Contact Order	Core	Services
Step 1 - Exploration of Feasibility PI contacts assigned departmental study research coordinator/s with research feasibility or research idea to investigate feasibility.	Research Coordinator Core (A part of the Clinical Research Unit/ClinicalTrials Core)	Guides investigators through the compliant and safe conduct of research throughout the project study lifecycle. Works with a variety of Sponsors, Research Managers, the IRB and staff in the Research Business Office on all aspects of the start up (including the completion and submission of the Study Start Up Packet with the appropriate Research Manager) and conduct of clinical research including: feasibility, logistics, CDAs, IRB submissions and other regulatory approvals . Guides PIs and other study staff through contacts in the Research Business office and elsewhere with contracting, onboarding, study education, study start up, recruitment, monitoring, amendments and more.
Step 1 a (As applicable) CDA's and contact as a part of the Research Business Office for Research Finance	Research Business Office (Contracts and Budgets)	Before requesting or sharing with other sites any business intelligence data collected during the trial feasiblity process, please have all site PIs finalize a **confidentiality agreement** through this office. This office is also responsible for negotiation and finalization of clinical trial agreements.
Step 1 b (As applicable) contact as a part of the the BERD for Clinical Informatics	Clinical Informatics	Manages the trial feasibility process, including assessment of cohort size availability at MH, preparatory to research
Step 1 c (As applicable) contact if needed for statistical services	Biostatistics (as a part of the CTSC BERD Core)	Provides consultation on statistics for study design; power and sample size calculations.

Step 2 - Moving forward with study, PI & Departmental Research Manager signs completed Study Start up Packet -	Research Navigation (A part of the Clinical Research Unit/ClinicalTrials Core)	Research Navigation identifies all clinical departments involved in the study. Guides investigators in working with various managers in the Research Business Office managers and other offices , i.e. for feasibility assessment, CDAs, study start-up and close-out, clinical trials budget creation and clinical trial management in coordination and in concert with all departments involved in the project.
Step 2 a (As applicable), contact as a part of the Research Business Office	Research Business Office (Sponsored Projects)	Provides oversight of processes and procedures related to the pre and post award administration of grants, contracts and subcontracts including obtaining institutional approval, ensuring compliance and establishing accounts on behalf of the MetroHealth System (MHS) and Case Western Reserve University (CWRU).
Step2 b (As applicable), contact as a part of the Research Business Office for information on grants and other sponsored projects	Research Business Office (Sponsored Programs)	Oversees the MetroHealth System (MHS) and Case Western Reserve University (CWRU) processes related to grants and research administration compliance, including facilitation of related (non-industrial) research contracting and the development, implementation, and monitoring of all associated policies, procedures, systems, and training activities. * Reviews and evaluates incoming award/contract (non-industrial) terms and conditions; negotiates routine contract issues with sponsors; monitors compliance. * Prepares, reviews, negotiates and issues outgoing (when MHS or CWRU is the prime recipient of the award) subcontract agreements and amendments to ensure compliance with funding agency requirements. * Reviews and coordinates DUAs/MTAs for non-industrial grants and contracts in conjunction with Compliance and Legal.

Step 3- IRB (review, approval)	Human Research Protections Program/Institutional Review Board	MHIRB oversees all research involving human subjects. Guides principal investigators(PIs)/site PIs in (IRB) Review and Reliant Review of protocols involving MH patients or personnel or multi-site research conducted at non-MH sites (when requested) originating from any CTSC institution.
Step 3 a (As applicable) contact as part of research navigation and budgeting process	MetroHealth Clinical Research Unit (A part of the Clinical Research/Clinical Trials Unit)	**Research Consultation:** consultation for pre-budget services, logistics, CRU lab or nursing services. **Research Facility**: adult and pediatric (outpatient) research **Staffing:** research nurses, study coordination services, bionutritionists, pre-analytical sample processing, research point of care services and biospeciment shipping. Special chemistry analytical lab (DNA extraction, PBMCs, ELISA technology); biospecimen management and storage.
Step 3 b (As applicable) contact as part of study management process	Project Management (Apart of the Clinical Research Unit/Clinical Trials Unit)	Provides fee-for-service research project management, regulatory support, including: IRB application consultation, FDA support and monitoring, and financial milestone oversight.
Step 3 c (As applicable) contact as part of patient outreach process	Participant Recruitment Specialist (A part of the Clinical Research Unit/Clinical Trials Unit)	Performs research participant recruitment consults, including strategy on how to access special and/or underserved populations.
Step 3 d (As applicable) contact as part of budgeting and study conduct process	Investigational Pharmacy Services	MetroHealth requires use of the Investigational Drug/Biologics Services to provide drug management for clinical trials conducted. Services include: preparation, dispensing, and/or management of the investigational drug or biologic as well as providing budgets for use of pharmacy in clinical research budgets.

Step 4 (As applicable), contact as a part of the the BERD for Clinical Informatics and to build EPIC study templates	Clinical Research Billing (A part of the Research Business Office)	Provides pricing for Grant submissions and an overview of clinical needs after protocol review, study coverage analysis, creation of the RSH (Study Record) within the epic research module, training for research billing and billing review and training on participant study status for accrual metrics.
General Research Navigation	Research Administration & Research Navigation (A part of the Clinical Research Unit/ClinicalTrials Unit)	Research navigation. Guides investigators in best practices for research navigation/research conduct, ensuring compliance with regulations, policies and procedures, and privacy/ethical standards. Manages and facilitates education and training for research community, mandatory orientations for new PIs and coordinators, and leads promotion and support of research activities across the system. Will assign/refer PI to Research Manager for proper routing of project through research study startup and beyond.

esearch Contacts

E-mail	Name
lhumbert@metrohealth.org	Departmentally assigned Research Coordinators - contact Lisa Humbert, Assistant Director of Research for Research Managers/Departmental assignments
bponomarenko@metrohealth.org	Bonni Ponomarenko, CRCP, Contracts & Budgets Administrator (Industry/pharma studies)
ytarabichi@metrohealth.org	Yasir Tarabichi, MD
dgunzler@metrohealth.org	Douglas Gunzler, MA, PhD

Team A: cnewman@metrohealth.org Team B: kruss@metrohealth.org Team C: dstrater@metrohealth.org	**Study Coordinator & Research Managers:** Assigned to specific Departments by teams: Team A - Cindy Newman RN, BSN; Team B - Kristine Russ, BS, MS; Team C - Deb Strater, RN, BSN, OCN
bbairdso@metrohealth.org	Brynna Baird-So, MS, Manager, Sponsored Programs
lcarnivale@metrohealth.org	Linda Carnivale, CRA, Research Compliance and Contracts Administrator (Grants and other sponsored projects)

cgorden@metrohealth.org	Carey Gordon, JD, MA, Manager, Human Research Protections Program
nroman@metrohealth.org	Noreen Roman, MBA, CRU Operations Manager
ebarnboym@metrohealth.rog	Emma Barnboym, Project Manager
nbernardo@metrohealth.org	Nicole Bernardo, MPH, Participant Recruitment Specialist
mgypp@metrohealth.org	Mary Gypp, Staff Pharmacist

lgullion@metrohealth.org	Lori Gullion, RN, Manager, Clinical Research Billing
lhumbert@metrohealth.org	Lisa Humbert, MSN, RN, CCRC, Assistant Director of Research

Phone
(216) 778-7129
(216) 778-5219
(216) 778-1791
(216) 778-2764

Team A: (216) 778-3237 Team B: (216) 778-5278 Team C: (216) 778-4568
(216) 778-8763
(216) 778-8993

(216) 778-2021
(216) 778-3130
(216) 778-3752
(216) 778-3749
(216) 778-7815

(216) 778-5219
(216) 778-7129