January 6, 2023

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.

OSP/Bridge Central Office requests should follow the JobAid to Submit a TRAcs request from OSP/Bridge or a Central Office. These submissions must come directly from the central office staff and ***NOT*** from the study team.

COVID FastTracs has been disabled at this time. Enter any COIVD related request in the usual manner, but indicate that the request is COVID-related (and RADx related, if applicable).

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 • Clinical trial services support (need a Biorepository Agreement) • Other	Description of request Draft Letter of Support (if applic, opt) For clinical trial services support/ biorepository agreement: - Protocol - Lab Manual (if available)	Biorepository & Tissue bank staff
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 • Pricing only - estimates for a proposed project • Other • Not sure, want to ask a question	Protocol or study plan Informed consent form Investigator Brochure (opt) Lab manual (opt)	CRC staff
Office of Clinical Research (OCR) : Contracts & Budgeting	Space for additional document (opt)	

TRAcs option	Documents to Upload / Required information	Service Provider Responsible
• OSP/Bridge Central Office Consult Request *(OSP/Bridge Central Office personnel only)*	Brief summary from OSP/Bridge Central Office staff Relevant Documents (opt) Deadline Request must be from OSP/Bridge Central Office Personnel Staff Only	OCR- Contract Team
• Have/want a new Data Use Agreement (DUA)	Email requesting the agreement (required) IRB approval letter (if applic, required) Draft DUA (if applic, required)	OCR – Contract Team
• Have/want a new Confidentiality Disclosure Agreement (CDA) or Non-Disclosure Agreement (NDA)	Email from sponsor (required) Confidentiality Disclosure Agreement (CDA) (if applic)	OCR – Contract Team
• Have/want a new Clinical Trial Agreement (CTA)	Protocol or study plan Informed consent form Sponsor budget NCT number eIRB study number External IRB study number (if applic) IDS Pharmacy Budget Draft Clinical Trial Agreement CRC service agreement (if applic) Funding Proposal No. from RMS (required) Investigator Brochure (opt) Lab manual (opt) Email from sponsor (required) IND or IDE Waiver (if applic) Feasibility Form (required)	OCR – Preaward OCR – Contract Team
• Have a newly awarded clinical research grant	Protocol or study plan Informed consent form NCT number eIRB study number External IRB study number (if applic) Notice of Grant Award Budget template with schedule of events or schedule of events Funding Proposal No. from RMS (required) IND or IDE Waiver (if applic) Investigator Brochure (opt) Lab manual (opt)	OCR - Preaward

TRAcs option	Documents to Upload / Required information	Service Provider Responsible
• 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 eIRB study number External IRB study number (if applic) National coverage analysis (opt) IND or IDE Waiver (if applic) CRC service agreement (if applic) Funding Proposal No. from RMS (required)	OCR - Preaward
• Have a new internally-funded clinical research trial	Protocol or study plan Informed consent form Budget template/schedule of events NCT number eIRB study number External IRB study number (if applic) Speedtype or FP number for invoices IND or IDE Waiver (if applic) CRC service agreement (if applic)	OCR - Preaward
• Compassionate use/Emergency Use Agreement		
• Have a protocol or contract amendment	Protocol/calendar - tracked Budget/contract – tracked	OCR – Postaward
• Need to revise/correct OnCore information	Protocol/calendar - tracked Budget/contract – tracked	OCR – Postaward
• Would like to obtain a Certificate of Confidentiality	IRB Approval letter Informed consent form UMMS CoC letter signed by the PI	OCR - Varies
• Want to submit a clinical research account closure request	Account closure form Reconciliation/tracking in any format Sponsor payment history (opt) Summit Screen	OCR – Postaward
• Need review/processing an Institutional Prior Approval (IPA) for a change in budget or extend study period	IPA form	OCR - Postaward
• Need help with the Conquering Diseases clinical study opportunities portal		TRAcs Navigator
• 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

TRAcs option	Documents to Upload / Required information	Service Provider Responsible
IRB consult or or Extramural Institutional Cert. • Extramural Institutional Certification • Question for IRB		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 – HRPP Compliance
Protocol Review Committee	Protocol or study plan Informed consent form Feasibility checklist	TRAcs Navigator
EPIC - new user account for clinical research	Need to have an existing OnCore account	OCR – Billing Compliance Team
OnCore - new user account for Clinical Trial Management System	Must be completed by individual who is requesting account (required)	Directed to IT ServiceNow and OnCore Wiki
DocuSign 21 CFR Part 11 Compliant Account (incurs charges to use)	Free DocuSign account for training (required) Speedtype for charges (required) Must be completed by individual who is requesting account (required)	OCR Administration
Recruitment Resources		
Question about Conquering Diseases		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 (Recruitment Core, Data ScienceCore, TriNetX) Recruitment Core • Just-in-Time Alerts (JITA) for recruitment • Get information about the National Cohort COVID Collaborative (N3C) • Obtain data from Data Lake for disease registry • Cohort Identification using the Data Lake • Recruit from Conquering Diseases volunteer registry or ResearchMatch registry • Request a research informatics or recruitment consultation • Request a TriNetX or an i2b2 account Research Informatics Core • Request a data set of existing data for a retrospective study • Request a consultation from the Research Informatics Core		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	Speedtype or Funding Proposal # for interpreter service requests	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	Space for additional document (opt)	TRAcs Navigator
Other Services or Requests		
3D Printing Core		Directed to 3D Printing Core forms
Bioinformatics		Email notification to Bioinformatics by TRAcs Administration
CCTS Membership		TRAcs Administration

TRAcs option	Documents to Upload / Required information	Service Provider Responsible
Education / Training / CRPG / Certification Scholarship • I would like to take a Study Coordinator course • I would like to request individual Education or Training for me or my team • Include me on the Clinical Research Professional Group (CRPG) email list • Professional Certification Scholarship Program • I would like to request phlebotomy training for me or my team	Names/emails of individuals to be trained or added to CRPG DG	CCTS Education Team
Find Funding Opportunities • 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
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
Proteomics/Olink (Biomarkers Core)	Types of samples Panel options Spreadsheet with sample identifiers (req)	Proteomics Core
Quantitative Methods Core • clinical research support in biostatistics, experimental design, and data management		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)	Pass through to SMSF by TRAcs Administration

TRAcs option	Documents to Upload / Required information	Service Provider Responsible
Science Participation Research Center (SPRC) • Increase engagement of special populations in translational research through tailored, culturally responsive strategies		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, and sponsor to eIRB 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 • Add "New Drug" to eIRB • 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