May 11, 2020

TRAcs – Menu

Below is a list of the options available in the UMCCTS TRAcs along with the files to be uploaded and required information. Files without notations or information listed without notations are required. Notations: (opt) = optional; (if applic) = if applicable

"Pass through" means that UMCCTS staff will forward the request to the appropriate service provider.

Some selected options will direct the user to the affiliated web pages to make their request.

COVID FastTracs – If you have an incomplete submission related to COVID-19 research, you can use the option for COVID-19 FastTracs. This option allows you to upload a number of files, without requiring all the files. The request will not be competed until all the files are available, but the OCR staff will be able to start the process, to the best of their ability, given the available documents.

TRAcs option	Documents to Upload / Required information	Service Provider Responsible
Protocol Start Up or Implementation		
Biorepository & Tissue bank • Obtain samples from the Biorepository/Tissue Bank • Provide samples to the Biorepository/Tissue Bank • Letter of support • Consultation • Request a quote • Other	Draft Letter of Support (if applic, opt)	Biorepository & Tissue bank staff Email notification to core by TRAcs Administration
Clinical Research Center • Clinical (blood draws, blood pressure etc.) • Space (clinic rooms, freezer storage, etc) • Data management (entry, etc) • Full study coordination • Update to an existing service agreement • Other • Not sure, want to ask a question • Regulatory services	Protocol or study plan Informed consent form Investigator Brochure (opt) Lab manual (opt)	CRC staff
Office of Clinical Research (OCR) : Contracts & Budgeting / Revise OnCore Information / EPIC Research Access	Space for additional document (opt)	
• Have/want a new Data Use Agreement (DUA)	Email requesting contract agreement IRB approval letter Draft DUA (if applic, required)	OCR - Research Compliance Contracts
• Have/want a new Confidentiality Disclosure Agreement (CDA) or Non-Disclosure Agreement (NDA)	Confidentiality Disclosure Agreement (CDA) (if applic) Email from sponsor (opt)	OCR - Research Compliance Contracts

TRAcs option	Documents to Upload / Required information	Service Provider Responsible
• Have/want a new Clinical Trial Agreement (CTA)	Protocol or study plan Informed consent form Sponsor budget NCT number IDS Pharmacy Budget Draft Clinical Trial Agreement CRC service agreement (if applic) Proposal Routing Form Investigator Brochure (opt) Lab manual (opt) Email from sponsor (if applic) IND or IDE Waiver (if applic)	OCR – Preaward OCR - Research Compliance Contracts
• Have a newly awarded clinical research grant	Protocol or study plan Informed consent form NCT number Notice of Grant Award Budget template ~~or~~ with schedule of events or schedule of events PIN Report (account number) IND or IDE Waiver (if applic) Investigator Brochure (opt) Lab manual (opt)	OCR - Preaward
• Have/want a new federally-funded cooperative group trial	Protocol or study plan Informed consent form Master/ Clinical Trial Agreement(s) Study fund sheet NCT number National coverage analysis (opt) IND or IDE Waiver (if applic) CRC service agreement (if applic) Proposal Routing Form or PIN Report (account number) (if needed)	OCR - Preaward
• Have a new internally-funded clinical research trial	Protocol or study plan Informed consent form Budget template/schedule of events NCT number Account number for invoices IND or IDE Waiver (if applic) CRC service agreement (if applic)	OCR - Preaward
• Have a protocol or contract amendment	Protocol/calendar - tracked Budget/contract – tracked	OCR - Preaward
• Need to revise/correct OnCore information	Protocol/calendar - tracked Budget/contract – tracked	OCR - Preaward
• Would like to obtain a Certificate of Confidentiality	IRB Approval letter Informed consent form UMMS CoC letter signed by the PI	OCR - Preaward

TRAcs option	Documents to Upload / Required information	Service Provider Responsible
• Want to submit a clinical research account closure request	Account closure form (opt) Reconciliation/tracking in any format Sponsor payment history (opt) PeopleSoft Reports/Summit Screen	OCR - Preaward
• Need review/processing an Institutional Prior Approval (IPA) for a change in budget	IPA form	OCR - Preaward
• Need help with the Conquering Diseases clinical study opportunities portal		TRAcs Navigator
• Need new user access for Epic		OCR - Postaward
• Don't know/ I want to ask a question	Space for additional document (opt)	TRAcs Navigator
Investigational Drug Services • Pricing for clinical trial support services • Set up to dispense drugs for a clinical study • Assistance with obtaining or renewing a Massachusetts Controlled Substances Registration (MCSR) for clinical research	Protocol or study plan Informed consent form Pharmacy manual (opt) Investigator Brochure (opt)	IDS Staff
IRB consult or question • Extramural Institutional Certification • IRB question / consult		TRAcs Administration
Clinical Trials.gov assistance • I need an account for myself • I need an account for someone else • I need help with entry / maintenance / navigation • Assistance determining whether an NCT number is required for my study • Other		OCR - Research Compliance Contracts
Protocol Review Committee	Protocol or study plan Informed consent form Feasibility checklist	TRAcs Navigator
Recruitment Resources		
Connect to Conquering Diseases or ResearchMatch research volunteer registry members about participation in a study • Access to volunteer registry for recruitment		TRAcs Navigator
Community Engagement		Directed to Community Engagement forms Email confirmation by TRAcs Administration

TRAcs option	Documents to Upload / Required information	Service Provider Responsible
Informatics (Data Lake, TriNetx, Cohort Identification) • Obtain data for research • Request a consultation • Request a TriNetX account		Directed to appropriate IT forms Email confirmation by TRAcs Administration
Interpreter or Translation Services for Research • Over the phone interpreter services • Video interpreter services • In-person interpreter services • Translation services		TRAcs Navigator
Research Navigator Service (consult) • Consult with the Navigator • Access to volunteer registry for recruitment • Information about the Trial Innovation Network (TIN) infrastructure and resources for multi-site trials • I'm not sure, I want to ask a question		TRAcs Navigator
Other Services or Requests		
Bioinformatics		Email notification to Bioinformatics by TRAcs Administration
CCTS Membership		TRAcs Administration
Education / Training / CRPG • I would like to take a Study Coordinator course • I would like to request individual Education or Training for me or my team (describe below) • Include me on the Clinical Research Professional Group (CRPG) email list		CCTS Educator
Funding • Interested in learning about UMCCTS funding opportunities • Interested in collaborating on UMCCTS pilot grant • Interested in other UMass funding opportunities • Interested in external funding opportunities • Other		CCTS Administration
Library Services		Directed to library forms

TRAcs option	Documents to Upload / Required information	Service Provider Responsible
Massachusetts Medical Device Development Center (M2D2) • I am interested in M2D2 funding opportunities • I am interested in M2D2 educational events • I am interested in talking about renting M2D2 space • I am interested in learning about M2D2 resources and services • Other		CCTS Administration
Quantitative Methods Core		Directed to QMC forms Email confirmation by TRAcs Administration
Small Molecule Screening Facility • SMSF Equipment use • Design of screening assays • Letter of support • Consultation • Request a quote • Other	Draft letter of support (opt)	Ann Han or Margaret McManus – pass through to SMSF
Science Participation Research Center (SPRC)		SPRC staff Email notification to SPRC by TRAcs Administration
Study Audit (Internal, QA)		CCTS Educator
Umbilical Cord Blood Core		Cord Blood Core staff Email notification to core by TRAcs Administration
Miscellaneous Study Conduct (e.g. lab certs, MCSR, etc) • I would like to a copy of the lab certifications • I would like information about MCSR (Massachusetts Controlled Substances Registration) • Add sponsor to eIRB and /or OnCore • Other		TRAcs Navigator
I can't find what I need		TRAcs Navigator

For more information:

Any questions can be directed to Clinical Research Navigator ann.han@umassmed.edu

who will be happy to assist you.

Questions related to OCR can be directed to: clinicalresearch@umassmed.edu