CANCER CENTER SUPPORT
Department of Health and Human Services
National Institutes of Health

NATIONAL CANCER INSTITUTE

Federal Award Date: 08/16/2019

Grant Number: 2P30CA016672-43
FAIN: P30CA016672

Principal Investigator(s):
PETER W PISTERS, MD

Project Title: Cancer Center Support Grant

Harrott, Wesley R.
Assoc VP, Research Administration
1515 Holcombe Boulevard
Unit 1676
Houston, TX 770304009

Award e-mailed to: AwardNotice@mdanderson.org

Period Of Performance:
Budget Period: 08/16/2019 – 06/30/2020
Project Period: 08/28/1996 – 06/30/2024

Dear Business Official:

The National Institutes of Health hereby awards a grant in the amount of $11,029,670 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to UNIVERSITY OF TX MD ANDERSON CAN CTR in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award including the "Terms and Conditions" is acknowledged by the grantee when funds are drawn down or otherwise obtained from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Cancer Institute of the National Institutes of Health under Award Number P30CA016672. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please contact the individual(s) referenced in Section IV.

Sincerely yours,

Jason Gill
Grants Management Officer
NATIONAL CANCER INSTITUTE

Additional information follows

SECTION I – AWARD DATA – 2P30CA016672-43

Award Calculation (U.S. Dollars)

Salaries and Wages	$4,437,453
Fringe Benefits	$1,242,471
Personnel Costs (Subtotal)	$5,679,924
Consultant Services	$84,800
Materials & Supplies	$146,098
Travel	$24,963
Other	$957,759
Federal Direct Costs	$6,893,544
Federal F&A Costs	$4,136,126
Approved Budget	$11,029,670
Total Amount of Federal Funds Obligated (Federal Share)	$11,029,670
TOTAL FEDERAL AWARD AMOUNT	$11,029,670
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$11,029,670

SUMMARY TOTALS FOR ALL YEARS		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
43	$11,029,670	$11,029,670
44	FUTURE COSTS,RECOMMENDED COSTS	
45		
46		
47		

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Fiscal Information:

CFDA Name:	Cancer Centers Support Grants
CFDA Number:	93.397
EIN:	1746001118A1
Document Number:	PCA016672L
PMS Account Type:	P (Subaccount)
Fiscal Year:	2019

IC	CAN	2019	2020	2021	2022	2023
CA	8423165	$11,029,670	FUTURE COSTS,RECOMMENDED COSTS			

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:
PCC: 1XMD / **OC**: 414B / **Released**: GILLJ0 08/12/2019
Award Processed: 08/16/2019 12:04:42 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 2P30CA016672-43

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – TERMS AND CONDITIONS – 2P30CA016672-43

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.

c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2. As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This award is subject to the requirements of 2 CFR Part 25 for institutions to receive a Dun & Bradstreet Universal Numbering System (DUNS) number and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a DUNS requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) P30CA016672. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

This award is not subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:
Additional Costs

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

REQUIREMENT: The awardee is required to adhere to the Cancer Center Support (CCSG) Guidelines.

REQUIREMENT: The requirements contained in the document, "Intellectual Property Option to Collaborator," are incorporated by reference as a condition of this award. The "Intellectual Property Option to Collaborator" document may be accessed at http://ctep.cancer.gov/industryCollaborations2/docs/Intellectual_Property_Option_to_Collaborators.doc or may be obtained from the Regulatory Affairs Branch, Cancer Therapy Evaluation Program, Division of Cancer Treatment and Diagnosis, NCI at (240) 276-6580.

INFORMATION: The University of Texas M.D. Anderson Cancer Center has been approved as an NCI-designated Comprehensive Cancer Center in accordance with PAR 17-095 . The NCI has registered, as a badge, the term "NCI-designated Comprehensive Cancer Center." An approved Center may identify itself accordingly by reflecting the official NCI-designated Comprehensive Cancer Center badge on its stationery and publications.

REQUIREMENT: The University of Texas M.D. Anderson Cancer Center is required to report all interventional trials supported in whole or in part by this award into the Clinical Trials Reporting Program (CTRP) database. This requirement includes externally peer-reviewed, institutional and industrial trials that utilize the supporting infrastructure of the NCI funded Cancer Center.

REQUIREMENT: The awardee is required to comply with the NCI Policy Ensuring Public Availability of Results from NCI-supported Clinical Trials (NOT-CA-15-011). The annual progress report for this project must include information on the steps the awardee is taking or plans to take to comply with this policy.

REQUIREMENT: The awardee is required to follow the data and safety monitoring plan included in the competing application and may not implement any changes in the plan without the written prior approval of the National Cancer Institute.

REQUIREMENT: The awardee is required to follow the Data Sharing and Model Sharing plans included in the competing application and may not implement any changes in the plan without the written prior approval of the National Cancer Institute.

INFORMATION: Although the budget period start date for this award is 08/16/2019, this award includes funds for twelve months of support. Future year budget periods will cycle on June 1. Allowable preaward costs may be charged to this award, in accordance with the conditions in the NIH Grants Policy Statement (October 2018), and with institutional requirements for prior approval.

INFORMATION: This award involves Human Subjects Research. See "Assurance Requirements and Institutional Review Boards" under Part II, Subpart A, Human Subjects, in the NIH Grants Policy Statement, for specific requirements and grantee responsibilities related to the protection of human subjects, which are applicable to and are a term and condition of this award.

This award reflects the National Cancer Institute's acceptance of the certification that all key personnel have completed education on the protection of human subjects, in accordance the NIH Grants Policy Statement, "Education in the Protection of Human Research Subjects."

Any individual involved in the design and conduct of the study that is not included in the certification must satisfy this requirement prior to participating in the project. Failure to comply can result in the suspension and/or termination of this award, withholding of support of the continuation award, audit disallowances, and/or other appropriate action.

INFORMATION: This award, including the budget and the budget period, has been discussed between Romy M. Reis of the National Cancer Institute and Rhonda Truitt on 08/05/2019.

INFORMATION: This project involves hazardous or potentially hazardous agents. Attention is called to the Health and Safety Regulations and Guidelines (Section 4.1.12) of the NIH Grants Policy Statement.

STAFF CONTACTS

The Grants Management Specialist is responsible for the negotiation, award and administration of this project and for interpretation of Grants Administration policies and provisions. The Program Official is responsible for the scientific, programmatic and technical aspects of this project. These individuals work together in overall project administration. Prior approval requests (signed by an Authorized Organizational Representative) should be submitted in writing to the Grants Management Specialist. Requests may be made via e-mail.

Grants Management Specialist: Romy Reis
Email: mondesir@mail.nih.gov **Phone**: (240) 276-6316

Program Official: Hasnaa Shafik
Email: shafikh@mail.nih.gov **Phone**: 240-276-5600 **Fax**: 240-276-5625

SPREADSHEET SUMMARY
GRANT NUMBER: 2P30CA016672-43

INSTITUTION: UNIVERSITY OF TX MD ANDERSON CAN CTR

Budget	Year 43	Year 44	Year 45	Year 46	Year 47
Salaries and Wages	$4,437,453	FUTURE COSTS			
Fringe Benefits	$1,242,471				
Personnel Costs (Subtotal)	$5,679,924				
Consultant Services	$84,800				
Materials & Supplies	$146,098				
Travel	$24,963				
Other	$957,759				
TOTAL FEDERAL DC	$6,893,544				
TOTAL FEDERAL F&A	$4,136,126				
TOTAL COST	$11,029,670				

Facilities and Administrative Costs	Year 43	Year 44	Year 45	Year 46	Year 47
F&A Cost Rate 1	60%	FUTURE COSTS			
F&A Cost Base 1	$6,893,544				
F&A Costs 1	$4,136,126				

OMB Number: 4040-0001
Expiration Date: 10/31/2019

APPLICATION FOR FEDERAL ASSISTANCE
SF 424 (R&R)

5. APPLICANT INFORMATION **Organizational DUNS*:** 8007721390000

Legal Name*:	THE UNIVERSITY OF TEXAS MD ANDERSON CANCER CENTER
Department:	
Division:	
Street1*:	1515 Holcombe Boulevard
Street2:	
City*:	HOUSTON
County:	
State*:	TX: Texas
Province:	
Country*:	USA: UNITED STATES
ZIP / Postal Code*:	770304009

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7. TYPE OF APPLICANT*

Other (Specify):

Small Business Organization Type ○ Women Owned ○ Socially and Economically Disadvantaged

11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT*
02 Research Animal Support Facility-Houston/Smithville

12. PROPOSED PROJECT

Start Date*	Ending Date*
07/01/2019	06/30/2024

OMB Number: 4040-0010
Expiration Date: 10/31/2019

Project/Performance Site Location(s)

Project/Performance Site Primary Location

○ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name:	THE UNIVERSITY OF TEXAS MD ANDERSON CANCER CENTER
Duns Number:	800772139000O
Street1*:	1515 Holcombe Boulevard
Street2:	
City*:	HOUSTON
County:	
State*:	TX: Texas
Province:	
Country*:	USA: UNITED STATES
Zip / Postal Code*:	770304009
Project/Performance Site Congressional District*:	TX-009

Additional Location(s) File Name:

OMB Number: 4040-0001
Expiration Date: 10/31/2019

RESEARCH & RELATED Other Project Information

1. Are Human Subjects Involved?* ○ **Yes** ● **No**

1.a. If YES to Human Subjects

Is the Project Exempt from Federal regulations? ○ Yes ○ No

If YES, check appropriate exemption number: _ 1 _ 2 _ 3 _ 4 _ 5 _ 6 _ 7 _ 8

If NO, is the IRB review Pending? ○ **Yes** ○ **No**

IRB Approval Date:

Human Subject Assurance Number

2. Are Vertebrate Animals Used?* ● **Yes** ○ **No**

2.a. If YES to Vertebrate Animals

Is the IACUC review Pending? ○ Yes ○ No

IACUC Approval Date:

Animal Welfare Assurance Number

3. Is proprietary/privileged information included in the application?* ○ **Yes** ● **No**

4.a. Does this project have an actual or potential impact - positive or negative - on the environment?* ○ **Yes** ● **No**

4.b. If yes, please explain:

4.c. If this project has an actual or potential impact on the environment, has an exemption been authorized or an environmental assessment (EA) or environmental impact statement (EIS) been performed? ○ Yes ○ No

4.d. If yes, please explain:

5. Is the research performance site designated, or eligible to be designated, as a historic place?* ○ **Yes** ● **No**

5.a. If yes, please explain:

6. Does this project involve activities outside the United States or partnership with international collaborators?* ○ **Yes** ● **No**

6.a. If yes, identify countries:

6.b. Optional Explanation:

	Filename
7. Project Summary/Abstract*	RASF_Summary.pdf
8. Project Narrative*	
9. Bibliography & References Cited	BIBLIOGRAPHY-390_RASF.pdf
10. Facilities & Other Resources	RASF_FacilitiesResources.pdf
11. Equipment	RASF_Equipment.pdf
12. Other Attachments	RASF_Sources_of_Support.pdf

PROJECT SUMMARY: RESEARCH ANIMAL SUPPORT FACILITY (RASF)

The Research Animal Support Facility in Houston (RASF-H) and the RASF in Smithville (RASF-S) are centralized AAALAC International accredited core animal resources providing housing, procedure space, and research services to support MD Anderson's animal research studies.

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During the current award period, the institution has provided approximately $15M in infrastructure and facility renovations, as well as $3,577,599 for the purchase of new equipment. In Yr42, peer-reviewed funding accounted for 96% of the total usage of the RASF. The annual operating budget of the RASF in Yr44 is expected to be $15,636,634, 6% ($875,532) of which is requested from the CCSG, with institutional support of $4,718,397 (30%) and philanthropic or other grant support of $589,831 (4%). The RASF has contributed to 881 manuscripts during the current award period, of which 632 (72%) were in journals with IF >5, and 255 (29%) in journals with IF >10. The Specific Aims are: **Aim 1:** To provide high-quality, state-of-the-art, affordable animal facilities that enhance animal study reproducibility by controlling for and minimizing variables, including factors that affect the environment, animal health, model fidelity, and data integrity. **Aim 2:** To provide expert consultation and collaboration in areas including animal husbandry, veterinary care, surgical and imaging techniques, and rodent colony management. **Aim 3:** To provide specialized services such as rodent-specific genetic characterization and research histology for both live animals and cell lines, to develop new surgical techniques and imaging procedures, and to collaborate on the design of animal studies for therapeutic discovery and preclinical drug development.

Overall Facilities and Resources: The University of Texas MD Anderson Cancer Center is one of 49 NCI-designated Comprehensive Cancer Centers, and it is the largest medical institution of The University of Texas System. MD Anderson's research program is considered one of the most productive efforts in the world aimed solely on cancer. The mission of MD Anderson is to eliminate cancer and allied diseases, and it is renowned for its integrated patient care, research, education, and prevention. MD Anderson was ranked #1 in cancer care in *US News and World Report*'s 2018 annual survey "America's Best Hospitals," and it has ranked first or second every single year since the survey began in 1990. MD Anderson offers a superior scientific environment for conducting biomedical and cancer research, and it provides state-of-the-art laboratory and office spaces with full access to the institution's computer networks, databases, and internet services for all faculty, staff, and trainees. At MD Anderson, a strong collaborative scientific community fosters intra-institutional and extramural collaborations between researchers in multidisciplinary fields of cancer research. This collaborative environment also facilitates data and resources sharing, technology development and data analysis, intellectual property disclosure and protection.

Total Space for Facilities: MD Anderson facilities total ~ 15 million gross sq ft for patient care, research, education, prevention, and administration and 9.5 million sq ft of assignable space, 1.9 million of which is dedicated for research. The North Campus (NC) of MD Anderson is located in the 1,345-acre Texas Medical Center, the largest medical complex in the world. One mile south, the South Campus (SC) houses a group of basic and translation research facilities, as well as the Proton Therapy Center and the Center for Advanced Biomedical Imaging Research. Between the NC and SC, the Mid Campus building houses administrative offices and conference facilities. In addition to its locations in Houston, MD Anderson also has major research facilities located elsewhere in Texas, including the Science Park campus (SP) with facilities in Bastrop and Smithville, Texas.

Research Facilities	
Location	**Assignable sq ft**
Houston	
North Campus	1,051,452
South Campus	669,988
Bastrop County	
[redacted] Center for Comparative Medicine	89,770
Smithville Science Park	91,354
TOTAL	**1,902,564**

Clinical Facilities: The NC consists of numerous inter-connected buildings that promote integration of inpatient, outpatient, research, educational, and cancer prevention activities. Clinical facilities are organized into multidisciplinary care centers in the R. Lee Clark Clinic and the Charles A. LeMaistre Clinic buildings, where teams of oncologists, surgeons, radiation oncologists and other professionals evaluate patients and jointly plan treatment. The Albert B. and Margaret M. Alkek provides 832,000 sq ft for patient rooms, diagnostic and treatment areas, nursing units, comprehensive critical care units, large and modern operating suites. The Ambulatory Clinical Building (ACB) provides 781,700 sq ft of space for diagnostic and treatment support functions such as diagnostic imaging, radiation oncology, outpatient surgery, diagnostic centers, pathology, fine needle aspiration, laboratory services, outpatient pharmacy, plastic surgery center, internal medicine center, infusion therapy, and transfusion services.

The Dan L. Duncan Building, formerly named the Cancer Prevention Building, is home to the Departments of Clinical Cancer Prevention, Behavioral Science, Epidemiology, and the Cancer Prevention Center which provides an array of services that includes risk assessment, cancer screening and detection, genetic counseling, smoking cessation classes and chemoprevention clinical trials. The 386,000 square foot facility provides office space for clinicians working in the adjacent ACB. A glass-enclosed pedestrian bridge connects the ACB, the Dan L. Duncan Building, the Faculty Center, the T. Boone Pickens Academic Tower, and the main hospital, which includes the R. Lee Clark Clinic and the Charles A. LeMaistre Clinic buildings and the Alkek Hospital.

MD Anderson provides cancer care at clinically integrated, convenient locations across the greater Houston area. Care centers in Bay Area, Katy, Sugar Land, Memorial City and The Woodlands provide prospective, multidisciplinary services including radiation oncology, medical oncology and surgical oncology, along with a range of supportive services and access to clinical trials. The Board of Regents, the governing body for The University of Texas System, has approved a $400 million budget for the regional replacement project in the greater Houston area. New facilities are under construction that will replace the currently leased facilities utilized by the Houston Area Location clinics. The new centers are planned to be more than 750,000 total square feet across the region. They will provide outpatient oncology services to adult patients and add some pediatric, pathology and endoscopy services, as well as offering access to selected clinical research protocols

Research Facilities. Approximately 1.9 million sq ft are committed to research divided between the NC and SC.

North Campus (NC). NC includes dedicated space for laboratories. The 833,553 sq ft George and Cynthia Mitchell Basic Sciences Research Building (BSRB) serves as a hub for scientists, physicians and students at MD Anderson and other TMC institutions. Key features of the BSRB include interstitial floors above every lab,

as well as the Department of Veterinary Medicine and Surgery's small animal vivarium, and 18 other shared resources. The classrooms and administrative office of the Graduate School of Biomedical Sciences are also housed in this facility, along with a large auditorium for lectures and seminars. The Sheikh Zayed bin Sultan Al Nahyan Building, a 12-story, 628,652 square foot facility houses the Institute for Personalized Cancer Therapy, the Sheikh Ahmed bin Zayed Al Nahyan Center for Pancreatic Cancer Research, a molecular diagnostics lab, a histocompatability testing lab and a pre-CLIA molecular pathology research lab.

South Campus (SC). At the UT Research Park in the SC, six research buildings are grouped together. In addition, thirteen shared resources are housed on SC. The R.E. "Bob" Smith Research Building has 32,000 sq ft of research space. The SC Research Building 1 (SCRB1) with 132,000 sq ft contains the Center for Cancer Immunology Research. The SCRB2 with 147,000 sq ft houses the Oncology Research for Biologics and Immunotherapy Translation (ORBIT) platform. The SC Research Building 3 (SCRB3) with 315,000 sq ft houses the Experimental Diagnostic Imaging Program and the Metastasis Center. The Institute for Applied Cancer Science is housed in the SC Research Building 4 (SCRB4), which has a total of 205,000 sq ft of space and includes laboratories, training classrooms and conference rooms as well as a satellite Research Medical Library.

Science Park in Smithville (SP). The Science Park campus is located on over 700 acres of land approximately 120 miles west of Houston. The campus encompasses four laboratory buildings totaling over 100,000 sq ft and houses the Department of Epigenetics and Molecular Carcinogenesis. Faculty members have well-equipped, modern research space. Individual laboratories range in size from 1,000 to 3,000 sq ft. Faculty members have private (100-120 sq ft) office space near their labs.

Supportive Facilities and Resources: MD Anderson contributes more research effort to patient care than any other academic center. MD Anderson is committed to translating scientific discoveries and knowledge gained in the laboratory to clinical care. In 2017, MD Anderson spent more than $745 million per year on research and ranks first in the number of NCI grants awarded. Currently, MD Anderson holds 9 Specialized Programs of Research Excellence grants from NCI.

Houston Animal Research Facilities. The Houston Campus animal facilities, which are accredited by AAALAC International, are composed of 132,212 total net sq ft divided between NC and SC. There are four separate animal facilities. CONFIDENTIAL INFORMATION,REQUESTER IN AGREEMENT . DVMS main administrative offices are located on the BSRB 4th floor. General types of animal housing available include conventional, hazard containment, quarantine, and specific pathogen-free barriers. The Department of Veterinary Medicine provides procedure training, administrative support for animal-related issues, surgical/clinical services, and clinical and anatomic pathology laboratories. The SC Vivarium (SCV) centralized animal facility contains 46,000 total net sq ft. The SCV is a dedicated specific pathogen-free rodent barrier with quarantine and hazard containment provided as well. The Experimental Radiation Oncology (ERO) animal facility,CONFIDENTIAL INFORMATION, I, is a dedicated gnotobiotic mouse facility with extensive breeding capabilities. CONFIDENTIAL INFORMATION,REQUESTER IN AGREEMENT CONFIDENTIAL INFORMATION,REQUESTER IN AGREEMENT

Smithville Animal Research Facilities. CONFIDENTIAL INFORMATION,REQUESTER IN AGREEMENT It has four components: *Animal Resources*, *Laboratory Animal Genetic Services*, *Research Histology, Pathology, and Imaging Core*, and the *Transgenic Animal Core*. The Animal Resource *Laboratory Animal Genetic Services* provides genetic consultation and rodent infectious disease testing; the *Research Histology, Pathology and Imaging Core* provides routine and specialized histology/immunohistochemistry services, animal pathology services, and in vivo imaging. The *Transgenic Animal Core* generates knock-in and knock-out mouse models using CRISPR/Cas9 and provides other services including rederivation of mouse lines and archival cryopreservation of embryos and sperm.

CONFIDENTIAL INFORMATION The Center for Comparative Medicine and Research is a 385-acre campus in Bastrop, TX, approximately 120 miles northwest of Houston. CONFIDENTIAL INFORMATION,REQUESTER IN AGREEMENT Animals contribute to research into improved prevention, diagnosis and treatment of cancer as well as investigations in hepatitis, HIV, diabetes, hypertension, obesity, vaccine development, cellular immunology, autoimmunity, aging and behavior. Research at the Keeling Center also contributes to the health and welfare of laboratory and companion animals.

Computing Facilities. MD Anderson provides technical support for office and laboratory computers, as well as an array of office and scientific software through multi-user licenses. The University of Texas MD Anderson

Cancer Center campus has wireless internet service, accessible from research, clinical, and office areas.

MD Anderson also maintains a high performance, high throughput computing environment that supports the requirements of computational scientists, statistical analysts, bioinformaticians, biostatisticians and genetic scientists.

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Support of Shared Resources: The year 2018 marks the 43rd year of MD Anderson's Cancer Center Support Grant (CCSG) from the NCI, which supports many of the shared resources that allow its faculty, trainees, and staff to carry out multiple research programs in laboratories. Some facilities are also funded by grants from the Cancer Prevention Research Institute of Texas and the Bone Disease Program of Texas. These grants, contract, and resources allow research to seamlessly advance in the continuum from laboratory research, biomarker discovery, phase I dose finding, phase II proof-of-concept, and phase III efficacy studies. Available facilities and services include:

- Advanced Microscopy Core (SC: NIH 1S10RR029552)
- Assessment, Intervention, and Measurement (NC: CCSG P30CA016672, CONFIDENTIAL INFORMATION REQUESTER IN AGREEMENT
- Bioinformatics Shared Resource (NC: CCSG P30CA016672)
- Biostatistics Resource Group (NC: CCSG P30CA016672)
- Bioinformatics and Statistics – Smithville (SP)
- Biomolecular Structure and Function Core (SC)
- BioNutrition Research Core (NC: [redacted] funded)
- Biospecimen Extraction Facility (NC: CCSG core)
- Bone Histomorphometry Core Laboratory (NC: Bone Disease Program of Texas funded)
- Characterized Cell Line Core (NC)
- Clinical and Translational Research Center (NC: CCSG P30CA016672)
- Epigenomics Profiling Core (NC: Center for Cancer Epigenetics)
- Flow Cytometry and Cellular Imaging Core (NC/SC: CCSG P30CA016672)
- Functional Genomics Core (NC: CCSG P30CA016672)
- Functional Proteomics Reverse Phase Protein Array Core Facility (NC: CCSG P30CA016672)
- Genetically Engineered Mouse Facility (NC: CCSG P30CA016672)
- High Resolution Electron Microscopy Facility (SC: CCSG P30CA016672)
- [redacted] Center for Comparative Medicine and Research – Bastrop (SP)
  - Squirrel Monkey colony (NIH 5P40OD010938-38)
  - Baboon colony (NIH 5P40OD024628-02)
  - Chimpanzee colony (NIH 5P40OD024628-02)
- Microbiome Facility (SC: CCSG P30CA016672)
- Monoclonal Antibody Core Facility (SC: CCSG P30CA016672)
- Molecular Cytogenetics Facility (NC)
- Next Generation Sequencing Core – Smithville (SP)
- Oncology Research and Immuno-Monitoring Core (SC: CCSG P30CA016672)

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- Protein Array and Analysis Core – Smithville (SP: CPRIT RP130432)
- Proteomics and Metabolomics (SC: CCSG P30CA016672, CRPIT RP130397, NIH 1S10OD01230401)
- Research Animal Support Facility (CCSG P30CA016672)
  - Research Animal Support Facility – Houston (NC/SC)
  - Research Animal Support Facility – Smithville (SP)
  - Laboratory Animal Genetic Services – Smithville (SP)
  - Research Histology, Pathology, and Imagine Core – Smithville (SP)
  - Transgenic Animal Core - Smithville (SP)
- Sequencing and Microarray Facility (NC: CCSG P30CA016672)
- Sequencing and Non-Coding RNA Program (SC)
- Shared Decision Making Core (NC: CCSG P30CA016672, CONFIDENTIAL INFORMATION REQUESTER IN AGREEMENT
- Small Animal Imaging Facility (NC/SC: CCSG P30CA016672, NIH 1S10OD010403, NIH 1S10OD01994601)
- Tissue Biospecimen and Pathology Resource (NC/SC: CCSG P30CA016672)
  - Institutional Tissue Bank
  - Research Histology Core Laboratory
- Translational and Analytical Chemistry Facility (SC)
  - Nuclear Magnetic Resonance Facility
  - Pharmaceutical Chemistry Facility

More recently, MD Anderson has been developing a number of **Platforms** to accelerate cancer research, including the following:

- The **Institute for Applied Cancer Science (IACS)** to develop novel small molecule drugs and biologics
- The **Institute for Personalized Cancer Therapy (IPCT)** to support the convergence of molecular diagnostics and therapeutics in patient care
- The **Clinical Genomics Lab (CGL)**, providing CLIA-compliant clinical sequencing infrastructure, including centralized biospecimen repository and processing
- **Cancer Prevention and Control (CPC)**, to implement policies and education strategies to effect prevention and early screening of cancers
- **Early Detection**, for discovery of proteomics biomarkers and risk models by imaging and serum/tissue and phenotypic markers to detect early-staged disease
- The **Center for Co-Clinical Trials**, to define indications for novel therapeutics and develop combination strategies using preclinical models
- **Translational Research Accelerator (Big Data)**, providing an IT environment enabling centralization and integration as well as secured access of all patient clinical and research data and analysis results
- **Adaptive patient-oriented longitudinal learning and optimization (APOLLO)**, bringing clinical medicine and genomic research together to enable rapid learning to improve clinical outcome, by leveraging the Clinical Genomics Lab, the Omics-Bioinformatics and Massive Data Analytics platforms
- **Immunotherapy (IMT)**, integrates cutting-edge basic immunology with novel clinical trials through in-depth analyses of animal models and patients' samples
- **Oncology Research for Biologics & Immunotherapy Translation (ORBIT)**, a centralized organization for biologics discovery and development to guide, inform, accelerate and execute the translation of novel discoveries into clinically relevant monoclonal antibodies
- **Adoptive Cell Therapy (ACT)**, develop and implement cell-based immunotherapies, such as customized T cells, launched by the moon shots.

Additional Resources:

Research Medical Library. To further advance integrated programs in patient care, research, education, and prevention, MD Anderson's 18,000 square foot Research Medical Library provides knowledge-based information resources and specialized services to faculty, staff, and trainees. Fifteen full-time professional librarians and three support staff provide services is open 5 days a week for nearly 60 hours per week. It carries over 30,000 electronic and print books, 5,500 full-text electronic journals, over 27,000 bound journal volumes, and over 140 searchable online databases. The Library participates in a cooperative agreement with the Houston Academy of Medicine - Texas Medical Center Library and the statewide TexShare program to maximize access to resources and services. In addition to standard library services, the Library offers specialized services, such as literature search by librarians for researchers and training classes for searching online databases and citations and using citation software to store and manage references when writing a paper. The availability of these services can benefit current projects by contributing to its informed methodology, and by providing the resources necessary

to obtain information that will be used in the scientific articles and presentations emanating from this work.

Department of Scientific Publications. This department employs 14 scientific editors (including editorial managers), many of whom have more than 25 years of editing experience. Staff members edit journal articles, book chapters, grant proposals, and abstracts; consult with authors on early drafts of their work; and answer questions about publishing, book and journal production, word usage, grammar, and style. These services are provided free upon request and will be helpful in preparing manuscripts, presentations, and grant applications emanating from this project.

Equipment in Shared Resources:

Please see the Equipment section of the Shared Resource Research Strategy.

For additional information, please see the more detailed **Equipment in Shared Resources** in the Overall section.

SOURCES OF SUPPORT: RESEARCH ANIMAL SUPPORT FACILITY (RASF)

Sources of CCSG Shared Resource Funding for 7/1/2018 through 6/30/2019 (Yr43)				
Income Source	Current Support	Current%	Proposed Support (Yr44)	Proposed % (Yr44)
CCSG	$856,854	PERCENTAGE OF EFFORT	$875,532	PERCENTAGE OF EFFORT
Chargebacks	$8,850,699		$9,452,874	
Institutional Support	$4,769,171		$4,778,962	
Other	$483,132		$589,831	
Total Operating Budget	$14,959,856		$15,697,199	

OMB Number: 4040-0001
Expiration Date: 10/31/2019

RESEARCH & RELATED Senior/Key Person Profile (Expanded)

PROFILE - Project Director/Principal Investigator

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Project Role*: Co-Investigator	Other Project Role Category:
Degree Type:	Degree Year:
Attach Biographical Sketch*: File Name:	
Attach Current & Pending Support: File Name:	

PROFILE - Senior/Key Person

CONFIDENTIAL INFORMATION, REQUESTER IN AGREEMENT

Project Role*: Co-Investigator	Other Project Role Category:
Degree Type:	Degree Year:
Attach Biographical Sketch*: File Name:	
Attach Current & Pending Support: File Name:	

OMB Number: 4040-0001
Expiration Date: 10/31/2019

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 1

ORGANIZATIONAL DUNS*: 8007721390000

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: THE UNIVERSITY OF TEXAS MD ANDERSON CANCER CENTER

Start Date*: 07-01-2019 **End Date*:** 06-30-2020 **Budget Period: 1**

A. Senior/Key Person

Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
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RESEARCH & RELATED Budget (A-B) (Funds Requested)

Funding Opportunity Number: PAR-17-095. Received Date: 2018-09-26T16:14:30.000-04:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 1

ORGANIZATIONAL DUNS*: 8007721390000
Budget Type*: ● Project ○ Subaward/Consortium
Enter name of Organization: THE UNIVERSITY OF TEXAS MD ANDERSON CANCER CENTER

Start Date*: 07-01-2019 **End Date*:** 06-30-2020 **Budget Period: 1**

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Funding Opportunity Number: PAR-17-095 Received Date: 2018-09-26T16:14:30.000-04:00

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 1

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OMB Number: 4040-0001
Expiration Date: 10/31/2019

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 2

ORGANIZATIONAL DUNS*: 8007721390000

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: THE UNIVERSITY OF TEXAS MD ANDERSON CANCER CENTER

Start Date*: 07-01-2020 **End Date*:** 06-30-2021 **Budget Period: 2**

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Funding Opportunity Number: PAR-17-095. Received Date: 2018-09-26T16:14:30.000-04:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 2

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RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 2

CONFIDENTIAL INFORMATION,REQUESTER IN AGREEMENT

OMB Number: 4040-0001
Expiration Date: 10/31/2019

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 3

CONFIDENTIAL INFORMATION,REQUESTER IN AGREEMENT

Tracking Number: GRANT12715350
Funding Opportunity Number: PAR-17-095. Received Date: 2018-09-26T16:14:30.000-04:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 3

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RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 3

CONFIDENTIAL INFORMATION,REQUESTER IN AGREEMENT

OMB Number: 4040-0001
Expiration Date: 10/31/2019

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 4

CONFIDENTIAL INFORMATION,REQUESTER IN AGREEMENT

Tracking Number: GRANT12715350
Funding Opportunity Number: PAR-17-095. Received Date: 2018-09-26T16:14:30.000-04:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 4

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RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 4

CONFIDENTIAL INFORMATION,REQUESTER IN AGREEMENT

OMB Number: 4040-0001
Expiration Date: 10/31/2019

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 5

CONFIDENTIAL INFORMATION,REQUESTER IN AGREEMENT

Tracking Number: GRANT12715350 Funding Opportunity Number: PAR-17-095. Received Date: 2018-09-26T16:14:30.000-04:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 5

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RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 5

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BUDGET JUSTIFICATION: RESEARCH ANIMAL SUPPORT FACILITY (RASF)

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RESEARCH & RELATED BUDGET - Cumulative Budget

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PHS 398 Cover Page Supplement

OMB Number: 0925-0001
Expiration Date: 03/31/2020

1. Vertebrate Animals Section

Are vertebrate animals euthanized? ● Yes ○ No

If "Yes" to euthanasia

Is the method consistent with American Veterinary Medical Association (AVMA) guidelines?

● Yes ○ No

If "No" to AVMA guidelines, describe method and provide scientific justification

2. *Program Income Section

*Is program income anticipated during the periods for which the grant support is requested?

○ Yes ● No

If you checked "yes" above (indicating that program income is anticipated), then use the format below to reflect the amount and source(s). Otherwise, leave this section blank.

*Budget Period *Anticipated Amount ($) *Source(s)

PHS 398 Cover Page Supplement

3. Human Embryonic Stem Cells Section

*Does the proposed project involve human embryonic stem cells? ○ Yes ● No

If the proposed project involves human embryonic stem cells, list below the registration number of the specific cell line(s) from the following list: http://grants.nih.gov/stem_cells/registry/current.htm. Or, if a specific stem cell line cannot be referenced at this time, check the box indicating that one from the registry will be used:

☐ Specific stem cell line cannot be referenced at this time. One from the registry will be used.

Cell Line(s) (Example: 0004):

4. Inventions and Patents Section (Renewal applications)

*Inventions and Patents: ● Yes ● No

If the answer is "Yes" then please answer the following:

*Previously Reported: ○ Yes ● No

5. Change of Investigator/Change of Institution Section

☑ Change of Project Director/Principal Investigator

Name of former Project Director/Principal Investigator

Prefix:

*First Name:

Middle Name:

*Last Name:

Suffix:

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☐ Change of Grantee Institution

*Name of former institution:

PHS 398 Research Plan

OMB Number: 0925-0001
Expiration Date: 03/31/2020

Introduction	
1. Introduction to Application (for Resubmission and Revision applications)	
Research Plan Section	
2. Specific Aims	RASF_Specific_Aims.pdf
3. Research Strategy*	RASF_Research_Strategy.pdf
4. Progress Report Publication List	RASF_Publications.pdf
Other Research Plan Section	
5. Vertebrate Animals	RASF_VERTEBRATE_ANIMALS.pdf
6. Select Agent Research	
7. Multiple PD/PI Leadership Plan	
8. Consortium/Contractual Arrangements	
9. Letters of Support	
10. Resource Sharing Plan(s)	RASF_Resource_Sharing_Plan.pdf
11. Authentication of Key Biological and/or Chemical Resources	RASF_Authentication_of_Resources.pdf
Appendix	
12. Appendix	

SPECIFIC AIMS: RESEARCH ANIMAL SUPPORT FACILITY (RASF)

The Research Animal Support Facility has two locations, in Houston (RASF-H) and in Smithville Science Park (RASF-S). The mission of the RASF is to maintain optimal animal health and well-being through provision of outstanding animal care, facilities, research collaboration, education, training, and customer service. The majority of the research that uses animals could not be accomplished without the high-quality animal facilities, services, and quality assurance (QA) programs provided by the RASF.

Aim 1. To provide high-quality, state-of-the-art, affordable animal facilities and enhance animal study reproducibility by controlling for and minimizing variables, including factors that affect the environment, animal health and model fidelity, and data integrity.

Aim 2. To offer expert consultation and collaboration in areas including animal husbandry, veterinary care, surgical and imaging techniques, and rodent colony management.

Aim 3. To provide specialized services such as rodent-specific genetic characterization and research histology for both live animals and cell lines, to develop new surgical techniques and imaging procedures, and to collaborate on the design of animal studies for therapeutic discovery and preclinical drug development.

I. DESCRIPTION OF THE RESEARCH ANIMAL SUPPORT FACILITY

A. Overview. The **RASF-H (Houston)** and **RASF-S (Smithville)** are centralized AAALAC International accredited core animal resources

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For the past 6 years, over $18M in institutional funding has been invested for equipment, renovations and RASF personnel expenses. In Yr42, peer-reviewed funding accounted for 96% of the total usage of RASF, and 6% ($875,532) of the total budget of $15,636,634 is requested from the CCSG. The RASF has contributed to 881 manuscripts during the current award period, of which 632 manuscripts (72%) were in journals with IF >5, including 255 manuscripts (29%) in journals with IF >10.

B. Response to Prior Critique. The resource was judged to have "Outstanding merit" with no remarkable weaknesses or criticisms identified. The reviewers acknowledged the critical nature of the comprehensive quality assessment programs.

Major Accomplishments since the Previous Grant Period: RASF-H

- Major renovations: CONFIDENTIAL INFORMATION, REQUESTER IN AGREEMENT 3) installed washroom automation; 4) BSRB rack washer replacement.
- Expanded DVMS animal delivery service CONFIDENTIAL INFORMATION, REQUESTER IN AGREEMENT
- Updated rodent QA program: 1) started use of dried blood spot and PCR technology for QA testing; 2) added bimonthly pinworm and fur mite testing via PCR of investigator mice.

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- Implemented CONFIDENTIAL as the replacement electronic colony management system.

Major Accomplishments since the Previous Grant Period: RASF-S

- **ARS:** Upgraded 47 ventilated cage racks to allow extension of cage change interval from 9 to 14 days.
- **LAGS:** Developed new panels of single nucleotide polymorphisms (SNPs) for mouse cell line characterization and to identify B6/J vs B6/N sub-strains; developed a new real-time PCR assay for detection of fur mites.
- **RHPI:** Expanded service to include imaging and histology service.

II. MAJOR SERVICES, TECHNOLOGIES AND EQUIPMENT

A. Key Services and Technologies. Specialized infrastructure and services include use of "smart technology" to support operations (facility and building automation and computerized animal management systems), animal surgical suites, irradiators, and veterinary pathology laboratories. Resource faculty collaborate in the design and operation of specialized areas for behavioral, gnotobiotic, metabolism, and PDX rodent models.

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RASF-S LAGS provides genetic consults, mouse cell line characterization, passenger gene mutation analyses, infectious disease PCR, and customized genome scans using polymorphic genetic markers to support speed congenic development and background strain characterization. **RASF-S RHPI**, formerly Mutant Mouse Pathology Service (MMPS), develops integrated imaging, pathology, and histology protocols, providing expert experimental pathology support and interpretation.

B. Equipment. The institution has provided approximately $15M in infrastructure and facility renovations. **RASF-H** has received a total of $3,146,863 and **RASF-S** has received $1,653,616 in additional institutional funds for the purchase of major equipment, including animal caging, sanitation equipment, and surgical and laboratory instrumentation.

C. Growth of Services (3/1/2012-2/28/2018). The **RASF-H** and the **RASF-S** had a combined increase of 11% in the average daily cage census compared with Yr37 (**Fig. 1a**). Overall, the use of additional services at **RASF-S** has increased primarily due to the **RHPI** (**Fig. 1b**).

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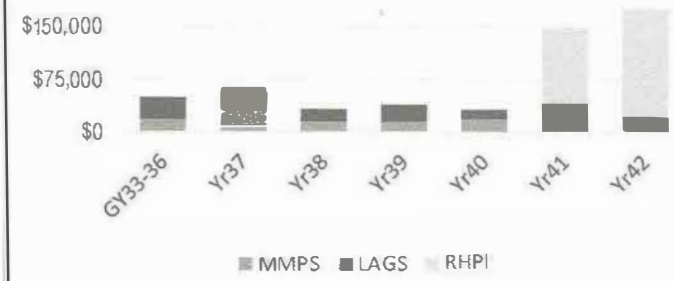
Fig. 1b. RASF-S Addtional Services Revenue



III. RESOURCE MANAGEMENT AND GOVERNANCE

A. Resource Leadership and Organization, Houston:

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C. Oversight Committee. The oversight committee meets yearly and comprises major faculty users and institutional leaders (ex *officio*). The committee reviews rates and discusses current and proposed services as well as other issues that arise.

D. External Advisors. The entire MD Anderson animal care program (including RASF-H and RASF-S) undergoes extensive external review by AAALAC International every 3 years, including reviews of animal program governance; administrative, compliance, and safety processes; animal and research facilities and operations; and veterinary care. The evaluation identifies areas of strength and weakness and suggest improvements. Additional external review of RASF-H is provided annually by the USDA APHIS. In 2016, MD Anderson hired an external consultant to conduct an extensive review of the animal resource facilities and services with the goals of maximizing use of existing vivarium space and streamlining operations. As a result, quarantine and biocontainment space was consolidated, additional high-density caging was deployed, and practices were harmonized to CONFIDENTIAL INFORMATION,REQU reduce personnel redundancy.

E. User Feedback. Houston: The 2014 and 2016 surveys showed that >83% of resource users were satisfied with the ease of access, faculty expertise and accessibility, and overall quality of the resource. The lowest-rated area was cost of services, with a 61% user satisfaction rate. Comments included "staff very knowledgeable and innovative" and "excellent service." Recommendations included creating electronic service forms, improving the website, and enhancing specialized surgical training. In response, hard-copy forms were converted to electronic forms and an integrated, web-based animal management system for investigators was implemented in 2017. The website was redesigned to include more information on services and staff contacts. A rodent surgery course was created in 2014 and is widely used by research personnel. **Smithville:** For RASF-S, both the 2014 and 2016 surveys showed that >85% of respondents and PIs/faculty were satisfied or very satisfied in all 22 areas. Sixteen areas among all respondents and 20 areas among PIs/faculty achieved 100% satisfaction rates. User comments included "RASF-S was an essential component that provided excellent, highly cost-effective services." In the 2018 survey, all facilities had an overall satisfaction rate of >95%.

IV. SCIENTIFIC IMPORTANCE AND VALUE ADDED

A. Innovation and Contributions. Animal studies are an integral part of basic and translational cancer research programs and could not be accomplished without the high-quality animal facilities, veterinary professional and technical services, and QA programs provided by the RASF. The facilities are equipped with high-density ventilated caging and watering systems that provide high-quality, stable conditions for the animals and reduce labor and feed/bedding costs. The veterinary faculty and staff develop, perform, and train personnel in established and novel surgical techniques, including orthotopic tumor and device implantation, bone fracture model creation, and endoscopic procedures. Besides housing, breeding colony management, and other veterinary/technical services, RASF-S LAGS provides specialized mouse and rat genetic QA for all MD Anderson campuses. To avoid confounding or unreliable experimental results, particularly with the increasing number of mouse and rat strains, attention to genetic background (including "flanking genes") and genetic monitoring are crucial and are emphasized in current research. RASF-S RHPI provides research pathology services to investigators at both the Smithville and Houston campuses, including development and validation of new tissue biomarkers, primarily with immunohistochemistry, for monitoring the efficacy and safety of cancer therapeutic agents in both human and mouse tissues. RHPI also provides morphometric analysis of the tissues for efficacy studies of novel cancer therapeutic agents and provides bioimaging of tumor progression for both development of cancer mouse models and therapeutic efficacy studies. Other services provided include design of animal studies for efficacy and safety evaluation of cancer therapeutic agents and safety screening of tissue-level toxicity of cancer therapeutic agents, for advancing them to clinical studies. CCSG support is used primarily to manage the QA programs that ensure integrity, fidelity, and reproducibility of all NIH-supported animal research. The following section summarizes some examples of studies conducted by MD Anderson investigators using the RASF.

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V. FACILITIES AND OPERATIONS

A. Operational Procedures and Policies. The resources are used by all MD Anderson faculty who have IACUC-approved protocols and perform animal studies as part of their research programs. Electronic databases record protocol approval, personnel training, and security access. The existing resources are adequate to support all current MD Anderson center members. The resources have internal webpages that feature contact information, service request forms, and a wealth of user information, including fee schedules. Resource faculty and staff provide training for research personnel on biomethodology, surgical techniques, and pathology procedures.

B. Rigor and Reproducibility. Animal study reproducibility requires controlling and minimizing variables, including factors that affect the environment, animal health and model fidelity, and data integrity. Facility design and controls include computerized building systems for environmental control, monitoring, and alarms; high-quality and stable animal environment through HVAC filtration, IVCRs, pathogen exclusion through sanitation/sterilization of equipment and supplies, rigorous QA programs, and computerized applications for

cage-side collection of veterinary and research data to reduce transcription errors.

C. Education and Training. RASF-H and RASF-S veterinary faculty contribute to team science across a spectrum of activities, such as the development and application of new animal models, especially genetically engineered rodent models, experimental surgery and imaging support and veterinary pathology investigations. Faculty and staff provide training sessions for research personnel on biomethodology, surgical techniques, and pathology procedures. Animal care staff are provided with job-specific training and attend classes to obtain American Association of Laboratory Animal Science certification (a job requirement). Faculty are instructors in the Graduate School of Biomedical Sciences (GSBS) courses and are coordinators for the Introduction to Animal Models (RASF-H) and Principles in Experimental Mouse Pathology (RASF-S) courses. Classes and demonstrations are provided for animal care staff, students, externs, and visiting scientists. RASF faculty have published texts and participate in national and international courses and master's programs for laboratory animal sciences. Programs for veterinary professional and para-professional students include the Gulf Coast Consortium Postdoctoral Veterinary Training Program and preceptorships for veterinary and veterinary technician students.

D. Collaboration with Other Shared Resources. The GEMF and SAIF cores are located within the RASF-H facilities; this physical proximity allows easy access to SPF rodents and research personnel. Biosecurity practices are coordinated among the cores to allow maximum access to animals of various pathogen statuses while protecting animal health. RASF-H personnel provide basic services for both core facilities, such as animal transport and specialized post-procedural housing and care (e.g., radioactive housing). RASF-S LAGS interacts frequently with the GEMF facility in Houston and provides speed congenics and genetic background characterization. The two RASF campuses conduct joint management meetings throughout the year to review current topics in laboratory animal science (such as use of environmental pathogen testing and exclusion strategies for emerging pathogens such as *C. bovis*) and implement shared best practices.

VI. COST EFFECTIVENESS OF THE RESOURCE

A. Comparative Service Fees. Shown in **Table 3** are the top 6 services of the RASF only. **RASF-H** fees are set to recover direct costs not covered by institutional or CCSG funds. The following rates were approved by **RASF-H**'s Program Income Advisory Committee for fiscal year 2018. **RASF-S** ARS instituted a series of annual increases starting with a 4.8% increase in fee schedule in January 2014, a 4.4% increase in January 2015, and a 3% increase in January 2016.

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B. Cost Efficiency/Effectiveness. The RASF has state-of-the-art animal facilities that use computerized environmental controls, individually ventilated cages, automated water and sanitation systems, and mobile veterinary health applications to achieve maximum efficiencies in space and workforce utilization while sustaining high levels of animal care. These strategies result in highly competitive per diem and specialized service charges. Costs for animal care are charged by daily cage census, which provides financial incentive to increase or maximize cage population density.

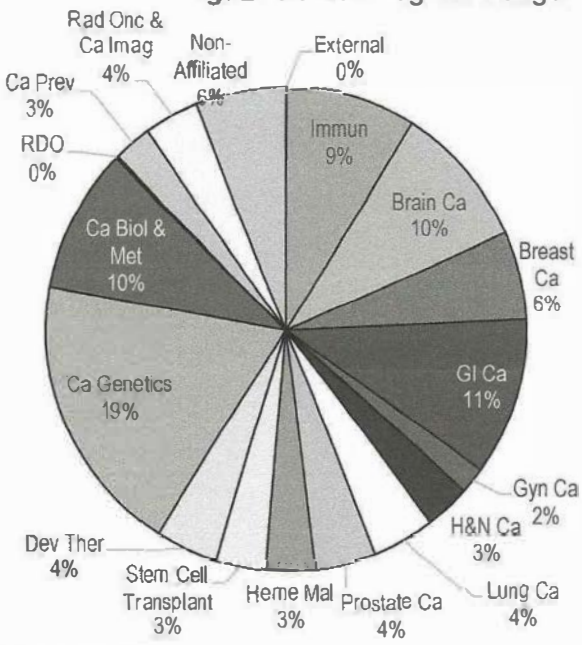
VII. USAGE OF THE RESOURCE

A. Usage Monitoring. In Yr42, 96% of total usage of the RASF-H and 97% of that of RASF-S was by peer review-funded users (**Table 4**). Although there are many external users of the unique LAGS services, most of the service for RASF-S is for mouse housing (ARS), and 99% of ARS usage is by peer review-funded cancer center members. In Yr42, Cancer Genetics and Epigenetics accounted for 19% of total usage, followed by GI Cancers at 11% and Brain Cancer and Cancer Biology and Metastasis at 10% each (**Fig. 2**).

Table 4. Peer Review-Funded Usage	# Users RASF-H Yr42 (Yr37-Yr42)	% Usage RASF-H Yr42 (Yr37-Yr42)	# Users RASF-S Yr42 (Yr37-Yr42)	% Usage RASF-S Yr42 (Yr37-Yr42)
Members with Peer-Reviewed Funding	216 (296)	96% (93%)	49 (65)	97% (98%)
Without Peer-Reviewed Funding	48 (113)	4% (7%)	7 (8)	1% (1%)
External Users	1 (2)	0% (0%)	26 (31)	2% (1%)

B. Capacity of the Resource. RASF-H facility occupancy in May 2018 was at 72% and 68% capacity at the North and South Campus vivaria, respectively. Total rodent cage census in Houston has increased at a 3% overall average annual rate during the past 6 years (2012-2018); recent growth has slowed as housing rooms reach maximum capacity. Experimental surgery and pathology services are well utilized and staffed appropriately to meet demand. Requests for rodent technical services continue to grow, and the technical services program has grown appreciably with additional staff to handle the increased workload. As of November 2017, the **RASF-S** ARS was operating at approximately 35% capacity. LAGS is operating at capacity for the services offered, and RHPI is operating at capacity for histology, imaging, and veterinary pathology. The Core directors are trying to determine whether the RASF-S, whose housing services are currently underutilized, can house animals from RASF-H to relieve overcrowding; however, the selection of animals targeted for relocation has not been finalized.

Fig. 2. CCSG Program Usage



VIII. SOURCES OF SUPPORT (See Attachment for details)

The total operating budget of the RASF in the current year is $14,959,856, 6% ($856,854) of which is from the CCSG. Chargebacks account for 59% ($8,850,699), yearly institutional support is 32% ($4,769,171), and other grant support is 3% ($483,132) of the budget. Over $18M was provided for equipment and renovations, with $15M provided for remodeling. RASF is requesting $875,532, which is a 2.2% increase from Yr43.

IX. FUTURE PLANS

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PUBLICATIONS: Research Animal Support Facility

from 03-01-2012 to present

881 Publications

Abbas HA, Bui NHB, Rajapakshe K, Wong J, Gunaratne P, Tsai KY, Coarfa C, Flores ER. Distinct TP63 Isoform-Driven Transcriptional Signatures Predict Tumor Progression and Clinical Outcomes. Cancer Res 78(2):451-462, 2018. PMCID: PMC5771893.

Abd-Elgaliel WR, Cruz-Monserrate Z, Wang H, Logsdon CD, Tung CH. Pancreatic cancer-associated Cathepsin E as a drug activator. J Control Release 167(3):221-7, 2013. PMCID: PMC3638719.

Abel EL, Boulware S, Fields T, McIvor E, Powell KL, DiGiovanni J, Vasquez KM, MacLeod MC. Sulforaphane induces phase II detoxication enzymes in mouse skin and prevents mutagenesis induced by a mustard gas analog. Toxicol Appl Pharmacol 266(3):439-42, 2013. PMCID: PMC3804329.

Abuelhija M, Weng CC, Shetty G, Meistrich ML. Rat models of post-irradiation recovery of spermatogenesis: interstrain differences. Andrology 1(2):206-15, 2013. PMCID: PMC3578348.

Acharya S, Xu J, Wang X, Jain S, Wang H, Zhang Q, Chang CC, Bower J, Arun B, Seewaldt V, Yu D. Downregulation of GLUT4 contributes to effective intervention of estrogen receptor-negative/HER2-overexpressing early stage breast disease progression by lapatinib. Am J Cancer Res 6(5):981-95, 2016. PMCID: PMC4889714.

Adachi M, Cui C, Dodge CT, Bhayani MK, Lai SY. Targeting STAT3 inhibits growth and enhances radiosensitivity in head and neck squamous cell carcinoma. Oral Oncol 48(12):1220-6, 2012. PMCID: PMC3734563.

Aggarwal G, Ramachandran V, Javeed N, Arumugam T, Dutta S, Klee GG, Klee EW, Smyrk TC, Bamlet W, Han JJ, Rumie Vittar NB, de Andrade M, Mukhopadhyay D, Petersen GM, Fernandez-Zapico ME, Logsdon CD, Chari ST. Adrenomedullin is up-regulated in patients with pancreatic cancer and causes insulin resistance in β cells and mice. Gastroenterology 143(6):1510-1517.e1, 2012. PMCID: PMC3787599.

Ahn JH, Yu HK, Lee HJ, Hong SW, Kim SJ, Kim JS. Suppression of colorectal cancer liver metastasis by apolipoprotein(a) kringle V in a nude mouse model through the induction of apoptosis in tumor-associated endothelial cells. PLoS One 9(4):e93794, 2014. PMCID: PMC3974802.

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PHS Human Subjects and Clinical Trials Information

OMB Number: 0925-0001 and 0925-0002
Expiration Date: 03/31/2020

Are Human Subjects Involved	○ Yes ● No
Is the Project Exempt from Federal regulations?	● Yes ○ No
Exemption Number	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8
Does the proposed research involve human specimens and/or data	○ Yes ● No

Other Requested information

Overall VERTEBRATE ANIMALS USE

Procedures - All procedures are conducted under aseptic conditions and using sterile surgical instruments, syringes, and needles. These procedures may cause discomfort or pain which we strive to minimize as much as possible. Anesthesia will be used for animals undergoing surgery. Anesthetic depth will be monitored by measuring corneal and pedal reflexes. Analgesics will be administrated prior to any invasive procedure and post-surgically to minimize pain.

Justification - Animal models such as the ones described in this proposal have made a major impact on our understanding of the molecular drivers in physiologically relevant tumorigenesis *in vivo*. Our facility is accredited by the American Association for Accreditation of Laboratory Animal Care and all animal work is performed under strict animal protocols that have been approved by the Institutional Animal Care and Use Committee at MD Anderson.

Minimization of Pain and Distress - We will make every effort to ensure that discomfort, distress, pain, and injury will be limited to that which is unavoidable in the conduct of scientifically-sound research.

Euthanasia - We strive to minimize as much as possible any pain or discomfort by euthanizing animals well before they become overtly moribund. Our euthanasia practices are consonant with the recommendations made by the Panel on Euthanasia of the American Veterinary Medical Association.

BIBLIOGRAPHY

Please see the Publication List in the Research Plan Section for references cited.

RESOURCE SHARING PLAN: RESEARCH ANIMAL SUPPORT FACILITY (RASF)

Public Access. Research Animal Support Facility (RASF) faculty and staff remind researchers about the NIH Public Access Policy to ensure that the public has access to the published results of this Cancer Center Support Grant funded facility. This requires that final peer-reviewed journal manuscripts arising from the RASF need to be submitted to the digital archive PubMed Central (PMC) upon acceptance for publication (and no later than 12 months post-publication), thereby making research readily accessible to the public, health care providers, and scientists. PMCID numbers need to accompany manuscripts cited on yearly progress reports.

Communicating and Acknowledging Federal Funding. In accordance with NIH grants policy, researchers are reminded that any publications including: research publications, press releases, or other publications or documents about research that is funded by the CCSG will include a statement such as: *"This research is supported by the NIH/NCI under award number P30CA016672 and used the Research Animal Support Facility."*

Sharing Model Organisms. Both RASF-H and RASH-S provide direct support to investigators that are exchanging animal models as mandated by the Sharing Model Organisms Policy. Both RASF-H sites (N and S), and Smithville have personnel, policies, procedures, and transportation vendors in place to facilitate investigator's animal model exports to other investigators, or repositories. Mechanisms for defining, informing, and obtaining pre-approval from the receiving institutional vivarium, including USDA interstate and international certificates of health, and/or other required permits for international shipments, are in place. If the transfer is not to an intramural investigator or a grant subcontractor, an MTA is required. The Office of Research Administration and Legal Services review these MTA, as well as those for potential transfers to commercial entities. ** RASF-H and RASF-S completed 68 and 26 extramural exports of animal models respectively in GY41.

Genomic Data Sharing (GDS): The RASF does not generate large-scale human or non-human genomic data.

Authentication of Key Biologicals and or Chemical Resources

Please see the Rigor and Reproducibility section of the Shared Resource Research Strategy.

For additional information, please see the more detailed **Authentication of Key Biologicals and or Chemical Resources** in the Overall section.