UK Clinical Research Support Office

OnCore/Epic – Research Team RPE Checklist

This checklist is a guidance document for research teams outlining tasks and data entry in OnCore in preparation for protocols sent to Epic.

These items must also be maintained throughout life of the protocol.

Processes to be completed outside of OnCore:

Workflow Process	Comments
Study team members responsible for updating information in OnCore request login access.	CTMS Login Access Qualtrics form: https://uky.az1.qualtrics.com/jfe/form/SV_cAfhHoNTquxO6Vv
Study team members requesting login access signup and perform their role-based training.	The CTMS trainer should contact you after completing the login request access Qualtrics form. If you have any questions or need help email the CTMS.support@uky.edu
Fill out REDcap request for Protocol/Calendar and Coverage Analysis, Financial Services, or Regulatory Services.	You must become a CCTS member and then click on the button entitled "Request Service": https://cctsdata.uky.edu/membership/ **NOTE:** You must check CRSO (CTMS calendar/Coverage Analysis) under the Request Service Information. **NOTE:** Add optional Grants Financial Management/Regulatory Management as a fee-based service for your protocol.
Fill out REDcap request for all protocol amendments.	https://redcap.uky.edu/redcap/surveys/?s=33X4PXNPJL **NOTE:** All amendments to the protocol are to be sent to the CRSO for review. You will be able to indicate on the REDcap form if it is only administrative changes or ones with substantial content changes.
Clinicaltrials.gov Registration	Any NIH-defined clinical trial with billable services to a 3rd party insurance company or to the patient must register with CT.gov. Additional information and guidance can be found on the OSPA website here: https://www.research.uky.edu/office-sponsored-projects-administration/clinicaltrialsgov
Investigational Drug and Investigational Device Registration for approved use by FDA.	For more information on registering an IND: https://www.fda.gov/drugs/types-applications/investigational-new-drug-ind-application For more information on registering an IDE: https://www.fda.gov/medical-devices/investigational-device-exemption-ide/ide-application
CGS Initial IDE and Humanitarian Use Device Approval	For more information on CGS Initial IDE approvals: https://cgsmedicare.com/partb/pubs/news/2014/1214/cope27849.html For more information on CGS and HUD approvals: https://cgsmedicare.com/partb/pubs/news/2013/1213/cope24209c.html
Clinical Trial Agreement from OSPA	For more information about Clinical Trial Agreements with UK OSPA: https://www.research.uky.edu/office-sponsored-projects-administration/clinical-trial-agreements
Grant Account/Cost Center / Internal Account #	For more information about Research Financial Services at UK: https://www.uky.edu/ufs/research-financial-services

Financial Budget using the Coverage Analysis	Contact the CRSO Financial Manager for more information: Patty Coleman Patricia.Coleman@uky.edu 859-562-2838	

Data Entry in OnCore:

Fields in OnCore	Location in OnCore	Comments
Staff Tab	PC Console > Main > Staff	The staff list must be maintained with any key personnel change at the IRB. **NOTE:** One Primary Study Contact, Principal Investigator, and any staff member responsible for performing the 1st tier billing review should be listed for any protocol going to Epic. **NOTE:** Adding key personnel will allow those users access to Epic research-related dashboards, components, and reports.
NCT Number	PC Console > Main >Details	The NCT No. must be entered prior to sending the protocol to Epic.
IRB Review Information	PC Console > Reviews > IRB	IRB Initial Approval must be entered as the first status making the protocol eligible to be sent to Epic pending all other required fields are filled out. All continuing reviews must be entered. Any major Modification Reviews (amendments) where changes to the Protocol or Consent occur – must be entered.
Protocol Status	PC Console > Status	All protocol status must be updated in OnCore within 24-hours (business days) of the true status change. All status changes from IRB Initial Approval until IRB Study Closure/Terminated will be sent to Epic.
IDE #	PC Console > Main > IND/IDE	Protocols with an approved Investigation Device Exception number must have it entered in OnCore for Epic and UKHC billing compliance.
Internal Account Number	PC Console > Main > Management	The protocol Grant number, Cost Center, SIO, or department internal account number must be entered.
Consent Date	Subject Console > Consent	Any subject enrolled into a protocol that is enabled to go to Epic must have their consent date entered. This is the first status can will automatically flag a patient in Epic. **NOTE:** All subject status updates must be entered into OnCore within 24-hours (business days) of the date the true status change.