

Sample Grant Text Perelman School of Medicine

Last revision date: 4/26/2021

About this Resource

The information provided in this document is offered to assist investigators in the preparation of grant submissions. Content featured is a compilation of information provided by UPenn faculty, who were generous enough to share their sample text.

Boilerplate text may be copied into grants and used as a foundation to create individualized proposals. Please note that the information provided is not exhaustive and may not be applicable to specific funders or grant guidelines. Please review both the grant guidelines and the boilerplate text carefully, and use only what is appropriate.

The provided text will evolve over time and undergo periodic updates. In addition to the sample text, please refer to our <u>PSOM Grant Support</u> for links to additional data resources. Please note that some grant sections require inputting current facts; investigators are encouraged to tailor these statements for your specific proposal as appropriate.

Table of Contents

- I. <u>Authentication of Key Resources</u>
- II. <u>Resource Sharing</u>
- III. <u>University of Pennsylvania</u>
 - a) Option 1: UPenn Text
 - b) Option 2: UPenn Text
 - c) Option 3: UPenn Text

IV. <u>Perelman School of Medicine</u>

- a) Option 1: PSOM Text
- b) Option 2: PSOM Text
- c) Option 3: PSOM Text
- V. <u>Hospital of the University of Pennsylvania</u>

VI. <u>Core Facilities & Shared Resources</u>

- a) Option 1: Facilities Text
- b) Option 2: Facilities Text
- VII. Digital Academic Research Transformation (DART)
- VIII. Penn Center for Health, Devices and Technology (Penn Health-Tech)
- IX. Office of Clinical Research (OCR)

I. AUTHENTICATION OF KEY RESOURCES

General: The proposed application includes study of (clinical trial or animal studies). All findings related to these studies will be recorded in laboratory notebooks that are maintained in a secure location in the laboratory and/or stored in electronic databases that are saved on password-protected computers. All tissues collected from animal or human subjects are identified only by study id for the purpose of assays by collaborating investigators. Thus, collaborating investigators are blinded to treatment groups. Study ids are HIPPA compliant and all human patient data is de-identified in laboratory records. Publications will include sufficient experimental detail to enable independent reproduction of methods. Raw data that is used to calculate summary statistics in publications will be provided in supplementary data as required by the journal or otherwise be available by request.

Antibodies: Antibodies to be used in this study are to be purchased through commercial vendors that include XXX and XXX. Every attempt will be made to consistently obtain antibodies of the same lot number for the duration of a study. Antibodies will be reconstituted (if needed), stored per manufacturer's instructions and used prior to the expiration date. Validation of new batches or lots of antibodies for signaling molecules will be performed via western blotting with comparisons to existing lots and confirmation of the protein band of interest in cells known to be positive for the protein. When possible, RNAi oligonucleotides will be employed to ensure that a band of appropriate molecular weight is no longer detected after knockdown. Antibodies to be used for immunohistochemistry will be tested in banked tissues previously determined to be positive for the marker of interest, with the specificity of staining confirmed via appropriate blocking peptides and/or competitive inhibition with a second antibody. Additional controls include replacement of the primary antibody) and exclusion of the primary antibody in the case of staining protocols that use a secondary antibody. Antibodies for flow cytometry will be similarly validated using isotype controls and investigation of known positive/negative cell types.

Verification of Cell Lines: Whenever possible cells lines will be obtained from commercial cell banks (e.g., ATCC). In the case of cell lines obtained from other laboratories, the lines will be subject to authenticity and mycoplasma testing (e.g., by IDEXX Bioresearch) before use in experiments. Any positive results will be reported to the donating laboratory. If cells are positive for mycoplasma, they will be treated for contamination using an accepted antimycoplasma reagent (e.g., by Lonza) and retested prior to use. All cells lines in use in the laboratory are subject to authenticity on an annual basis. Cells are monitored for contamination (e.g., fungus or yeast) on an ongoing basis by visualization under a microscope. Cells maintained in vitro are identified by serial passage numbers with designated passage numbers used for in vitro and in vivo studies.

Transgenic Animals: XXXX transgenic mice will be procured from XXXXX. The genotypes will be confirmed using validated primers. Validation of the genotypes will be done in all progenies.

Drugs/Chemicals: *Plasmids:* All plasmids (expression and lentiviral vectors) obtained from other laboratories or generated in our laboratory will be subjected to sequencing to confirm their identity prior to any use. *Specialty Chemicals:* Chemicals for these studies will be purchased from reputable commercial vendors, such as Sigma-Aldrich. All reagents will be stored as recommended and utilized by their expiration date. All compounds that are frozen will be stored in batches at –20°C or –80°C as appropriate, and subjected only to a single freeze-thaw cycle.

All studies will include appropriate controls to ensure the expected biological activity. XX Add information here on the source and storage of any specific drugs to be used in the proposed studies XXX

II. RESOURCE SHARING

The leadership of the XX concurs completely with the policy of the NIH to share data with the scientific community. In fact, the policy of the University of Pennsylvania requires that research results generated at the University in the conduct of sponsored research be made available to the scientific community and public in a timely and open manner, while preserving research freedom and safeguarding appropriate authorship. This policy reinforces open scientific inquiry, encourages diversity of analysis and opinion, promotes new research, makes possible the testing of new or alternative hypotheses and methods of analysis, supports studies on data collection methods and measurement, facilitates the education of new researchers, enables the exploration of topics not envisioned by the initial investigators, and permits the creation of newer data sets when data from multiple sources are combined.

The primary methods to be used for Data Sharing will be: 1) Publication of full length manuscripts in archival journals, 2) Presentation of research results at national conferences and other forums, 3) Direct response to requests for data and information from the community at large, and 4) Posting data to the XX website when appropriate. In all instances, protection of privacy and rights of individuals will be the first priority prior to data sharing. The Penn Center for Innovation (PCI) takes reasonable steps to streamline the process of transferring research tools and samples to other academic research institutions. We will work with PCI to ensure that our data sharing meets the requirements of the NIH and the University.

III. UNIVERSITY OF PENNSYLVANIA

A. OPTION 1: UNIVERSITY OF PENNSYLVANIA

This proposed research draws upon the outstanding educational and research resources of the University of Pennsylvania (Penn), a nationally-ranked university, as well as the educational and research resources of two nationally-ranked hospitals, the Hospital of the University of Pennsylvania (HUP) and The Children's Hospital of Philadelphia (CHOP). Penn is home to a diverse body of nearly 11,000 full-time students enrolled in its four undergraduate schools and more than 12,000 students enrolled in its 12 graduate and professional schools, each a national leader in its field. Penn's schools are located on a compact campus, the geographical unity of which supports and fosters its multidisciplinary approach to education, scholarship, and research.

Research and research training are substantial and esteemed enterprises at Penn. Its research community includes more than 4,800 faculty, 1,300 postdoctoral fellows, nearly 3,800 PhD students, and 5,700 professional, administrative, and support staff bolstered by an annual academic budget of \$2.44B.

Penn's 189 research centers and institutes bring together researchers from multiple departments, schools, and disciplines and provide the infrastructure through which faculty conduct research in a highly collaborative atmosphere. Clinical and basic research flourish side by side, with advances in knowledge and technique being translated immediately into practice.

Penn Medicine

Penn's Perelman School of Medicine, together with the University of Pennsylvania Health System (UPHS), form PENN Medicine, an almost \$9B enterprise dedicated to the related missions of medical education, biomedical research, and quality of patient care. PENN Medicine seeks to accomplish its missions through the recruitment and retention of a world-class faculty and staff who strive for excellence, innovation, quality, and professionalism. PENN Medicine's goal is to be recognized nationally as the most accomplished and respected School of Medicine and Health System. Penn Medicine employs over 44,000 people.

B. OPTION 2: UNIVERSITY OF PENNSYLVANIA

Abramson Cancer Center (ACC) of the University of Pennsylvania and Shared Resources Founded in 1973 as the University of Pennsylvania Cancer Center, the ACC was renamed in 2002 in recognition of the support of Leonard and Madlyn Abramson and family. The ACC serves as the focus of cancer-related research, patient care, and educational activities at the University of Pennsylvania. It is one of just 51 Comprehensive Cancer Centers in the country approved and designated by the National Cancer Institute. The ACC has been continuously funded by the National Cancer Institute since its founding. In 2020, the Cancer Center under the directorship of Robert Vonderheide, M.D., DPhil., underwent a highly successful competitive renewal of the Cancer Center Support Grant (CCSG), receiving the maximum five-year approval and an "exceptional" rating. The Cancer Center provides an organizational framework that promotes and enhances interdisciplinary cancer research within the Perelman School of Medicine and throughout the University. The ACC has more than 300 physicians and scientists who are drawn from 47 Departments with investigators strategically spread across the University, from departments in the Medical School, as well as the Schools of Arts and Sciences, Engineering and Applied Science Veterinary Medicine, Dental Medicine, Nursing, Social Work, Wharton Business,

and Arts and Sciences. Cancer Center members have \$167 million of extramural funding (direct), of which \$48 million is from the NCI. The accrual to interventional trials was 1,889 in 2014, an increase of 11% compared to 2011. Collaborative working relationships are extensive and wellestablished among Cancer Center members from different Departments and Schools, as is evident in all aspects of Cancer Center research, patient care and educational activities. There are a number of research cores that are supported by the Center including small animal imaging, transgenic mouse facility, proteomics, sequencing and oligonucleotide synthesis, a biomedical instrumentation machine shop, a confocal microscopy facility, cell sorting and a cell center for purchasing reagents and cell lines (see list of specific core facilities below).

The School of Veterinary Medicine at the University of Pennsylvania

The School of Veterinary Medicine at the University of Pennsylvania was founded in 1884, and has a long-standing tradition as a global leader in veterinary medicine education, research, and clinical care, and is the only veterinary school developed in association with a medical school. As part of the University of Pennsylvania. Penn Vet is a key partner in our biomedical research and teaching centers, focusing on Cancer, Infectious Disease, Regenerative medicine and Neuroscience. Penn Vet includes several core centers that work to enhance collaborative research efforts. The Veterinary Clinical Investigations Center (VCIC) has the expertise to implement and manage all aspects of veterinary clinical trials, from study set-up and recruitment to data collection and analysis, final study reporting and closeout. The center works closely with faculty members trained in epidemiology and trial design to ensure that projects are powered appropriately with a robust plan for statistical analysis in order to yield meaningful results. The Comparative Pathology Core (CPC) is an Abramson Cancer Center shared resource, providing expert pathological characterization and validation of mouse and other animal models used in biomedical research by offering the expertise of board-certified veterinary pathologists and access to state-of-the-art histology, immunohistochemistry, and digital pathology services. The Penn Vet Imaging Core (PVIC) provides access to cutting-edge optical imaging capabilities for researchers at the University of Pennsylvania, Children's Hospital of Philadelphia, and Wistar Institute, and includes instruments to perform widefield, confocal, multiphoton, fluorescence lifetime, and total internal reflection fluorescence (TIRF) microscopy, as well as software tools for image analysis. They have a Flow Cytometry Core run in association with the School of Medicine Cytomics and Cell Sorting Resource Laboratory. A unique core within Penn Vet is the Referral Center for animal Models of Human Genetic Diseases (RCAM), whose mission is to discover, create, characterize, treat, and share naturally occurring hereditary disorders in dogs and cats that are orthologous to those found in human patients.

Computer

Each of the investigators has a top-of-the line computer, printer, with direct Internet connection. In-house hardware and software support, as well as administrative support for all workstations are readily available. All clinical and laboratory investigators have comparable Internet access, and all are on Penn's network. Additional details are provided in the resource sections of projects and cores.

Office

All project leaders and project investigators and managers have high quality office space. Specific information about the offices of Penn investigators involved in this P01 can be found in the resource sections of the projects and cores.

C. OPTION 3: UNIVERSITY OF PENNSYLVANIA

A great strength at the University of Pennsylvania is that all Schools are located on a single campus (Arts and Sciences, Business, Dental, Engineering, Law, Medicine, Veterinary, etc) with no laboratory or faculty office more than a 12 minute walk and most labs and offices located within a single complex of immediately adjacent and interconnected buildings. While many universities can boast that many of its schools are centrally located and others are only a short car, train or shuttle bus ride away, literally all schools at Penn are represented on a single campus. While this may not seem like a critical feature, it greatly increases opportunities for exchange between faculty of diverse expertise.

IV. PERELMAN SCHOOL OF MEDICINE

A. OPTION 1: PERELMAN SCHOOL OF MEDICINE

The Perelman School of Medicine prides itself on the vision of Benjamin Franklin — founder of the University — that education should be oriented toward combining theory and practice for the betterment of humanity. Penn can rightfully be called the "birthplace of American medicine," as it includes the nation's first hospital (Pennsylvania Hospital in 1751), first medical school (1765), first university hospital (HUP in 1874), and first integrated academic health system (1993). The School of Medicine is the nation's third-ranked medical school (2020 *US News and World Report*) and third-largest recipient of National Institutes of Health (NIH) funding (2020). The School of Medicine has a distinguished faculty of over 2,800 which includes 15 members of the National Academy of Sciences (43 at Penn altogether) and 110 members of the National Academy of Medicine (formerly the Institute of Medicine); and a major research facility of the Howard Hughes Medical Institute, with a total of five investigators in the School of Medicine.

The School of Medicine has an internationally renowned research faculty and programs in all fundamental areas of basic and clinical biomedical science, including epidemiology, biostatistics, and informatics. The School of Medicine boasts a long record of innovation in both clinical and basic science, resulting in numerous landmark achievements, and is supported by state-of-the-art research core facilities and major clinical research facilities. The total area of all Penn Medicine facilities is 6.8M net sq. ft. School of Medicine facilities has an estimated 2.15M gross sq. ft., and the area dedicated for research is approximately 1.2M net sq. ft. Of the 1.2M net sq. ft. of research space, approximately 70% of this space is new or has been renovated since 1989.

Research and clinical training programs at PENN Medicine span the full range of participants – from high school and undergraduate students, through MD (778 current), PhD (735 current) and master's-level (more than 300 currently) trainees, to postdoctoral (903 current) and clinical (more than 1,400 current) residents and fellows. These programs are remarkable for their integration and breadth. The School of Medicine has one of the nation's oldest and largest MD-PhD programs, and is supported, in part by, by one of the biggest NIH MSTP training grants in the country. There are currently 202 students in the program, enrolled in 11 graduate groups. Close to 90% are in programs within Biomedical Graduate Studies, but the program also includes students in Bioengineering, History and Sociology of Science, and Health Care Systems (Wharton). In addition to the MD-PhD program, the School of Medicine supports six MD-Masters programs: MD-MSCE, MD-MBA, MD-M Bioethics, MD-Masters in Health Policy Research, MD-Masters in Translational Research, and the MD-MPH.

The School of Medicine library on campus provides current literature for faculty and students. Its own resources include interlibrary loans, photocopy, and reference assistance. The library also provides access to important internet resources such as 91 medical databases including Medline, CancerLit, Grateful Med, the Database of Abstracts of Reviews of Effectiveness (DARE) and others. It contains over 170,000 volumes, annually acquires over 2,500 books, and subscribes to more than 8,600 current periodicals.

B. OPTION 2: PERELMAN SCHOOL OF MEDICINE

Founded in 1765, the School of Medicine graduated its first students in 1768, and its emphasis from the outset has been on integrating medical research and education. Today, Penn's Perelman School of Medicine is ranks in the top 3 in the nation by the U.S. News & World Report ranking of top research-oriented medical schools. J. Larry Jameson, MD, PhD is Dean of the Perelman School of Medicine and Executive Vice President of the University of Pennsylvania Health System (Penn Medicine). The Perelman School of Medicine is a major research base and has a long tradition of interdisciplinary commitment, as exemplified by its many biomedical research Centers and Institutes. Currently there are 1.2 million net sq. ft. of research space, 70% of which is new or has been renovated since 1989. The Perelman School of Medicine is recognized nationally for its strong program in Biomedical Graduate Studies. The PhD training programs include biology, biochemistry and molecular biophysics, genomics and computational biology, bioengineering, cell and molecular biology, immunology, neuroscience, pharmacological sciences, epidemiology, and biostatistics. Penn's NIH-sponsored Medical Scientist Training Program remains the largest in the nation. The scope of the School's research enterprise is broad, encompassing all areas of contemporary biomedical investigation and, unusually, is unified on a single campus. In particular, the School is strong is immunology and cancer. The School comprises 28 basic and clinical departments and has more than 2,800 faculty members and 2,200 students and trainees. It is one of the institutions with the highest funding from NIH research awards.

C. OPTION 3: PERELMAN SCHOOL OF MEDICINE

Penn Medicine is dedicated to the related missions of delivery of outstanding care to our patients, teaching the next generation of physicians and investigators, generation of new biomedical knowledge, and translation of that knowledge to improve the population's health. It comprises The University of Pennsylvania Perelman School of Medicine (PSOM) and the University of Pennsylvania Health System (UPHS). Dr. J. Larry Jameson is the Executive Vice President of the University for the Health System and Dean of the PSOM. Dr Jameson oversees both UPHS and the PSOM. PENN Medicine employs more than 44,000 people and had total annual revenue in FY2020 of \$8.9 billion. The School was founded in 1765 by John Morgan and William Shippen, native Philadelphians who graduated from the medical school of the University of Edinburgh, Scotland. The emphasis, from the outset, was to integrate medical research with education. The PSOM continues to be ranked in the top five medical schools in the country (US News and World Report). Please note that institutional support for the XX specifically is described in the main Overall text (and support letter from Dr. J. Larry Jameson).

Research at the Perelman School of Medicine

The Penn PSOM has continued to enhance its leadership role in biomedical research. In federal FY2019, the PSOM received more than \$580 million in NIH research awards (rank #3 amongst other medical schools). Currently, the total area of all PSOM facilities dedicated for research is more than 1.2M net square feet.

An important institutional resource which supports patient-oriented research is the Institute for Translational Medicine and Therapeutics (ITMAT). Under the leadership of director Garret A. FitzGerald, M.D., ITMAT (support letter provided in this application) supports research at the interface of basic and clinical research. ITMAT includes its own basic research space, the former General Clinical Research Center (GCRC) which has been integrated with that of Children's Hospital of Philadelphia (CHOP) to form the Clinical and Translational Research Center (CTRC) and an expanding repertoire of cores, programs, and centers designed to support research endeavors between proof of concept in cellular and animal model systems across the translational divide into proof of concept and dose selection in humans. Educational programs relating to translational research, including a newly founded Masters in Translational

Research, are also housed within ITMAT. ITMAT has expanded to include investigators focused on clinical and translational research in all schools at Penn, CHOP, the Wistar Institute, and the University of Sciences in Philadelphia. These partner institutions competed successfully for the Clinical and Translational Science Award (CTSA) funded under the NIH Roadmap, designating ITMAT as the academic home for the program.

The School provides substantial support for more than 75 biomedical research cores which offer a number of services, ranging from molecular profiling to cell sorting to high resolution electron microscopy. Through these diverse and extensive resources, the School provides access to state-of-the-art equipment and instrumentation, technical expertise and training and education all designed to support innovative, cutting edge research. A complete listing of each core is found on the PSOM website.

V. HOSPITAL OF THE UNIVERSITY OF PENNSYLVANIA

The Hospital of the University of Pennsylvania (HUP) was the first hospital in the nation built by a university specifically to provide bedside teaching for its medical school. Founded in 1874, HUP is the flagship hospital of UPHS. As one of the largest hospitals in the region, this 814-bed institution serves as a regional and national referral center, offering the most sophisticated diagnostic and treatment services available in the country, while the tradition of medical and scientific excellence continues. The hospital has a full-time faculty of 1,713 in addition to more than 1,100 residents and fellows.

HUP is featured in *US News & World Report's* "Best Hospitals in America" guide, ranking prominently at national and regional levels. The HUP complex includes 16 interconnected buildings, representing 2M net sq. ft. Hospital features include the Abramson Cancer Center, one of only 51 National Cancer Institute (NCI) designated comprehensive cancer centers in the nation; the Clinical and Translational Research Center (CTRC), which conducts clinical trials; and PennSTAR, a critical-care flight program with three helicopters that transfer critically injured patients in the Philadelphia region. HUP has implemented a computerized physician order entry system, which represents a major opportunity for research.

The Perelman Center for Advanced Medicine (PCAM)

The Renal Division's outpatient nephrology practice is based at PCAM, a state-of-the-art, 500,000 square foot outpatient facility located within the HUP campus. PCAM was designed to create an ideal environment for patient-focused care and collaboration among health professionals. This outpatient care center includes a comprehensive range of medical and surgical subspecialty clinics in addition to primary care and a personalized preventative care program. The center's mission combines pioneering research, academic excellence and outstanding clinical care to advance the practice of medicine and the quality of care provided. Thus, researchers work in close collaboration with clinicians throughout the site.

VI. CORE FACILITIES & SHARED RESOURCES

A. OPTION 1: CORE FACILITIES & SHARED RESOURCES

Core Facilities

In addition to our research laboratories and department-based services centers, we have access to many core facilities. The Biomedical Research Core Facilities of the University of Pennsylvania Perelman School of Medicine provides access to over 75 research core facilities to advance the research endeavors of its faculty. These facilities include resources related to animal research/model development (Small Animal Imaging, Transgenic and Chimeric Mouse Facility, Stem Cell and Xenograft Core, CRISPR Cas9 Mouse Targeting Core); Genomic/Proteomic Analyses (DNA Sequencing, High Throughput Screening, Molecular Profiling, Next Generation Sequencing, Quantitative Proteomics, Vector Core); behavioral studies (*Neurobehavioral Testing*) and immunological investigations (*Human Immunology*). They provide support for informatics and clinical services (Investigational Drug Service, Bioinformatics, Clinical Research Computing Unit), as well as "backbone" resources for biological investigations (CDB Microscopy, Flow Cytometry and Cell Sorting, Electron Microscopy, Cell Center Services/Stockroom). A Research Instrument Shop supports the design and construction of laboratory and clinical instrumentation. Additional core services in pathology are available through the Children's Hospital of Pennsylvania (Pathology Core Labs) and PennVet (Comparative Pathology Core).

Institute for Translational Medicine and Therapeutics

The Department of Radiation Oncology maintains a clinical research core of research nurses and data managers who assist with the regulatory, nursing, sample collection, and data management aspects of a clinical trial. Moreover, The Institute for Translational Medicine and Therapeutics (ITMAT) at Penn supports research at the interface of basic and clinical research focusing on developing new and safer therapeutics. ITMAT offers research cores, educational programs, and research programs and centers. These are designed to facilitate training and research particularly from proof of concept in cellular and animal model systems across the translational divide to proof of concept and dose selection in humans. ITMAT includes faculty, basic research space, and the Center for Human Phenomic Science. This Center serves to provide resources, environment, operations, and training to support and promote high-quality clinical and translational research by qualified investigators. This includes an Investigational Drug Service and the Research Nurse Core to support inpatient and outpatient clinical research.

Abramson Cancer Center

The University of Pennsylvania Abramson Cancer Center was founded in 1973. The National Cancer Institute designated it as a Comprehensive Cancer Center in 1991. The Cancer Center's programmatic structure stimulates and supports interdisciplinary research, in basic sciences and translational medicine. The Cancer Center has programs in tumor cell biology, gene structure and regulation, tumor metabolism, virology, pediatric oncology, radiation biology, clinical investigation and cancer control. There are currently more than 300 members in these Cancer Center programs. These investigators are strategically spread across the University, from departments in the School of Arts and Sciences, School of Engineering and Applied Science as well as the School of Medicine and School of Nursing.

School of Medicine

The School of Medicine at the University of Pennsylvania has several common resources that benefit our research. Core Research Facilities are detailed above. The School also boasts of an expansive and highly integrated library system. The biomedical library is located at the juncture

of the Hospital and the School of Medicine, contains over 170,000 total volumes and over 8,500 journal subscriptions. In addition to the printed materials, the Library provides access to over 500 full-text electronic journals, over 230 bibliographic databases and numerous other web-based resources. It aids faculty investigators and research trainees through such services such as interlibrary loans, reference assistance, and hands-on computer instruction provided by highly trained medical librarians. In addition to the Biomedical Library, we have access to additional health sciences libraries on or near campus, including those at the Veterinary and Dental Schools and Children's Hospital, as well as all the other Penn Libraries.

Penn Vet

The School of Veterinary Medicine at the University of Pennsylvania was founded in 1884, and has a long-standing tradition as a global leader in veterinary medicine education, research, and clinical care, and is the only veterinary school developed in association with a medical school. As part of the University of Pennsylvania, Penn Vet is a key partner in our biomedical research and teaching centers, focusing on Cancer, Infectious Disease, Regenerative medicine and Neuroscience. Penn Vet includes several core centers that work to enhance collaborative research efforts. The Veterinary Clinical Investigations Center (VCIC) has the expertise to implement and manage all aspects of veterinary clinical trials, from study set-up and recruitment to data collection and analysis, final study reporting and closeout. The center works closely with faculty members trained in epidemiology and trial design to ensure that projects are powered appropriately with a robust plan for statistical analysis in order to yield meaningful results. The Comparative Pathology Core (CPC) is an Abramson Cancer Center shared resource, providing expert pathological characterization and validation of mouse and other animal models used in biomedical research by offering the expertise of board-certified veterinary pathologists and access to state-of-the-art histology, immunohistochemistry, and digital pathology services. The Penn Vet Imaging Core (PVIC) provides access to cutting-edge optical imaging capabilities for researchers at the University of Pennsylvania, Children's Hospital of Philadelphia, and Wistar Institute, and includes instruments to perform widefield, confocal, multiphoton, fluorescence lifetime, and total internal reflection fluorescence (TIRF) microscopy, as well as software tools for image analysis. They have a Flow Cytometry Core run in association with the School of Medicine Cytomics and Cell Sorting Resource Laboratory. A unique core within Penn Vet is the Referral Center for animal Models of Human Genetic Diseases (RCAM), whose mission is to discover, create, characterize, treat, and share naturally occurring hereditary disorders in dogs and cats that are orthologous to those found in human patients.

B. OPTION 2: CORE FACILITIES & SHARED RESOURCES

Other resources:

<u>Libraries</u>: The University of Pennsylvania Libraries' collections and services support the University in its mission encompassing teaching, learning, research, clinical care, and innovation, and represent the depth and range of scholarship at Penn.

The Libraries hold 304,659 e-journals, 2 million e-books, 4.5 million digitized images, 2,695 print journal subscriptions, 6.7 million printed book volumes, and 4.27 million items in microfilm. The Libraries' holdings are supplemented by numerous consortia and systems for obtaining journal articles and borrowing books, such as EZ Borrow, RAPID ILL, DOCLINE, and Hathi Trust, to name a few. The Biomedical Library upholds an "e-book preferred" purchasing policy in health sciences areas and an ongoing commitment to provide access to the most significant evidence-based research.

The Biomedical Library's dedicated and highly skilled staff support the Perelman School of Medicine, Penn Medicine, the School of Nursing, the Biology Department, and interdisciplinary centers and programs with services such as in-depth research consultations, course-integrated instruction, workshops, systematic review and literature search support, bioinformatics database support, research impact metrics and author services, 3D printing and modeling, data visualization, and scientific poster design and printing.

Currently, the Biomedical Library is undergoing a multi-million dollar renovation due to be completed in summer 2021. The renovated library will provide new and expanded spaces fostering both collaboration and contemplation, such as: upgraded and additional consultation and small-group study spaces; dedicated spaces for active learning; Design-Thinking room; Relaxation room; Mixed Reality Lab; collaborative classrooms and conference room; event space; and an enlarged and upgraded Digital Fabrication Lab, which includes the 3D and poster printing services with production and design specialist staff available.

These and all other library resources at Penn, including extensive collections in Physics, Mathematics, and Engineering, will be made available to all members of our team, including visitors.

<u>Machine Shop and Electronics Shop</u>. There is a machine shop with two expert machinists who are available to create, modify or repair equipment for the project; their services have been invaluable in the past. There is an electronics shop with one expert electronics engineer who is also available to create, modify or repair equipment for the project.

VII. DIGITAL ACADEMIC RESEARCH TRANSFORMATION (DART)

Originally formed in 2012 as Penn Medicine Academic Computing Services (PMACS) to provide computing services for the Perelman School of Medicine's departments, centers, and institutes, Digital Academic Research Transformation (DART) has grown and matured into a 140+ department of technology professionals providing a wide range of services including:

- Desktop Support
- Server Administration
- Storage Management
- Both High Performance Computing (HPC) and Limited Performance Computing (LPC)
- Software development
- Web design and development
- Database development
- Enterprise application development and support
- Consulting services that provide options to best support research initiatives

DART ensures that they are in compliance with applicable laws and regulations such as the HIPAA Security Rule, and FISMA. Computing technologies and resources are identified below within major functional information technology (IT) environments:

1. Data Centers: DART operates within a Tier-1+ data center and also within a Tier-3 SSAE 16/SAS 70 Type II Audit compliant colocation/datacenter facility located within the local geographical area to Penn's campus. Within the framework of standardized operating procedures for large and complex systems, there also exist specialized systems for targeted research projects. Physical access to these resources is restricted to authorized personnel only. There are network and firewall protections in place, plus data backup routines, and other activities that produce an environment suitable for meeting the various compliance standards imposed by the broader research mission of PENN Medicine.

2. Network Environments: The data communication networks support the secure transfer and movement of all data, application logic, and computer programs and project information developed. This category of activity encompasses: a) physical networks; b) logical networks; and c) security within these networks.

3. Computing Hardware Environments: This includes the hardware configurations on which all applications and software are built, run, and supported. Activity encompasses: a) infrastructure services platforms; b) data storage platforms; c) high performance computing platforms; d) database services platforms; and e) business continuity/recovery platforms.

4. Software/Application Environments: The applications and research software used to develop, maintain, process, and analyze data are supported. This category of activity encompasses: a) operating systems; b) statistical applications; c) database applications; and d) printing/scanning.

DART focuses on providing hardware and software services, systems administration, business continuity, and security services to research projects within the Perelman School of Medicine as well as other Schools associated with Penn Medicine. The various certifications held by staff members include ORACLE® certified database administration, Juniper Networking

certifications, VMware certifications, SUN Microsystems Solaris® certified systems administration, A+ hardware certifications, multiple security, Unix, and Microsoft Certified Solutions Expert certifications.

DART is focused on delivering state of the art technology solutions in the most cost-conscious manner in support of the education, administrative and research needs of the Perelman School of Medicine.

VIII. PENN HEALTH-TECH

The Penn Center for Health, Devices and Technology (Penn Health-Tech) is an interdisciplinary collaboration between Penn Medicine and Penn Engineering to advance world-class breakthroughs in novel devices and health technologies to solve the world's most pressing health care needs. Penn Health-Tech fosters a culture of collaboration and innovation across the University among faculty, postdoctoral fellows, and students.

TRANSLATION

Empower Penn innovators to develop transformative devices and technologies by connecting academia, healthcare organizations, investors, and other stakeholders

INNOVATION

Foster novel healthcare ideas and interdisciplinary collaborations based on science and technology developed at the University of Pennsylvania

CONNECTION

Stimulate engagement and support the education of future entrepreneurs in health technology

A University-wide initiative, Penn Health-Tech aims to:

• Enable Inventors: Penn Health-Tech supports faculty inventors by providing key development expertise, programming, and connections to internally incubate medical devices

• **Connect the Ecosystem**: Penn Health-Tech creates new teams across Medicine & Engineering (and beyond) to tackle unmet needs in healthcare and accelerate innovation

Funding for the center has been generously provided by the Perelman School of Medicine, the School of Engineering and Applied Science, the Office of the Vice Provost for Research, and the Children's Hospital of Philadelphia (CHOP).

PENN HEALTH-TECH ACCELERATOR PROGRAM

The Penn Health-Tech Accelerator program empowers faculty and staff from the University of Pennsylvania, Penn Medicine, and CHOP to develop and commercialize medical devices and health technologies to advance health and health care. The program is co-sponsored by Penn Health-Tech and the Acceleration Lab at the Penn Medicine Center for Health Care Innovation.

Penn Health-Tech holds an annual funding cycle, known as the Call for Proposals, where inventors submit proposals for technology solutions to unmet needs. Projects at different maturity stages are selected to participate in the accelerator program and move through multiple phases, facilitating the ideation, development, and commercialization of medical devices and health technologies based upon research and clinical expertise from University of Pennsylvania, Penn Medicine, and the Children's Hospital of Philadelphia.

EDUCATIONAL OFFERINGS

Faculty Salons

The Faculty Salon is an invitation only, structured brainstorming session focused on building collaborations between cutting-edge engineering innovators and leaders in translational

medicine. Penn Health-Tech engages Penn subject-matter experts to address acute clinical or technical challenges for cutting edge medical technologies being developed by some of Penn's most productive scientists. Faculty are chosen based on expertise and track record of achievement. The goal is to leave the Salon with potential collaborations, concrete plans for developing technology solutions to unmet clinical needs, and applicable funding opportunities to support this collaborative work.

Health+Tech Speaker Series

The Health+Tech Speaker Series is a 1-hour lunch lecture. Penn Health-Tech welcomes experts working at the intersection of healthcare and technology, leaders, researchers, inventors, and entrepreneurs. These events are an opportunity to explore the science and business of innovation and discuss the successes and challenges. All talks are held in-person or virtually through Zoom.

StartUP Sprint Entrepreneurial Workshops

The StartUP Sprint is an immersive workshop series leading teams through essential elements of the Health-Tech entrepreneurial process. The workshops offer participants access to advisors and resources in the form of subject matter experts who are brought in to lead a session on various topics. Each session will focus on one domain (i.e. regulatory, product validation, fundraising) and participants work with the advisor to sketch out how the concept impacts their specific project.

• *Format*. One-hour lecture followed by invite-only one-hour small group working session or office hours

• *Eligibility*: Open to all PHT-funded teams as well as other interested Penn and CHOP engineers, clinicians, and scientists to increase resource accessibility to projects at different maturity points within the medical device development process

• *Highlights Ecosystem*: Drives the utilization of Penn's rich research ecosystem and entrepreneurial resources

IX. OFFICE OF CLINICAL RESEARCH (OCR)

The Office of Clinical Research (OCR) is a central office in the Perelman School of Medicine (PSOM) designed to support the management and conduct of clinical research while promoting compliance. This is accomplished through standardizing the approach to clinical research across the various research centers and departments in the Perelman School of Medicine, and supporting investigative teams through regulatory and operational assistance, and enhancements in study management and oversight.

OCR features multiple units: Operations, Finance, Compliance, Sponsor Support, and Clinical Trial Contracting. Led by Vice Dean for Clinical Research & Chief Clinical Research Officer Emma A. Meagher, M.D., the OCR team of 50+ faculty and staff promotes human research for the advancement of healthcare while ensuring the highest level of research participant safety and facilitating the highest quality research by:

- Realizing the best research standards through adherence to university and government research policies and regulations;
- Supporting investigators and research teams through process improvement, innovative technologies, and education and training initiatives;
- Propagating best operational practices to maximize the efficiencies of research activities;
- Collaborating with University organizations involved with human research.

OCR provides expert guidance as well as extensive resources including guides, forms, tools and templates to facilitate robust, appropriate and compliant research practice.