CASE WESTERN RESERVE UNIVERSITY
Clinical and Translational Science Collaborative

Cleveland Clinic | University Hospitals | MetroHealth

VA U.S. Department of Veterans Affairs Veterans Health Administration VA Northeast Ohio Healthcare System | The University of Toledo | Northeast Ohio Medical University

Voucher Application Rubric

Application Components	Criteria
Research Navigator Review - Meets Voucher Requirements (If any of these requirements are not met, the application will receive an automatic **return** and encouraged to resubmit)	• **Two or more** CTSC institutional sites and faculty investigators AND/ OR at LEAST one CTSC faculty investigator and one community partner investigator (within Ohio) • **Service must be selected** for requested funding (select "Other" for services not listed in Voucher Service Catalog) • Eligible **itemized quote(s)** of services including cost of each line item, financial contact, and clear information on how the voucher will be spent • **1-page proposal** of a translational or clinical research study that aligns with central research goals • Voucher **budget is within $7,500** limit per application • **Investigator has no active voucher award or has not applied within a 6-month period** • Services requested for **funding will be completed within 3 months** of award letter
	1-page Research Proposal Elements
Project Overview Hypothesis, rationale, aims, research plan/ methods & innovation/ translational impact	The project's research question/hypothesis, specific aims, and research plan/methods are clearly articulated and easy to understand. Each institution's and investigator's responsibilities are well-defined, ensuring clarity in roles. Additionally, the project's potential impact is clearly indicated.
The Project Scientific Advancements and Dissemination	The project will build research capacity and further advance science through publication of a peer-reviewed manuscript, preliminary data with grant submission proposed and/or a presentation at a nationally/ internationally recognized conference, and/or support larger funding opportunities.
Activities and Time Frame	Project services/activities requested for funding will be completed within 3 months of award letter. **The proposal must include a description of the 3-month timeline for spending Voucher Award funds in order to be considered.** Projects utilizing voucher funds for regulatory support (e.g. IRB, IND/IDE, FDA) must have regulatory application submitted within the 3-month period. Projects that require IRB approval to get started with services/activities supported by the voucher program must have IRB application already submitted prior to applying for a Voucher Award.
Budget and Funding Utilization	Itemized quote includes the cost of each service (e.g., flat rate or hourly rate), contact information for the financial representative, and contact information for the investigator or the individual for whom the services are intended. ***Quote cannot include support for Principal Investigator salary.***

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1-Page Voucher Application Proposal

Project Title:

Principal Investigator:
(name and primary organization)

1. **Abstract (or Study Objective, if no abstract available)**

2. **Specific Aims and Hypothesis**

3. **Research Plan/Methods**
   Please include a bulleted list of research activities you will perform to test your hypothesis that can be achieved with the budget and responsibility of partnering institution(s)/community partners. **Research plan must include a 3-month timeline.**

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4. **Innovation or Translational Impact**
   Please also include how the voucher funds will support the success of your project, support the mission of the UM1, and future funding.

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CT SC Collaborative Voucher Service Quote - [ENTER CORE/ORGANIZATION HERE]

To Recipient:

Name (Required)
Title
Institution (Required)
Address
Email (Required)
Phone

From Service Provider:

Name (Required)
Title
Institution (Required)
Address
Email (Required)
Phone

Date:

Study/Project Name:

Principal Investigator:

Investigator Primary Institution/Department:

An itemized list of services with hourly charges, fees, and costs associated with each item is required. Your voucher application may be returned if the quote is too general. A separate quote must be submitted for each service provider. Voucher services should be rendered and invoiced within 3 months from the award date. Voucher funds that are not utilized within 3 months may be rescinded. Voucher awardees are eligible for one voucher within a 6-month period following their award date.

Service	Description	Cost	Quantity	Total
D&I Consultation-general	*Initial D&I Consultation: SPARC Service Request 6310; completed 3/26/2024*	*No Charge*	*1*	*-*
D&I Qualitative-general	*Advising for qualitative data collection and qualitative analysis for implementation outcomes. Duration (6 months): Once every 2 weeks for first 2 months; once per month for 4 months.*	*$175/ hour*	*8*	*$1,400*
			Total	***$1,400***

We would appreciate your acknowledgement on any poster, presentation, or publication submission by citing:
"This project was supported by the Clinical and Translational Science Collaborative of Northern Ohio which is funded by the National Center for Advancing Translational Sciences (NCATS) of the National Institutes of Health, UM1TR004528. The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH."

*When support from the CTSC will be acknowledged in a publication, the publication must be submitted to **PubMed Central** to comply with the **NIH Public Access Policy**. Refer to these sites for submission requirements.*

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CTSC Voucher Program Services Catalog

BERD (Biostatistics, Epidemiology and Research Design)*	**Contact:** Jennifer Gassman, PhD Email: gassmaj@ccf.org
Voucher Service	**Description**
Grant development work	Grant development work fulfilling the requirements of the proposal RFA
Data Analysis	Efforts of biostatistician(s) who will be doing QC of the data set and performing statistical analyses.

**NEOMED and University of Toledo must partner with CCF, UH, MH, CWRU, or the VA in order to utilize this service.*

D&I (Dissemination & Implementation) Accelerator	**Contact:** Mario Scarcipino, RN, BSN, MBA Email: mascar@ccf.org
Voucher Service	**Description**
D&I Consultation - general/ mixed methods	Advising on implementation study design, data collection and outcomes
D&I Qualitative - general	Advising for qualitative data collection and qualitative analysis for implementation outcomes
D&I Quantitative - general/ cost	Advising for quantitative data collection and quantitative analysis for implementation outcomes, including implementation cost
D&I Quantitative - cost	Advising on data collection and analysis for implementation cost

Local & FDA Regulatory Support	**Contact:** Heather Tribout, BS, CCRP; Kathryn DiFrancesco **Email:** Heather.Tribout@UHhospitals.org; Kathryn.DiFrancesco@UHhospitals.org
Voucher Service	**Description**
Study Start-up/Transfer: FDA Regulatory	Services available: (1) IND/IDE pre-submission and submission; (2) Study Design/ Protocol Development; (3) End of Phase Meeting; (4) Gap Analysis; (5) Regulatory Strategy
Study Conduct and Close-Out: FDA Regulatory	Services available: (1) FDA amendment and reporting; (2) ClinicalTrials.gov Registration, annual maintenance and end final report; (3) Writing services (i.e. Protocol, Investigator's Brochure, Non-clinical Reports, Clinical Report)
Study Start-up: Local Regulatory	Services available: (1) Study Design/Protocol Development; (2) IRB submission; (3) Facilitate Site-Initiation Visits and protocol training; (4)
Study Conduct and Close-out: Local Regulatory	Services available: (1) Annual Continuing Review; (2) Mobile Research Unit; (3) Recruitment (i.e. recruitment strategy and materials, recruitment and retention support); (4) Compliance review and audit preparation; (5) IRB closure and close-out visit; (6) Protocol amendment

Diversity, Equity, Inclusion & Accessibility Consultations & Services	**Contacts:** Gelise Thomas, JD and Cynthia Owusu, MD Email: gelise@case.edu; Cynthia.Owusu@UHhospitals.org
Voucher Service	**Description**
READI Consultation	Schedule a one-hour Research Equity, Accessibility, Diversity, and Inclusion (READI) consultation with the READI leads at the CTSC. Consultations may include but are not limited to: review of a grant proposal for READI principles and values, review and editing of scripts or other materials related to a research project or trial for inclusive language, identification of READI awareness and learning opportunities, preparation of a workforce development plan for your study team, and more.
Diversity Action Plan Development	Diversity action plans will be required by law 180 days after the FDA publishes final guidance on diversity action plans. To date, the FDA has received diversity action plans for review and provided feedback, largely for oncology trials. Work with the CTSC's READI team to develop a draft diversity action plan for your clinical trial.
Research Equity, Awareness, Diversity, and Inclusion (READI) Awareness and Learning Experience	Curated alignment with research equity, accessibility, diversity, and inclusion (READI) awareness and learning experience. Voucher will pay for experience.
Health Equity Consultation	Advice and guidance will be offered on study design, study conduct, intervention development, data collection and outcomes guided by the NIMHD Disparities Framework. Consultation will be provided by the Community Advisory Board Health Equity Subcommittee.
Embedding of Health Equity Advocate in Study	Embedded Health Equity Advocate will work closely with research team offering interacting closely with research team, offering advice and guidance and may participate in study conduct and complete study procedures. Advocate may be a member of the CAB Health Equity Subcommittee or a Non-CAB Community member.
Health Equity Research Training Consultation	Advice and guidance will be offered on appropriate training needs and health equity research skills that align with investigator and study needs. Information on how to fulfil such training needs will be provided.

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Bioethics and Medical Humanities Research Consultation and Collaboration	**Contact:** Aaron Goldenberg, PhD (Case Western) and Rick Kodish, MD (Cleveland Clinic) Email: ajg10@case.edu, kodishe@ccf.org

The bioethics and medical humanities voucher service aims at providing consultation and collaboration on clinical and research ethics and related social science, humanities, and health policy issues within clinical and public health research. Our aim is help with the integration of bioethics and medical humanities into research design, project implementation, and dissemination of research findings. The Bioethics and Medical Humanities faculty available through this voucher program come from a wide variety of disciplinary backgrounds including bioethics, medical or health humanities, sociology, anthropology, philosophy, history, education, public health, law, and medicine.

Voucher Service	**Description**
Research Ethics Consultation	Available support: 1) Reviewing consent and participant outreach/educational materials 2) Consultation on IRB review questions or feedback 3) Support for other research ethics questions in study design (strategies for ethical study design such as equipoise, component analysis, participant compensation questions, other questions) 4) Reviewing plans for data dissemination and return of general (whole cohort) and individual research results ***Note: This service is <u>not</u> meant to provide direct support for writing or submitting IRB protocols for research studies**
Empirical Bioethics, Social Science and Medical Humanities Research Support	Available support: 1) Support for designing and integrating a social science/ethics research questions into future or existing research programs (ex. a survey to assess participant perspectives on genetic testing or long-term storage and use of biospecimens) 2) Support for integrating qualitative study methods into existing or future research programs including in-depth participant interviews or focus groups (ex. a set of interviews with study participants about their experience with a particular study intervention) 3) Support for designing and integrating other medical humanities research approaches including narrative data collection and analysis 4) Support for quantitative or qualitative data analysis associated with social science/ethics/med humanities research questions

Clinical Ethics Support	Available support: 1) Consultation and support for engaging and enrolling patients as research subjects in complex healthcare settings- including addressing issues related potential subjects with poor clinical prognosis, compromised decision-making capacity, , advance directives and research, surrogate decision making in research, or other ethical issues at the intersection of research and clinical care.
Health Policy and Data Dissemination	Available support: 1) Support for translating study findings into practice or policy recommendations or best practices. 2) Other support for data dissemination or outreach

Community and Stakeholder Engaged (CSE) Research	**Contact:** Ivory Simms, PhD, MBA **Email:** Ivory.Simms@case.edu
Voucher Service	**Description**
Proposal writing development: Qualitative or Quantitative Methods	Three service available: (1) One round of detailed review of methods section includes detailed written feedback. (2) Up to 4 coaching sessions on development of methods section with detailed feedback, and some writing of original content. (3) Creation of step-by-step plan for methods section and connecting investigator with collaborators as needed.
Proposal writing development: Preliminary Data Collection in Communities	Two services available: (1) Up to 4 coaching sessions to develop data instruments. (2) Support to collect preliminary data (e.g., costs related to mailing, recruitment, enrollment, analyzing data, etc.).
Preparing Team for Collaborative CTS Research	Services to support team building with community-academic partnerships include team building or coaching for PIs. Support a retreat (4 hours) including pre- and post-meetings with follow up report. Monthly team coaching (1.5 hours) with kick off and close out sessions for 3 – 6 months.
CAB Technical Assistance for CTS Research Projects: Supports to establish a CAB	Three services available: (1) Two 1-hour coaching sessions with faculty and community partner that includes a pre-meeting and close out report to start a CAB. (2) Support from faculty and community partner in up to two areas of CAB development. (3) Faculty and community support for establishment of a CAB charter, with direct engagement with CAB in 3 (2 hour) sessions.
CAB Technical Assistance for CTS Research Projects: Support for managing CAB	Up to 3 (4 hour) retreats including pre and post meetings (1 per retreat) with summary report in any of the three following areas: team building, conflict management, strategic planning

Community Dissemination of CTS Research Findings	Two services available. Design support for one-pager and/or social media with design materials, color pallet, etc., and includes two rounds of feedback based on investigator's design. Creation of a 1–2-page report of community accessible findings including infographics, message development, all design features, etc.
Community-based Data Collection for CTS Research	Two services available: (1) Up to 4 coaching sessions of data collection instruments such as surveys, interview guides, focus groups, etc., with pre-work for sessions and written feedback on drafts. (2) Develop data collection instruments entirely through conducting up to 4 focus groups with participant stipends, data collection costs, and/or analyzing qualitative or quantitative data already collected.