protocol number is used to find a protocol in any of the Select Protocol find-as-you-type fields throughout OnCore.
4	NCT Number	Enter the NCT number that can be found on clinicaltrials.gov or in the protocol.	The protocol identifier assigned by clinicaltrials.gov.
5	Department	Select the principal investigator's department	Identifies the institutional funding body for the study. Fiduciary reporting is available based upon this field. Additionally, the permission scope of Department is driven off of this field.
6	Title	Enter the full protocol title.	Identifies the full-length name of the protocol. The title populates to other pages within the OnCore application and is displayed in some reports. It is the only title used on the NCI Data Table 4 report. The Title and Short Title both populate the SIP Console.
7	Short Title	Enter the commonly-used nickname/acronym as assigned by the sponsor or the study team.	Contains abbreviated version (100 characters maximum) of the protocol title. The short title entered here populates to other screens within the OnCore application and is displayed in some reports. The Short Title and Title both populate to the SIP Console.
8	Objectives	Enter a brief summary/description of the study and a few of the main objectives. Limited to 500 characters. This field also flows into the eIRB application section "7.1 Study Overview."	Identifies the objective for the protocol according to your institution's SOPs. Objectives populate to the SIP Console and display on the public website.
9	Phase	Select the phase of the trial as indicated in the protocol or on clinicaltrials.gov	Indicates the study phase of the protocol. The phase selected here populates to the SIP Console and displays on

			the public website. Protocol Search provides a Search By Phase option.
10	Scope	Select "Local" for trials that are only being conducted at Rutgers (i.e., investigator-initiated trials). OR Select "National" for trials that are also being conducted at sites outside of Rutgers (i.e., industry-sponsored trials).	Indicates the enrollment scope. Typically, Local indicates the trial will only be open for the research center; National indicates a multi-institutional trial.
11	Age	Select if trial participants include adults, children, or both.	Indicates the age of subject participants. Options are Adult, Children, or Both.
12	Consent at Age of Majority	If Age is indicated as either "Children" or "Both," this field will become active. • Select "Yes" if the trial will require children to consent when they are 18 years of age. • Select "No" if the trial will not require child participants to consent when they are 18 years of age.	Triggers warnings to reconsent subjects at the age of majority when set to Yes. This field is only active when the Age selected is Children or Both.
13	Drug Accountability	Select "Yes" if drug accountability will be required, "No" if drug accountability will not be required, or N/A if drug is not part of the study design.	Indicates whether drugs are being used and recorded within the protocol. Options are Yes, No, or N/A.
14	Investigator Initiated Protocol	Select "Yes" if the local Rutgers principal investigator initiated the protocol.	Indicates whether the principal investigator at the Cancer Center or Research Center initiated the protocol; options are Yes, No, or blank. This field is used in the Data Table 4 Revised -- Clinical Research Protocols report.
15	Involves Therapy	Select "Yes" if the primary study objective has therapeutic intent.	Used with the configuration DISABLE_DUPLICATE_THERAPEUTIC_ENROLLMENT to determine whether a protocol is therapeutic. Options are Yes, No, or N/A.
16	Exclude Protocol On Web	Leave checkbox unchecked.	Excludes the protocol from displaying on the SIP (Study Information Portal) if the box is checked.
17	Open For Affiliates Only	In rare situations, some studies could be conducted solely at non-Rutgers affiliate sites. "No" should be selected unless otherwise indicated by CTO staff.	Indicates if the protocol can be opened for accrual at affiliate sites but not at the Research Center if set to Yes.
18	Summary Accrual Info. Only	Select "No" unless otherwise indicated by CTO staff.	This field is marked as Yes when only summary subject data will be collected for a protocol. This enables the collection of subject accrual data summaries on the Accrual tab in PC Console, and disables the Subjects > CRA Console > Register Subject page. This setting cannot be changed once subjects are accrued to the protocol.
19	Protocol Type	Select the option that best matches what type of clinical intervention the study is investigating. Most common choices will be "Treatment" or "Device Feasibility."	Indicates the type of protocol and is used for reporting purposes. The reference list for this field has a parent of either Therapeutic or Non-Therapeutic.
20	Registration Center	This field captures the type of system in which newly enrolled subjects are registered. Select whichever option fits best.	Typically used to indicate the type of organization responsible for subject registration.
21	Involves Correlates or Companions	This field enables OnCore to link multiple studies if they are related. "No" should be selected unless otherwise indicated by CTO staff.	Enables the Correlates & Companions tab in the PC Console when set to Yes. This tab allows you to do two things: assign companion studies and track correlates (basic specimen collection information).

22	Data Monitoring	Select the option that best matches the study's data and safety monitoring board or committee.	Records the party responsible for monitoring the protocol data.
23	Adjuvant	"N/A" should be selected unless otherwise indicated by CTO staff. This field captures whether or not the study treatment is subsequent to the primary treatment (primarily for Oncology).	Indicates that the study drug is enhancing or otherwise affecting the impact of another treatment, if set to Yes.
24	Includes Specimen Banking?	This checkbox should only be selected if OnCore's specimen banking module will be used to manage the specimen samples. This checkbox should not be selected unless otherwise indicated by CTO staff.	Indicates whether the protocol is a specimen banking protocol. Checking this box causes the Specimen Collection Configuration tab to display. It also indicates that consent records are tracked in the Specimen Collection Console instead of Subject Console > Consent.
25	Companion Study?	This checkbox should only be selected if the sponsor has a "companion" or "sister" study on which Rutgers is also participating. This box should typically remain unchecked.	Indicates that this protocol is a companion to another study.
26	Multi-site Trial	Select "Yes" if the study will be conducted at more than one site.	For non-oncology protocols, this is an information-only field and does not drive any OnCore functionality.
27	Investigational Drug	Select the option that best matches the protocol design.	This field sets the value of the Investigational Drug field on the Main > IND/IDE tab, and vice versa.
28	Precision Trial	This field is primarily relevant to Oncology. "No" should be selected unless otherwise indicated by CTO staff.	Indicates whether the protocol uses precision medicine.
29	Precision Trial Classification	This field is primarily relevant to Oncology. This field will not be active if "Precision Trial" is selected at "No."	If Precision Trial is set to Yes, users can set a value in this field to further classify the precision trial.
30	Pilot	Select "Yes" only if the study is a pilot study.	Indicates whether the study is a pilot phase.
31	Investigational Device	Select the option that best matches the protocol design.	This field sets the value of the Investigational Device field on the Main > IND/IDE tab, and vice versa.
32	Rare Disease	Select the option that best matches the protocol design.	Indicates whether the protocol is rare disease.
33	Certificate(s) of Confidentiality	Select "Yes" if the study has a certificate of confidentiality.	
34	GCRC Participation	The label for this field is related to the General Clinical Research Center. Select "No" unless instructed otherwise.	Select from the drop-down list. The label for this field and others related to the General Clinical Research Center is configurable and therefore might be different in your system. In the image above, the label has been configured as CTSI rather than GCRC.
35	Protocol Target Accrual	Enter the sites target for local subject enrollment throughout the duration of the entire enrollment period. If an estimate was provided as part of a sponsor's	Use the Protocol Target Accrual to enter the number of subjects to accrue for the protocol. The target accrual number entered displays in the top header of most screens within OnCore and will populate in some reports. This

		feasibility or qualification process, enter that estimate here.	number also triggers the system-generated Protocol Target Accrual Met notifications if the notification is activated.
36	RC Total Accrual Goal (Lower)	Enter a more conservative estimate of enrolled subjects that might take into account unforeseen or unlikely enrollment barriers throughout the duration of the enrollment period. (RC is short for Research Center)	Indicates the minimum side of the range for the research center total accrual. Enter the minimum number of subjects to accrue for the research center running the protocol. If there is no upper goal, enter the total research center accrual in this field. The Low Accrual Report utilizes this field.
37	RC Total Accrual Goal (Upper)	Enter a more liberal estimate of enrolled subjects in the event there are more eligible subjects than expected throughout the duration of the enrollment period. (RC is short for Research Center)	Indicates the maximum side of the range for the research center total accrual. Enter the maximum number of subjects to accrue for the research center running the protocol.
38	RC Annual Accrual Goal	Enter the enrollment estimate in a twelve month period. (RC is short for Research Center)	Indicates the estimated number of subjects that will accrue for the year at the research center running the protocol.
39	Affiliate Accrual Goal	In some situations, a study may work with a non-Rutgers affiliate site. "0" should be entered unless otherwise indicated by CTO staff.	Indicates the estimated number of subjects that will accrue at the Affiliates running the protocol. This field should include any institution but the research center (e.g. affiliate institutions and VA.)
40	Accrual Duration (Months)	Enter the period of time the sponsor expects enrollment to remain open in months. If a sponsor does not specific, please enter a best estimate.	Indicates the estimated number of months the protocol will be accepting subjects to accrue.
41	Primary Completion Date	Enter the date that the sponsor aims to complete all interventions and procedures as they relate to the primary objective and data collection. "Anticipated" should be selected until the sponsor has concluded all such interventions and procedures, at which point an "Actual" date should be updated and populated.	The date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical trial concluded according to the pre-specified protocol or was terminated. For active studies, select Anticipated and specify the expected completion date, updating the date as needed over the course of the study. Upon study completion, select Actual and update the date if necessary.
42	Study Completion Date	Enter the date that the sponsor aims to complete all study-related activity, e.g., regulatory maintenance. "Anticipated" should be selected until the study has fully closed, at which point an "Actual" date should be updated and populated.	Final date on which data was (or is expected to be) collected. Use the Anticipated or Actual choices as described above.
43	Administrative Groups	In the pop-up window, select the appropriate group(s) that will support the study, if applicable.	N/A
44	Diagnosis Group	In the pop-up window, select the most relevant diagnosis category or disease under study.	N/A
45	Institutions	In the pop-up window, select Rutgers University, then, when the main webpage updates, select the applicable school/affiliate.	N/A
46	Sponsors	In the pop-up window, select the sponsor(s) and/or CRO of the trial. If the sponsor does not appear in the list, the CTO can add it to the list by request.	N/A
47	Competing Protocols	If you are aware of any competing trials, select the protocol from the pop-up window, then choose Add. If none, select the "No Competing Protocol" checkbox.	N/A
48	Documents	The following documents types are required to the uploaded, as applicable:	Version dates for each document are required fields, but description and expiration date fields are optional.

		1. protocol, 2. draft consent form(s), 3. draft contract, 4. draft budget, 5. contact information for sponsor/CRO 6. partner hospital application 7. FDA Form 1572 Additional documents, such as lab/imaging manuals, IBs, sponsor feasibility questionnaires, etc. are welcomed.	
49	Protocol Staff	Include as many protocol staff as possible, including contacts for regulatory, study coordinator, PI, sub-I, research nurse, research pharmacist, billing/finance manager, etc. • If a staff member's name does not populate, they will need to request OnCore access from the CTO. • If the study team has used OnCore for a different study, choose "Select Team" and type in the prior study to copy an entire study team to the protocol, rather than individual staff.	Adding staff members to this list will allow them to view and access this specific study in OnCore.
50	Signoffs	This field does not require data entry and should be left blank.	N/A