

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 has been disabled at this time. Enter any COVID 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 / Prerequisites	Service Provider Responsible
Protocol Start Up or Implementation		
Biorepository & Tissue bank <ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> • 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)	
<ul style="list-style-type: none"> • Have/want a new Data Use Agreement (DUA) 	Email requesting contract agreement IRB approval letter Draft DUA (if applic, required)	OCR - Research Compliance Contracts
<ul style="list-style-type: none"> • 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 / Prerequisites	Service Provider Responsible
<ul style="list-style-type: none"> 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) Funding Proposal No. from RMS (required) Investigator Brochure (opt) Lab manual (opt) Email from sponsor (if applic) IND or IDE Waiver (if applic)	OCR – Preaward OCR - Research Compliance Contracts
<ul style="list-style-type: none"> Have a newly awarded clinical research grant 	Protocol or study plan Informed consent form NCT number 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
<ul style="list-style-type: none"> 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) Funding Proposal No. from RMS (required)	OCR - Preaward
<ul style="list-style-type: none"> 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
<ul style="list-style-type: none"> Have a protocol or contract amendment 	Protocol/calendar - tracked Budget/contract – tracked	OCR - Preaward
<ul style="list-style-type: none"> Need to revise/correct OnCore information 	Protocol/calendar - tracked Budget/contract – tracked	OCR - Preaward
<ul style="list-style-type: none"> 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 / Prerequisites	Service Provider Responsible
<ul style="list-style-type: none"> Want to submit a clinical research account closure request 	Account closure form (opt) Reconciliation/tracking in any format Sponsor payment history (opt) Summit Screen	OCR - Preaward
<ul style="list-style-type: none"> Need review/processing an Institutional Prior Approval (IPA) for a change in budget or extend study period 	IPA form	OCR - Preaward
<ul style="list-style-type: none"> Need help with the Conquering Diseases clinical study opportunities portal 		TRAcS Navigator
<ul style="list-style-type: none"> Need new user access for Epic 	Need to have an existing OnCore account	OCR - Postaward
<ul style="list-style-type: none"> Don't know/ I want to ask a question 	Space for additional document (opt)	TRAcS Navigator
Investigational Drug Services <ul style="list-style-type: none"> 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 Extramural Institutional Cert. <ul style="list-style-type: none"> Extramural Institutional Certification Question for IRB 		TRAcS Administration
Clinical Trials.gov assistance <ul style="list-style-type: none"> 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
EPIC - new user account for Clinical Trial Management	Need to have an existing OnCore account	OCR - Postaward
OnCore - new user account for Clinical Trial Management		Directed to IT ServiceNow and OnCore Wiki
DocuSign 21 CFR Part 11 Compliant Account (incurs charges to use)	Free DocuSign account for training Speedtype for charges	OCR Administration
Recruitment Resources		
Question about Conquering Diseases website		TRAcS Navigator

TRAcS option	Documents to Upload / Required information / Prerequisites	Service Provider Responsible
<p>Community Engagement</p>		<p>Directed to Community Engagement forms</p> <p>Email confirmation by TRAcS Administration</p>
<p>Informatics (Recruitment Core, Data ScienceCore, TriNetX)</p> <p>Recruitment Core</p> <ul style="list-style-type: none"> • 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 <p>Data Science Core</p> <ul style="list-style-type: none"> • Request a data set of existing data for a retrospective study • Request a consultation from the Data Science Core 		<p>Directed to appropriate IT forms</p> <p>Email confirmation by TRAcS Administration</p>
<p>Interpreter or Translation Services for Research</p> <ul style="list-style-type: none"> • Over the phone interpreter services • Video interpreter services • In-person interpreter services • Translation services 		<p>TRAcS Navigator</p>
<p>Research Navigator Service (consult)</p> <ul style="list-style-type: none"> • 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 		<p>TRAcS Navigator</p>
<p>Other Services or Requests</p>		
<p>3D Printing Core</p>		<p>Directed to 3D Printing Core forms</p>

TRAcS option	Documents to Upload / Required information / Prerequisites	Service Provider Responsible
Bioinformatics		Email notification to Bioinformatics by TRAcS Administration
CCTS Membership		TRAcS Administration
Education / Training / CRPG <ul style="list-style-type: none"> • 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 		CCTS Educator
Find Funding Opportunities <ul style="list-style-type: none"> • 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) <ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> • Clinical research support in biostatistics, experimental design, and data management 		Directed to QMC forms Email confirmation by TRAcS Administration
Small Molecule Screening Facility <ul style="list-style-type: none"> • 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

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TRAcS option	Documents to Upload / Required information / Prerequisites	Service Provider Responsible
Science Participation Research Center (SPRC) <ul style="list-style-type: none"> • 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) <ul style="list-style-type: none"> • 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