**Department of Pediatrics-UMMC**

**Intradepartmental Discovery Support Program (IDSP)**

Return complete application form via e-mail to PedsDiscoveryCouncil@umc.edu

**Date:** Click here to enter a date.

**Department of Pediatrics Applicant Information**

* Applicant Name: Click here to enter text.
* Degree: Click here to enter text.
* Title: Click here to enter text.
* UMMC Employee Number: Click here to enter text.
* Telephone Number: Click here to enter text.
* E-mail Address: Click here to enter text.
* Applicant type

[ ] Instructor [ ] Assistant Professor [ ] Associate Professor [ ] Professor

**Project Information**

* Project Title: Click here to enter text.
* Application Type

[ ]  New Project [ ]  Bridge Funding

[ ]  Follow-up to external application (attach summary sheets)

* Project Type

[ ] Basic Science [ ] Clinical Research [ ] Quality Improvement

* Proposed project start: Click here to enter a date. end: Click here to enter a date.
* Total funds Requested: Click here to enter text.

**PERCENT EFFORT ON PROPOSED PROJECT** (if funded): Click here to enter text.

**CO-PRINCIPAL INVESTIGATORS ONLY:**

Interdepartmental Co-Principal Investigators (Appendix E). Faculty with a secondary appointment or without an appointment to the School of Medicine Department of Pediatrics are allowed to apply as an IDSP principal investigator under the following conditions:

1. A faculty member with a primary appointment in the Department of Pediatrics is a Co-Principal Investigator
2. A Co-Principal Investigator plan (½ to 1 page) must be submitted that outlines division of responsibilities, planned research meetings, data storage and monitoring, and each PI’s study related tasks.

**RESEARCH PLAN:**

**1. Introduction to Application (for RESUBMISSION or REVISION only; 1 page limit)**

**2. Specific Aims Page (1 page limit):** Provide a brief statement of the problem, your proposed sample size and methods, your study aims and your hypotheses. Include a conceptual model or figure when available. Briefly state how this study will inform future research. Describe external funding plans for this research.

**3. Research Strategy – 4 to 6 pages. Include the following topics**

1. **Significance:** Discuss why the questions addressed are important. How significant is the proposed research in terms of addressing a pressing need or an important gap in current knowledge?

1. **Research Team:** List and describe the research expertise of key research team members (e.g., co-investigator, biostatistician).
2. **Innovation:** Discuss why the proposed study is novel. How does the application challenge and seek to shift current research or clinical practice? Are novel theories, methodologies, measurements/instruments, or interventions used? Is the current application refining or improving existing theories, approaches, methodologies, or interventions?
3. **Approach:** Discuss the research strategy, methodology, and statistical analyses to be used in the project. Discuss potential problems, and alternative strategies. See below for example subsections.

**Preliminary Data**

[Include previous research or preliminary studies of the trainee or mentor that support the current study and/or demonstrates feasibility of study methods, recruitment, etc.]

**Planning and Study Timeline**

List time frame for IRB application, starting and ending recruitment, publications, and future grant submission.

|  |  |
| --- | --- |
| **Example Table X. Project Timeline** | **Year 1** |
|  | Q1 | Q2 | Q3 | Q4 |
| Startup: hiring, IRB, recruitment documents |  |  |  |  |
| Recruitment & data collection (*n =* x) |  | *n =* x | *n =* x | *n =* x |
| Intervention (*n =* x) |  | *n =* x | *n =* x | *n =* x |
| Data analysis |  |  |  |  |
| Manuscript preparation |  |  |  |  |
| Grant preparation |  |  |  |  |

**Participants/Animal Sample/Tissue Sample**

[Include information on available patient population/animal model/or tissue samples. Where will patients be recruited from or animals/tissue obtained from? How many patients are seen at UMMC in a year, week, and/or month?]

*Inclusion Criteria:*

*Exclusion Criteria:*

*Biological Variables* (See Appendix A)*:*

**Procedures**

*Recruitment.*

*Rigor & Reproducibility* (See Appendix A)*:*

*Study Procedures.*

*Compensation.*

*Medical tests [Vital signs, Blood draws, other procedures. Include description of each test, reliability, and what populations it has been used in.]:*

*Questionnaires [Demographic forms, surveys, qualitative interviews. Include description of each test, reliability, and what populations it has been used in.]:*

*Medical chart review.*

*Animal/Experimental procedures.*

*Isolation of cells.*

*Staining and acquisition.*

*Cell data outcomes.*

**Statistical Analyses**

[Who will help conduct statistical analyses? Name the biostatistician on the project.]

Sample size calculations: [Either (a) pilot data sample size calculations based on available patient population and study timeline or (b) power analyses to ensure large enough sample size to answer study question(s).]

Aim 1: Statistical analyses to test hypothesis 1.

Aim 2: Statistical analyses to test hypothesis 2.

Aim 3: Statistical analyses to test hypothesis 3.

**Potential Problems and Alternative Strategies**

1. **REFERENCES** (Literature Cited; Page limit as needed)
2. **OTHER FORMS**
3. **PROPOSED BUDGET. Please use UMMC Detailed Budget Excel Template for 1 year. Follow the link** <https://intranet.umc.edu/Research/Research%20Offices/Office%20of%20Research%20and%20Sponsored%20Programs/Forms%20and%20Templates.html>
4. **BUDGET JUSTIFICATION** (See Appendix B)**.** Justify the requested budget in each cost category.
5. **FACILITIES** **& OTHER RESOURCES** (See Appendix C)
6. **NIH Biosketch of the PI. Please use NIH Format** (See Appendix D)
7. **Provide NIH biosketches for Co-Investigators and Consultants.**
8. **Letter of Support from the Division Chief stating protected time and facilities available for research should be attached.**
9. **IRB or IACUC research proposal Proof of Submission** should be submitted to PedsDiscoveryCouncil@umc.edu no later than **2 weeks after** the submission deadline.

**SIGNATURES**

The applicant(s) assures that the information provided in this application is true, complete and accurate; and acknowledges that any fraudulent statement may subject applicant to administrative penalties. The applicant accepts responsibility for the scientific conduct of the project and agrees to provide progress reports as required by a resulting award. Those signing below assure they will abide by the rules and regulation of the IDSP program at the University of Mississippi Medical Center.

|  |  |  |  |
| --- | --- | --- | --- |
| **Role** | **Name** | **Signature** | **E-mail** |
| Department of Pediatrics Applicant |  |  |  |
| Co-Principal Investigator (if applicable) |  |  |  |
| Division Chief |  |  |  |

**APPENDIX A**

**APPENDIX B**

**EXAMPLE BUDGET JUSTIFICATION: YEAR 1**

***Delete header prior to including in your grant application***

# Budget Justification

1. **Senior/Key Personnel**Describe and justify personnel information for each position budgeted by providing a brief description of each individual’s responsibility on the project. Including the following information for each position:
* Name
* Degree(s)
* Title
* Time Commitment
* Duties and responsibilities in relation to the project goals and objectives

***Examples:***

**Jane Smith MD, PhD, Principal Investigator** (1.2 calendar months/10% effort)
Dr. Smith will be responsible for the overall coordination and supervision of all aspects of the study. This includes hiring, training and supervising staff, recruiting study participants; coordinating treatment and assessment components; scheduling and staff assignments; and data management. In addition, she will conduct the orientation sessions, assist with statistical analyses, and be responsible for reporting the study’s findings.

**John Doe, PhD, Co-Investigator** (2.4 cal months/20% effort)
Dr. Doe will be responsible for the collection and analyses of the blood samples. He will also assist with manuscript preparation.

1. **Other Personnel**

**Peter Paul, PhD, Consultant** (No effort committed)
Dr. Paul will provide expertise on genomic testing on an as-needed basis. No salary support is requested.

**TBD – Postdoctoral Fellow** (12 cal months/100% effort)
This individual will assist in assessments, be responsible for data entry of all treatment-related data and serve as an interventionist.

**TBD – Research Assistant** (12 cal months/100% effort)
This individual will assist with recruitment, ordering supplies and intervention materials, assessments, collection of data, daily management of study data, and scoring and data entry of assessments.

1. **Equipment**Describe and itemize all equipment expenses by budget year. Items are only considered equipment if they have a single purchase cost of $5,000 or more and have a useful life of more than one year.
2. **Travel**For each trip, include the person(s) traveling, dates of travel, purpose of trip as it pertains to the scope of work, location and approximate cost. The approximate cost should include an expense breakdown for registration, hotel, mileage, meals, parking, etc. Indicate the travel and per diem expenses.
3. **Participant/Trainee Support Costs**

Describe any Tuition/Fees/Health Insurance, Stipends, Travel or Subsistence for participants or trainees. Be sure to itemize each expense per participant and include a total for each category. This category is normally only used for training and conference grants. ***Incentives and travel reimbursement for clinical trial participants should be budgeted under Other Direct Costs and justified separately.***

1. **Other Direct Costs**
	1. **Materials and Supplies**Justify the requested dollar amount by listing the items to be purchased and the cost for each (i.e., per unit, per box, per animal etc.) Include how the costs were derived for each category.
	2. **Publications**List the journal you plan to submit your publication and outline their costs per page, per article, etc.
	3. **Consultant Services**If consultant services are budgeted, provide the following details: Consultant name; list as “TBD” if not known; Brief description of services to be provided; Basis for the Cost - approximate number of consulting hours and/or days to perform the deliverable that will be contracted for and the hourly/daily rate; and total costs
	4. **ADP/Computer Services**
	Describe in detail any computer services (not purchases, those should be included under Materials and Supplies) that will be used and any software/technical commodity you will need and the costs per license. This includes items such as reserving time on supercomputers or getting specialized software to help run your statistics.
	5. **Subawards/Consortium/Contractual Costs**Identify the Subcontract Principal Investigator and Institution/Company. Provide a brief description of services to be provided; basis of the costs and project years. Include total costs.
	6. **Equipment or Facility Rental/User Fees**Describe and list rates/cost breakdown. [Identify the lab by full name, try to avoid acronyms] Costs for animal care (not purchase) can be described here.
	7. **Research Patient Care Costs**
	Provide the names of any hospitals and/or clinics and the amounts requested for each. If both inpatient and outpatient costs are requested, provide information for each separately. Provide a cost breakdown, number of days, number of patients and costs of tests/treatments. Justify the costs associated.
	8. Other
	Justify any other expenses included in the budget including participant incentives

**Fringe Benefits**Per agreement dated May 18, 2018, the negotiated fringe benefit rates for the University of Mississippi Medical Center are 28.6% for full-time employees and 9.7% for part-time employees and graduate students.

***Only include information that is applicable to and accurate for your project. This template is for planning purposes only.***

**APPENDIX C**

**FACILITIES AND OTHER RESOURCES**

**UPDATED and EXPANDED UMMC Boilerplate Language for Grants is located at:**

<https://intranet.umc.edu/Research/Boilerplate%20Language%20for%20Grants/Boilerplate%20Language%20for%20Grants.html>

**Please use up-to-date information from the above link.**

**EXAMPLE-Make Specific to your project**

**UNIVERSITY OF MISSISSIPPI MEDICAL CENTER**

**Environment Contributions to Success:** Within UMMC’s 164-acre campus are six separate schools: medicine, dentistry, nursing, health related professions, pharmacy, and graduate studies in the health sciences. It offers programs that lead to MD, PhD, D.M.D., M.S., and nursing degrees. The facilities and other resources available to the Leadership research team at the University of Mississippi includes the necessary support, equipment and materials to undertake and complete pediatric clinical trials within the ISPCTN successfully. PI Barr’s office is located within the Administrative offices of the Department of Pediatrics at the University of Mississippi Medical Center and the Blair E. Batson Hospital for Children. The PI is located in the Department of Pediatrics at the Center for the Advancement of Youth, on the same campus as PI Barr. The PIs communicate daily by email and by telephone when necessary.

**UNIVERSITY OF MISSISSIPPI MEDICAL CENTER FACILITIES**

UMMC is the state’s only academic health science center. Located in Jackson, Mississippi, UMMC encompasses six health science schools on the 164-acre campus including medicine, nursing, dentistry, health-related professions, graduate studies, and pharmacy. UMMC offers programs that lead to MD, PhD, DMD, MS, and nursing degrees. Slightly more than 22% of the 2,400 UMMC students are enrolled in its medical school. Residency and fellowship training programs are offered in all major medical specialties and subspecialties. UMMC encompasses a spectrum of patient care facilities including Mississippi’s only children’s hospital, a women and infants’ hospital, and a critical care hospital. It serves as the 722-bed diagnostic and treatment referral center, a Level III neonatal intensive care unit, and the only Level I trauma center in Mississippi. Inpatient stays total about 29,000 annually with more than 584,000 outpatient and emergency visits every year.

**University of Mississippi Medical Center (UMMC).** UMMC oversees wide-ranging patient programs to support the UMMC education and research mission. UMHC offers Mississippi’s broadest range of specialty clinics and services including the Children’s Cancer Clinic; UMMC Heart Center for diagnosis and treatment of heart disease; a heart failure clinic; Mississippi’s only transplant center with heart, kidney, cornea, and bone marrow services; a comprehensive stroke unit; state-of-the-art radiological imaging systems; a sleep disorders laboratory; an *in vitro* fertilization program; interventional magnetic resonance imaging (MRI); and statewide Air Care Service (helicopter transport).

*UMMC hospitals include the following:*

* **University Hospital.** This facility has 256 beds for adult patient care.
* **Wiser Hospital for Women and Infants.** The 60-bed Wiser offers complete care for women and infants with the only OB/GYN emergency room in the state.
* **Children’s of Mississippi.** This is the only children’s hospital in Mississippi. Included in the 230-bed facility are areas for physical therapy, infant care, treatment rooms, bone marrow transplantation, a pediatric pharmacy, a children’s surgical suite, a pediatric emergency room, and the state’s only pediatric intensive care unit. The neonatal intensive care unit offers the highest level of care for critically-ill infants with one of the only Level IV designations in Mississippi. Children’s of Mississippi includes a Children’s Cancer Clinic, Jackson Medical Mall Clinic, Eli Manning Children’s Clinics, and Select Specialty Clinic that provide outpatient services. Children’s of Mississippi inpatient and outpatient visits totaled more than 150,000 in 2015.
* **Wallace R. Conerly Critical Care Hospital.** This facility has a 70-bed specialized intensive care for medical, cardiac, surgical, and neuroscience patients. Specialty services include complete cardiac care, a stroke unit, an artificial kidney unit, and a transplant center with heart, kidney, liver, bone marrow, and cornea services. Critical care services also include Intensiview, which uses an advanced monitoring system to provide a second level of attention to critical care patients.

**Department of Pediatrics**. The department is comprised of more than 30 divisions encompassing 100 faculty. The department is very supportive to scientific research and strongly encourages new investigators or early stage investigators to develop their independent research career. Pediatrics encourages research by developing a special foundation to provide departmental research awards (up to $20,000 each, up to four awards per year). Within the department, the *PEDIATRIC CLINICAL RESEARCH CENTER (PCRC)* is engaged in the conduct of industry-sponsored. The center assists with protocol and submissions, ensures research is conducted according to ICH/GCP (International Council for Harmonization/Good Clinical Practices) guidelines by assembling qualified research certified personnel, provides 24-hour on-call coverage for patient Recruitment and adverse-events monitoring, and educates students, interns, residents, staff, and faculty regarding research components. The PCRC oversees activities in all areas of research including regulatory, clinical and laboratory. The PCRC consists of a Director, an Administrative Assistant, a Clinical Research Coordinator, a Research Nurse, a Business Analyst and a Research Editor. The PCRC is housed on the 2 East wing of UMMC, adjacent to the Eli Manning Pediatric specialty clinics, and consists of 2,695 square feet of space. There are 2 rooms for children, adolescents and adults for research visits/ procedures. There is 1 patient room for infants which is designed to be of comfort to both infant and parent. Clinical equipment includes physical exam equipment (i.e., BP/Temperature machine, height and weight scales), an EKG machine, otoscope and stethoscope. The PCRC is equipped with a secure laboratory that houses an ambient and a refrigerated centrifuge, two (-8) degree Celsius refrigerators, a (-20) degree freezer, and a brand new (-80) degree freezer (with a 24 hour out-of-range alarm alert in Physical Facilities). The laboratory refrigerator and freezer temperatures are monitored daily and are on the UMC Skytron/ Awarepoint system.

**Specialty Clinics and Services**

UMMC features the broadest range of specialty care in Mississippi. These services include:

* Children’s Cancer Clinic;
* The UMMC Heart Center for diagnosis and treatment of heart disease;
* A heart failure clinic;
* Mississippi’s only transplant center with heart, kidney, cornea and bone marrow services;
* A comprehensive stroke unit;
* State-of-the-art radiological imaging systems;
* A sleep disorders laboratory;
* An in vitro fertilization program;
* An interventional MRI; and
* Air Care Service (helicopter transport) across Mississippi.

**School of Medicine.** UMMC was founded in 1955, but its beginnings date to 1903 when a two-year medical school was established on the parent campus in Oxford, MS. Admission preference is given to Mississippi residents in an effort to supply professionals to meet the state's healthcare needs. UMMC has a diverse student population drawn from all counties within Mississippi. Service learning is an important component of the curriculum as students learn first-hand how to serve fellow Mississippians. With more than 9,100 full- and part-time employees, UMMC is one of the largest employers in Mississippi. UMMC’s $1.6 billion annual budget approximately one-tenth from state appropriations—represents 10% of the Jackson metro area economy and 2% of the state economy. Despite the recent national recession, UMMC continues to grow in all its mission areas.

**University Hospitals and Health System.** University Hospitals and Health System encompasses specialty hospitals and clinical practice sites across the state of Mississippi. It serves as the 722-bed diagnostic and treatment referral center for the state. The system provides the only Level I trauma center in Mississippi and also has a Level III neonatal intensive care unit. Inpatient stays total about 34,000 annually with more than 455,000 outpatient and emergency visits every year. University Hospitals has 256 beds for adult patient care. A part of the University Hospital, the 70-bed Wallace R. Conerly Critical Care Hospital has specialized intensive care for medical, cardiac, surgical, and neuroscience patients. Specialty services include complete cardiac care, a stroke unit, an artificial kidney unit, and a transplant center with heart, kidney, liver, bone marrow, and cornea services. Critical care services also include Intensiview, which uses an advanced monitoring system to provide a second level of attention to critical care patients. The 160-bed Wiser Hospital for Women and Infants offers complete care for women and infants with the only OB/GYN emergency room in the state. The neonatal intensive care unit offers the highest level of care for critically ill infants with one of the only Level III designations in Mississippi. Batson Children’s Hospital is the only children’s hospital in Mississippi. Included in the 130-bed facility are areas for physical therapy, infant care, treatment rooms, bone marrow transplantation, a pediatric pharmacy, a children’s surgical suite, a pediatric emergency room, and the state’s only pediatric intensive care unit. Batson also includes a Children’s Cancer Clinic, Specialty Clinic and the Eli Manning Children’s Clinics for outpatient services. Batson inpatient and outpatient visits totaled over 150,000 last year.

**University Physicians Medical Pavilion**. This is the practice clinic site for the faculty physicians of UMHC and hosts a range of general medical and subspecialty clinics. Most procedures ordered by the physicians can be performed on site. The clinics feature a full-service lab, radiology services including mammography and MRI, a physical therapy room adjacent to the orthopedics clinic, and cardiology testing including echocardiograms and cardiac stress testing. Procedures such as bone marrow aspirations, lumbar punctures, endoscopy, and minor surgery also are performed in the Medical Pavilion.

**Jackson Medical Mall**. One mile west of campus, the Jackson Medical Mall houses the UMMC Cancer Institute and a comprehensive tobacco cessation program. It is also home to the National Heart, Lung, and Blood Institute (NHLBI)’s Jackson Heart Study and Genetic Epidemiology Network of Arteriopathy (GENOA) study.

**RESEARCH AND SPONSORED PROGRAMS**

**Sponsored Program Management**. UMMC coordinates the management of sponsored programs under the auspices of the Associate Vice- Chancellor for Financial Affairs and the Associate Vice Chancellor for Research. Day-to-day accounting transactions are processed through a centralized accounting department under the direction of the Comptroller. A central purchasing department operates under state guidelines. The purchasing mechanisms take advantage of bids, state contracts and other fund management procedures. The legal office, a centralized computer and information department, property control, compliance committees and many other core units provide services to sponsored program management and investigators. The State of Mississippi Audit Office conducts annual audits that meet State and OMB A-133 guidelines.

UMMC has a long history in managing Federal awards and has a thorough understanding of Federal requirements. UMMC functions as a prime recipient or as a contractor with other state offices and institutions. As a prime recipient, UMMC also manages funds under formal subcontracting mechanisms with organizations and institutions across the country and has a history of managing federal contracts that have multiple field sites and/or cooperative partners for the conduct of clinical trials or long-term epidemiological studies.

**UMMC Office of Research**. The Office of Research submits extramural proposals and contracts for research, instructional and service activities. The primary functions of the unit are to: assist faculty with budgets and other business requirements of proposals; receive, review and negotiate changes in awarded grants and contracts; serve as a source of information with regard to grant/contract procedures and regulations; ensure that policies and procedures are followed, negotiate terms and conditions, administer the program of intramural research grants; serve as the institutional interface with Grants.gov; and coordinate all aspects of electronic research administration. The Office provides oversight and staffing for activities focused on compliance with regulations for research involving humans, vertebrate animals, radiation/laser safety and bio-hazardous agents. It also coordinates management of conflict of interest, financial disclosure, and scientific integrity issues. The unit also serves the administration of the university by implementing policy decisions affecting grants and contracts, by protecting the university's interests in interaction with sponsoring agencies, as well as internal review of grant/contract matters, and by providing information concerning proposal and award activity.

**RESEARCH RESOURCES**

**Pediatric Clinical Research Center (PCRC).** The PCRC facilitates the conduct of industry-sponsored research, assist with protocol and grant development and submissions, and ensure research is conducted according to ICH/GCP guidelines by assembling qualified research certified personnel. The PCRC provides 24-hour on-call coverage for patient recruitment and adverse events monitoring, and educates students, interns, residents, staff and faculty in regards to research components. Additional activities of the PCRC include oversight of activities in all areas of research including regulatory, clinical and laboratory. The Pediatric Clinical Research department consists of a Director, an Administrative Assistant, a Clinical Research Coordinator, a Research Nurse, a Business Analyst and a Research Editor. The PCRC is housed on the 2 East wing of UMMC, adjacent to the Eli Manning Pediatric specialty clinics, and consists of 2,695 square feet of space. There are 2 rooms for children, adolescents and adults for research visits/ procedures. There is 1 patient room for infants which is designed to be of comfort to both infant and parent. Clinical equipment includes physical exam equipment (i.e., BP/Temperature machine, height and weight scales), an EKG machine, otoscope and stethoscope. The PCRC is equipped with a secure laboratory that houses an ambient and a refrigerated centrifuge, two (-8) degree Celsius refrigerators, a (-20) degree freezer, and a brand new (-80) degree freezer (with a 24 hour out-of-range alarm alert in Physical Facilities). The laboratory refrigerator and freezer temperatures are monitored daily and are on the UMC Skytron/Awarepoint system.

**Clinical Research Support Program (CRSP).** CRSP supports the initiation and coordination of trials throughout the medical center and provide training and quality services that ensure high quality trials and results. CRSP has one Clinical Research RN and one Clinical Research Coordinator who can provide full services ranging from regulatory documentation and study start-up, participant recruitment, data collection, case report forms and monitoring of visits through study close out, plus other services depending on the needs of the study. Within CRSP, the **Clinical Research Professionals Interest Group** (CRPIG) was formed in 2012 to provide education and mentorship opportunities to the faculty, staff and students who work in or are interested in clinical research.

**Center of Biostatistics and Bioinformatics*.*** *SERVICES—*This center collaborates with investigators on all statistical aspects of research studies including study design, sample-size analysis, data analysis, interpretation, translation, and manuscript writing. Pre-study consultation helps to define objectives and endpoints, select an appropriate design, devise a blinding and randomization scheme, compute an adequate sample size, specify the statistical methods, and estimate the time required to accrue the total patient population. The center provides guidance and preliminary analysis throughout the project and completes final analysis and supports manuscript development at the end of the project. In addition to providing statistical support, the center also provides data services, which include support for capturing, cleaning, managing, and distributing data. A central platform for data coordination activities is the secure web application REDCap, designed exclusively to support data capture for research studies. The REDCap application allows users to build and manage online surveys and databases quickly and securely and is currently in use or in database- development status for more than 21,000 studies with over 30,000 end-users spanning numerous research focus areas across the REDCap consortium of more than 250 active institutional partners including the Clinical and Translational Sciences Award, General Clinical Research Center, RCMI, and other institutions. REDCap provides audit trails for tracking data manipulation and user activity, as well as automated export procedures for seamless data downloads to Excel, PDF, and common statistical packages (R, SAS, SPSS, and STATA.). Also included are a built-in project calendar, a scheduling module, ad hoc reporting tools, and advanced features such as branching logic, file uploading, and calculated fields. UMMC is already an active REDCap consortium member with 33 current projects; The Center of Biostatistics and Bioinformatics core comprises the REDCap development and implementation team for existing studies at UMMC. The center uses a team-based approach to provide services for investigators across campus by assembling a team consisting of a faculty biostatistician, a statistical analyst, and a data programmer. This approach develops enduring research collaborations that employ novel research designs and sophisticated statistical models that produce numerous publications and other studies.

**Library Services.** *ROWLAND MEDICAL LIBRARY* provides access to knowledge-based resources for students and faculty and acquires, preserves, and manages print and electronic resources in the biomedical and health sciences to support the UMMC educational, research, and clinical mission. Occupied in July 1982, the library has 55,612 sf and provides seating for 420 users. There is a computer lab, networked printing and scanning, three public photocopiers, individual carrels, and group study areas. The library provides wireless network access for individual study and research. Rowland’s collection numbers slightly more than 250,000 print books and bound periodicals, with total holdings of 310,000 volumes. Rowland has access to over 4,800 e-journals in health sciences and many other titles outside the stated scope of the library.

**University Biospecimen Repository (UBR)**. UMMC established the UBR to support translational and clinical research in addition to serving as the Tissue Bank Core of the Cancer Institute. The UBR began operations in November 2011, with a focus on cancer-related surgery specimens. In March 2013, expansion to include blood collections to other areas including the transplant, gastrointestinal, congenital heart disease, and HIV clinics. To date, the UBR has over 2,300 participants, 45% of which are African Americans.

The UBR is led by a Medical Director and Co-Investigator and a Director of Operations. The current facilities are housed within the main hospital and 600 square feet of laboratory space for processing specimens, equipped with ambient and cold centrifuges, biological safety cabinet, seven -80°C freezers, liquid nitrogen and liquid nitrogen storage, and dry ice. The UBR is the only on-campus provider of dry ice to the UMMC research community.

The UBR has dedicated biorepository specialists for consenting patients and specimen processing. Blood samples are procured by operating room and general phlebotomy staff. Physicians in anatomic pathology aid with fresh tissue sample procurement. Specimens are transported to the UBR, processed and stored in temperature-controlled freezers (–80 °C; on back-up power with alarm system, 24-hour remote monitoring). Participants are registered in our database along with demographic and histology variables. Our current database is Biological Specimen Inventory System (BSI) software. Samples collected include whole blood, serum, plasma, white blood cells, tumor and normal tissue, handled according to the International Society for Biological and Environmental Repositories (ISBER) Best Practices.

Our consent allows access to historical and future clinical data through the electronic health record (EHR) to facilitate in-depth translational research. Very few patients approached to participate in the UBR decline, resulting in an exceptionally high consent rate of 98.7%. At UMMC, we use Epic as our EHR and as the source for a large portion of data in our electronic data warehouse (EDW). We are integrating specimens housed in the UBR directly with patient information in the EDW.

The UBR performs clinical specimen processing, sample storage, and shipping for a wide variety of industry- sponsored clinical trials and investigator-initiated research studies. All staff are certified by the International Air Transportation Authority to ship clinical specimens (IATA). Specimens are shipped according to protocol and can be shipped at ambient temperature, cold (ice packs), or frozen (dry ice). The UBR staff works closely with each study team to provide superior sample management services. The UBR is currently supporting two NIH grants and processing biospecimens for over 25 industry-sponsored projects.

**The ACT Center for Tobacco Treatment, Education, and Research (MOVE)**. The purpose of the ACT Center for Tobacco Treatment, Education, and Research is to improve the health of Mississippians by reducing tobacco use through research, education, and treatment. The ACT Center provides state-of-the-art evidence- based treatment to help individuals who use tobacco to achieve long-term abstinence. The ACT Center has established a system of tobacco treatment clinics across the state of Mississippi, and clinics are available in hospitals in all nine public districts.

**Center for Telehealth**. The Center works to improve the availability of medical services in Mississippi. Using online video technology, UMMC provides remote medical care, health education and public health services through telehealth. The Center for Telehealth offers telemedicine, wellness care, disaster response, workforce development, business development, research and education to people in all parts of our state.

**Clinical Research Support Program (CRSP)**. The CRSP building is, located adjacent to the main campus and is easily accessible by interstate and state highways. Ample free front-door parking is available for clinical trial participants. The 8,000-square-foot CRP facility comprises a reception area, 18 examination rooms, two laboratories for phlebotomy and storage of supplies, two conference rooms, and private offices/cubicle workstations. The following equipment is housed in the CRP and is at the disposal of the project investigators: a Thermo Electron Revco -80oC upright freezer, a So-Low C85-5 -85oC ultra-low chest freezer, several centrifuges (Eppendorf 5702R, Fisher Scientific Centrific 228, Clay Adams Dynac), a biohazard refrigerator, several mercury sphygmomanometers, one Healthometer and one Detecto 350-lb. capacity balance scales, and a Seca stadiometer. The facility also provides secure storage of study records, a photocopier, paper shredder, fax machine, several networked laser printers, and desktop computers networked to the internet and to UMMC’s intranet.

**Mississippi Center for Obesity Research (MCOR)**. The Center seeks to address both mechanisms contributing to obesity in Mississippians and clinical interventions that directly address this statewide health problem and its associated morbidities. MCOR is the centerpiece of an aggressive, coordinated strategy to bring together researchers, health-care providers, state and local governments, business leaders and community groups to provide solutions to the obesity epidemic in Mississippi. The center encompasses both clinical and research activities, including the **Wellness and Weight Clinic** for obese and overweight children. The Center has become a collaborator in a multi-site registry, the **Pediatric Obesity and Weight Evaluation Registry (POWER)**. This is a collaboration with Cincinnati Children’s Hospital and part of a 29 site consortium to identify individuals with obesity that may be contacted for participation in obesity research for which they may be eligible. UMMC joined this registry consortium in 2014.

**Myrlie Evers-Williams Institute for the Elimination of Health Disparities**. Founded in 2014, the Institute for the Elimination of Health Disparities, serves as the research arm of the Office of Population Health at the University of Mississippi Medical Center. Through a family-centered approach, the Institute seeks to decrease health disparities through, education, research, research training, and community-based programs and services.

**Children’s Cancer Center (CCC)**. The CCC is comprised of a multidisciplinary collaborative research team that was motivated by the realization that team science and completely new strategies are needed if we are to develop novel curative therapies and early interventions for all childhood cancers. The CCC research team has expertise in the most lethal pediatric cancers, and is combining their experience and commitment to a sustained effort to improve cure rates. The Center is a partner in the **Children’s Oncology Group** cooperative network to enhance care for children with cancer.

**Comprehensive Epilepsy Center (CEC)**. The Center is dedicated to the care of children and adults with epilepsy. The center offers state-of-the-art medical and surgical treatment of seizures/ epilepsy in adults and children. The center's goal is to help patients gain control of seizures and optimize their quality of life. Patients benefit from the intervention of an experienced multidisciplinary team that includes neurologists, neurosurgeons, neurophysiologist, neuroradiologists, EEG technologists, clinical nurse specialists, neuropsychologists and psychiatrists.

**CORE FACILITIES**

**Analytical/Assay Core**. The Assay and Analytical Laboratory, located on the fourth floor of the Arthur C. Guyton Research Center, is operated by the Department of Physiology and Biophysics. Supported by a knowledgeable staff, the facility provides support for various radioimmunoassay, enzyme-linked immunoassays (ELISA), molecular, and chemical analyses. These facilities and services are available to faculty at UMMC and other educational and research institutions for a service based fee.

**Analytical Ultracentrifuge Core**. The Analytical Ultracentrifuge Facility is located in the Department of Biochemistry, G208-G209, in the Guyton Research Building. The facility includes a Beckman XLA Analytical Ultracentrifuge equipped with absorption optics, an AVIV FDS system for fluorescence detection, an Anton Paar DMA 5000 for density measurements, and an Anton Paar AMVm micro viscometer.

**Biomedical Materials Laboratories**. Biomedical Materials Laboratories are available for the development, processing, and characterization of a diverse range of materials (metals, polymers, ceramics, composites) with a wide range of properties (physical, mechanical, electrochemical, biological) and at all levels of interest – from atomistic to macroscopic. Core laboratories include facilities for tissue engineering, histology, computer modeling, metallography, corrosion, wear, fast fracture, fatigue, and failure analysis. All together these laboratories cover approximately 5,500 square feet of the first and fifth floors of the School of Dentistry.

**Confocal Microscopy Core**. The Confocal Microscopy Core, located on the second floor of the Arthur C. Guyton Research Building, is primarily an equipment core, though all users must be pre-approved and pass through a training course before they are allowed to use the state of the art equipment. This equipment includes a Leica TCS-SP2 laser scanning confocal upright microscope. The system has 3 separate lasers (488/546/633 nm) for use along with 3 standard visible length fluorescence dyes and transmitted light. This confocal microscope is capable of imaging standard fluorescence dyes within the visible spectra including FITC/TRITC, CY2/CY3/CY5, green fluorescence protein variants (GFP/YFP/RFP/DsRed) and several different indicator dyes (i.e. Ca 2+, pH, membrane potential, oxidative stress, etc).

Capabilities of the Confocal Microscopy Core include:

* Standard confocal microscopy with simultaneous or sequential image collection
* Line scan and Z-scan modes
* 10X, 20X, 40X, 40X oil, 60X oil and 100X oil objectives
* Transmitted light detection
* Tunable filter
* Time lapse
* FRET/FRAP (Fluorescence resonance excitation transfer/ Fluorescence recovery after photo bleaching)
* 3D Reconstruction

**Genomics/Microarray Core**. Our Genomics Facility is a 750 sq ft. training facility that provides access to specialized equipment typically associated with microarray technology. This facility was established through a BRIN grant and is currently supported by an INBRE grant to the Mississippi Functional Genomics Network (MFGN, University of Southern Mississippi). In addition to offering a microarray facility, the Gemomics Core staff members have over thirty years of experience in all aspects of molecular biology and quantitative RNA analysis, offered to all Core uses. They also provide a mutagenesis service for an at-cost fee. For microarray analysis they use an Agilent 2100 “Lab-on-a-chip” bioanalyzer to assess the quality of RNA and a NanoDrop for quantitation prior to labeling.

**Histology Core**. Located on the second level of the Arthur C. Guyton Research Center, the Histology Core provides high quality histological services including tissue fixation and processing, tissue sectioning (cryosectioning and paraffin), histological and immunohistochemical staining and image analysis.

**Laser Capture Core**. A laser capture microdissection system, complete with fluorescence capabilities, is available for all medical center faculty researchers through the Center for Psychiatric Neuroscience (CPN). The system was developed by the National Institutes of Health through an intensive collaboration between bioengineering and cancer pathology groups. It provides a method for capturing a single cell or pure multiple cell types from specific microscopic regions of tissue sections, permitting scientists to dramatically increase the sensitivity and accuracy of downstream biological assays (gene expression arrays, quantitative PCR, Western blot, etc.) on discrete populations of cells. The CPN will provide training in the operation of the LCM.

**HPLC/Mass Spectrometry Analytical Core**. The HPLC/ Mass Spectrometry Core occupies approximately 1800 square feet of laboratory and office space in rooms R414, R416 and G477. The core provides the instrumentation and analytical expertise to perform quantitative analysis of a variety of endogenous compounds including: lipids (prostaglandins, isoprostanes, Cyp eicosanoids), catecholamines, creatinine, carbon monoxide, citrulline assay (NOS activity), steroid hormones and circulating peptides (angiotensin II and Ang1-7). Major equipment includes four HPLC systems equipped with UV, fluorescence, radioactive and light scattering detectors, two liquid chromatography/tandem mass spectrometer systems (LC/MS/MS), a gas chromatograph/quadrapole mass spectrometer (Voyager® Thermo Scientific), and a gas chromatography system (Agilent) with FID, electron capture or phosphorus detectors. The LC/MS/MS systems consist of ABSCIOEX QTRAP® 4000 and 5500 systems each equipped with Dionex® HPLC systems and temperature controlled auto samplers. The 4000 LC/MS system was installed in March 2010 and has been optimized for the identification and quantification of drug and drug metabolites, xenobiotics, lipids and steroids. The 5500 LC/MS/MS system was installed in June 2010 is optimized for proteomic identification of peptides and proteins, quantitative analysis of peptide/protein concentrations and the identification of posttranslational modifications of proteins. The core staff has extensive expertise to develop new analytical procedures and provides instruction in sample collection and storage, extraction and data interpretation.

**Molecular Core**. The Molecular Laboratory occupies 800 ft2 of laboratory space in the Guyton Center. Separate office space (200 ft2) is located adjacent to the Molecular lab. The Core also contains a 300 square feet HPLC Facility in the Molecular laboratory, which provides sample purification and assays for the measurement of glycol-lipids such as hyaluronan and its metabolites, creatinine, and catecholamines. Current services of the Molecular core include MicroArray hybridization and scanning, RNA isolation including quality control, cDNA synthesis, manual sequencing, and RNase protection Assays. Available equipment includes the following:

***Only include information that is applicable to and accurate for your project. This template is for planning purposes only.***

**APPENDIX D**

OMB No. 0925-0001 and 0925-0002 (Rev. 03/2020 Approved Through 02/28/2023)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME:

eRA COMMONS USER NAME (credential, e.g., agency login):

POSITION TITLE:

EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)

| INSTITUTION AND LOCATION | DEGREE(if applicable) | Completion DateMM/YYYY | FIELD OF STUDY |
| --- | --- | --- | --- |
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**A. Personal Statement**

**B. Positions and Honors**

**C. Contributions to Science**

**D. Additional Information: Research Support and/or Scholastic Performance**

**APPENDIX E**

**CO-PRINCIPAL INVESTIGATOR PLAN**

**Department of Pediatrics Applicant Information**

* Applicant Name: Click here to enter text.
* Degree: Click here to enter text.
* Title: Click here to enter text.
* UMMC Employee Number: Click here to enter text.
* Telephone Number: Click here to enter text.
* E-mail Address: Click here to enter text.

**Co-Principal Investigator Applicant Information**

* Co-Principal Investigator Name: Click here to enter text.
* Degree: Click here to enter text.
* Title: Click here to enter text.
* School: Click here to enter text.
* Department: Click here to enter text.
* Division: Click here to enter text.
* UMMC Employee Number: Click here to enter text.
* Telephone Number: Click here to enter text.
* E-mail Address: Click here to enter text.

**Co-Principal Investigator Plan** **(½ to 1 page):**

Division of study tasks and responsibilities:

Joint research meeting schedule:

Data storage and monitoring: