



Institute of **C**linical and
Translational **S**ciences

Support/Services of the Human Imaging Unit of the ICTS

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ICTS Services at Every Phase



<http://icts.wustl.edu/>



Human Imaging Unit (HIU) Aims

Aim 1: Provide ICTS investigators with increased access to sophisticated imaging equipment and trained imaging research specialists.

Aim 2: Facilitate the integration of advanced bioimaging into clinical and translational research protocols.

Aim 3: Develop and support new educational, training and career development opportunities for bioimaging in clinical and translational research.



Center for Clinical Imaging Research

Biograph PET/CT



HR Plus PET



Trio 3.0 T MRI



Avanto 1.5 T MRI



Acuson Antares US



Dimension 64 DS CT





HIU Support & Services

Setup, Assess &
Develop Protocols

Integrate & Execute
Protocols

Manage Study
& Facilities

Manage & Analyze
Image Data

Close Out Study

- Facilitate interactions with imaging experts and other CTSA core functions, e.g., biostatistics
- Help define research study and assess feasibility
- Identify needs & establish workflow
- Develop new imaging protocols
- Review existing imaging protocols
- Prepare preliminary & final budget analyses
- Create QC & QA processes
- Review consent forms, SOPs, & CRFs
- Contribute to internal/external grant preparation
- Establish and support execution of necessary academic & industrial external agreements



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Close Out Study

- Train new investigators how to navigate the research environment
- Optimize protocols/data acquisition methods
- Integrate protocols and study specific QC/QA practices
- Provide subject coordination services, including IRB &/or assistance for obtaining approval
- Oversee scheduling & consenting (optional)
- Operate scanners using dedicated technologist
- Deliver nursing support, e.g., EKG, blood, urine collection ... etc.
- Support standard-of-care practices, including in-patient, ICU patient and pediatric cases
- Generate radiation dose estimates (CT)
- Assign & work with authorized user (PET, PET/CT)



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Close Out Study

- Establish & manage data access control, rules-based routing and work lists
- Offer centralized scheduling services
- Maintain daily facility QC/QA testing schedule
- Schedule/coordinate/support contrast agent and radioisotope delivery & usage
- Monitor & track monthly acquisition/service costs and bill accordingly, including transmission to grants accounting
- Evaluate & maintain inventory, records, and statistics
- Coordinate compliance checks &/or monitor visits
- Maintain & update CRFs and study report (optional)



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Study Closure

- Develop & enhance facility infrastructural management software, *i.e.*, protocol management
- Store & maintain image data repository
- Provide data transfer services including verification of data integrity
- Query, retrieve, & integrate previous clinical data for comparison to research results
- Retrieve PHI, de-identified &/or anonymized data
- Support & manage 3rd party image analysis solutions
- Offer data analysis services
- Develop new data analysis software tools
- Build customized/automated data analysis routines
- Train users to process data using manual tools &/or automated procedures



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Close Out Study

- Archive & transfer all image data
- Organize & present analysis results
- Compile usage statistics
- Finalize data, regulatory, and IRB information (in some cases)
- Capture & integrate new methods and technologies into facility "toolbox" for future use by other studies
- Co-author manuscripts/grants

Additional HIU Activities

- Sponsor Seminar Series
- Host vendor training courses, e.g., Siemens cardiovascular
- Test and release new vendor hardware/software
- Integrate new imaging technologies
- Train new investigators and research personnel
- Mentor Fellow/Resident/K-Awardees



Internal Study Breakdown

Department	# Studies	Department	# Studies
Anatomy and Neurobiology	1	Orthopaedic Surgery	7
Anesthesiology	1	Otolaryngology	3
anthropology	1	Pediatrics	1
Biomedical Engineering	1	Pediatrics Cardiology	3
Cardiac Bioelectricity Center	1	Pediatrics Critical Care	2
Cardio Surg	1	Pediatrics Endocrinology&Diabetes	4
Developmental Biology	1	Pediatrics Genetics & Genomics	1
Int Med - ACTU	2	Pediatrics Hematology/Oncology	7
Int Med - Bone Marrow Transplant	1	Pediatrics Nephrology	1
Int Med - Bone&Mineral Diseases	1	Pediatrics Newborn Medicine	4
Int Med - Cardiovascular Division	5	Peds Allergy Immun Pulmonary Med	2
Int Med - Endocrine/Metabolism	7	Physical Therapy	2
Int Med - Gastroenterology	7	Physical Therapy Program	1
Int Med - Geriatrics	2	Physics - Arts & Sci	2
Int Med - Hematology	2	Program In Physical Therapy	9
Int Med - Medical Oncology	14	Program Occupational Therapy	1
Int Med - Medical Oncology	14	Psychiatry	19
Int Med - Nutritional Science	6	Psychology	1
Int Med - Pulmonary	5	Psychology - A&S	5
Int Med - Renal	4	Rad Onc - Clinical Divisions	7
Int Med - Rheumatology	1	Radiation Oncol-Bioinformatics	1
Int Med -Medical Oncology	4	Radiation Oncology	2
Int Med-Cardiology Consultants	9	Radiological Sciences	2
Int Med-Cardiovascular Division	1	Radiology	33
Mechanical Engineering & Aerospace	1	Radiology - Nuclear Medicine	24
Medical Oncology	1	Radiology - Rad Sciences	8
Neurology	58	Surgery	1
Neurosurgery	3	Urogynecology	1
Ophthalmology & Visual Science	3		

Study Status Sept. 2010

Total Studies	441
Active	271
Pending	20
Closed	75
Special	4
MR Development	61
CT Development	10

CCIR Staff:

Role	No.
Admin	4
IT	3
Nursing	2
Technologists	8



Industrial Interactions

+ CCIR Industry Sponsors (54)		
Astellas	BMS PI-initiated study	Medtronic
Abbott Labs	BodyAesthetic	Miltenyl Biotec, Inc.
ACRIN	Calistoga Pharmaceuticals	Molecular Insight Pharmaceutical
Actelion	Cephalon	Novartis
Aegerion Pharm	Coaxia	Paringenix
Allergan	Cook Industries	Pfizer
Ambility	Edwards Lifesciences	PTC Therapeutics
Amicus Therapeutics	Eli Lilly and Co	Repligen Corporation
Array BioPharma	Genentech	Roche
AtriCure, Inc.	Genzyme	Seimens
Atrium Medical Corp.	Glaxo Smith Kline	Seattle Genetics
AVID Radiopharmaceuticals	Guerbet	Steba Biotech
Bayer	Incyte Corporation	Synosia Therapeutics
Biogen Idec	Isis Pharmacueticals	Threshold Pharmaceuticals
BioMS Techynologies	Isotrace	Tibotec Therapeutics
Biovex	Lantheus Medical Imaging	TransMolecular
Bracco Diagnostic	LifeCell	Wyeth Pharmaceuticals (Pfizer)
Bradmer Pharm	Medimmune	Zenith

Percent Industry

Modality	FY09	FY10
3T	9%	1%
1.5	2%	1%
PET	2%	0%
PET/CT	2%	4%
CT	4%	7%
US	2%	3%
TOTAL	21%	16%

Future Directions

- Continue refinement of infrastructure and processes
- Establish a more seamless image archiving system for management and sharing of data acquisition and analysis capabilities
- Expand a set of management, research information and data analysis tools
- Increase access to additional imaging research technologies
- Integrate the HIU more tightly with other ICTS functions
- Increase multidisciplinary training efforts



Challenges

- We must increase service with limited resources.
- We must improve and integrate IT infrastructure for electronic billing, tracking, record keeping and data management.
- We must continue to deploy, validate and standardize new imaging technologies with limited resources.



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Acknowledgment

Supported by the

Clinical and Translational Science Award (CTSA)

program of the

National Center for Research Resources (NCRR)

at the National Institutes of Health (NIH)

Grant Number UL1 RR024992