New Resident Orientation – July 8, 2014
Office of Academic Development

Kathryn Stockbauer, PhD, Manager

HOUSTON
Methodist
LEADING MEDICINE

Research is a requirement of our training programs

- It can seem intimidating, especially if you have no prior research experience

- There are resources and support available:
  - Faculty
  - Chief Residents, Chief Fellow
  - Office of Academic Development

Chief Residents: Jaclyn Jerz, MD (PGY3)
                 Eric Salazar, MD, PhD (PGY2)

Chief Fellow: Lauren King, MD

OFFICE OF ACADEMIC DEVELOPMENT

- In operation since 2010

- 3 employees: manager, scientific writer, grants administrator

- Completely supported by the Department (no cost to faculty or trainees)

- Support academic/research activity
    - Provide guidance and support
    - Direct you to appropriate HMRI resources

OFFICE OF ACADEMIC DEVELOPMENT

- Provide editing services for grant applications, manuscripts, book chapters, and posters

- Assist with MORTI issues (e.g. ARAF and IRB protocol writing and submission)

- Conduct seminars and workshops on scientific writing and presenting

RESEARCH PROCESS AND MORTI

Before you begin any research project:

1. Credentialing

   hmricredentialing@houstonmethodist.org

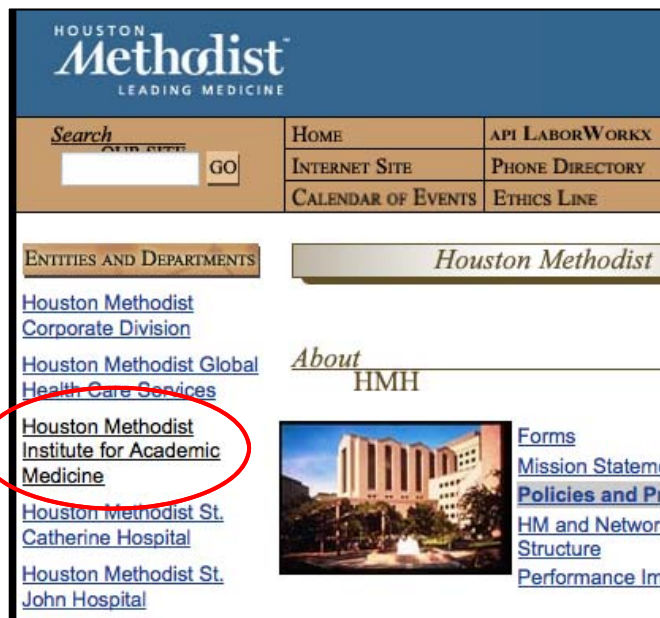2. Administrative Review and Approval (ARAF) Form

   ARAF is necessary for any research project!

3. IRB (if necessary, but it most likely is)

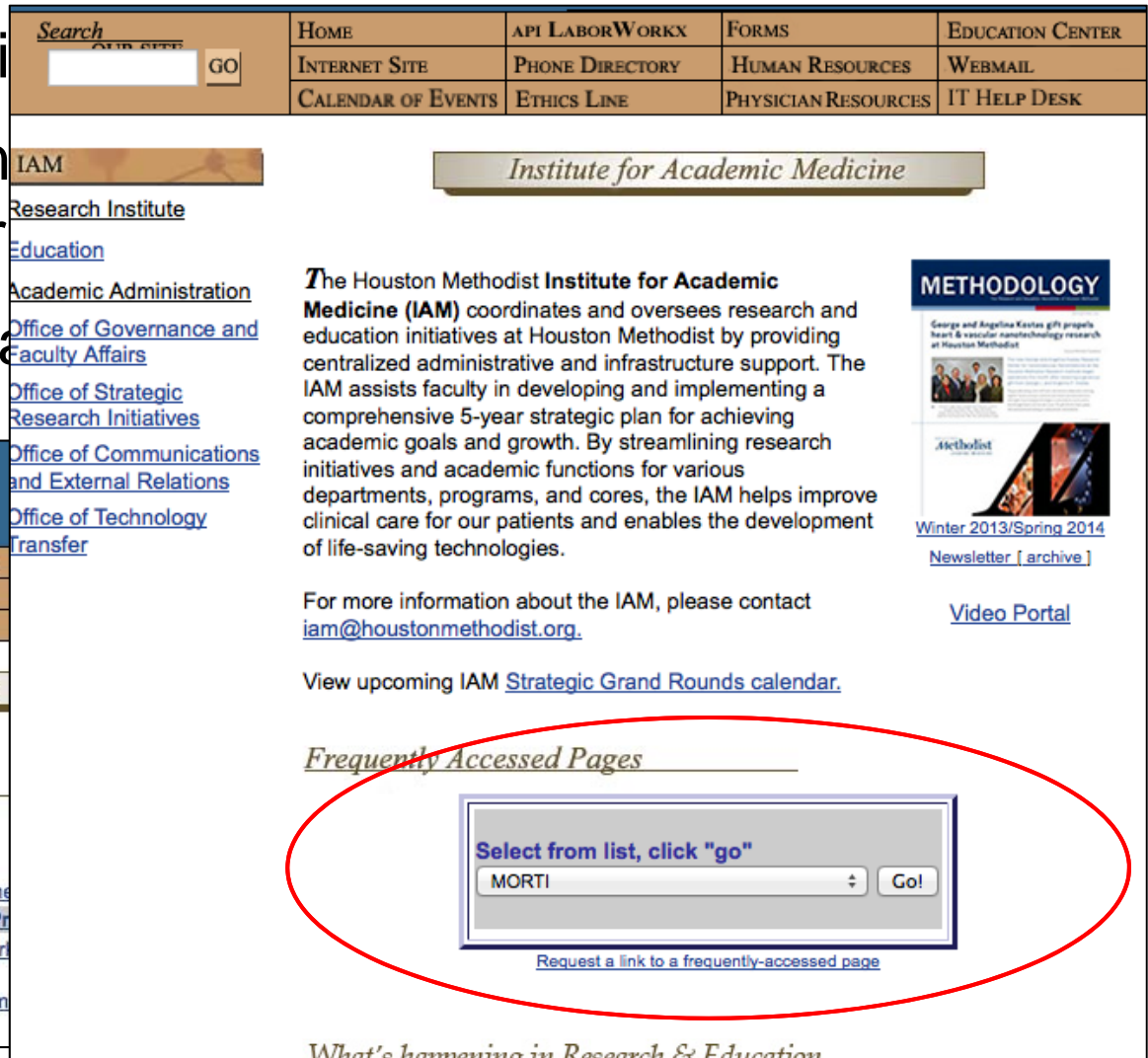# OVERVIEW: EXAMPLE TRAINEE RESEARCH PROJECT

In course of clinical duti

Want to perform immun
cases in Methodist Bior

Go to MORTI to fill out a

OVERVIEW: EXAMPLE TRAINEE RESEARCH PROJECT

MORTI > Log in using HMH username and password (Will not have access until credentialing is completed)

OVERVIEW: EXAMPLE TRAINEE RESEARCH PROJECT

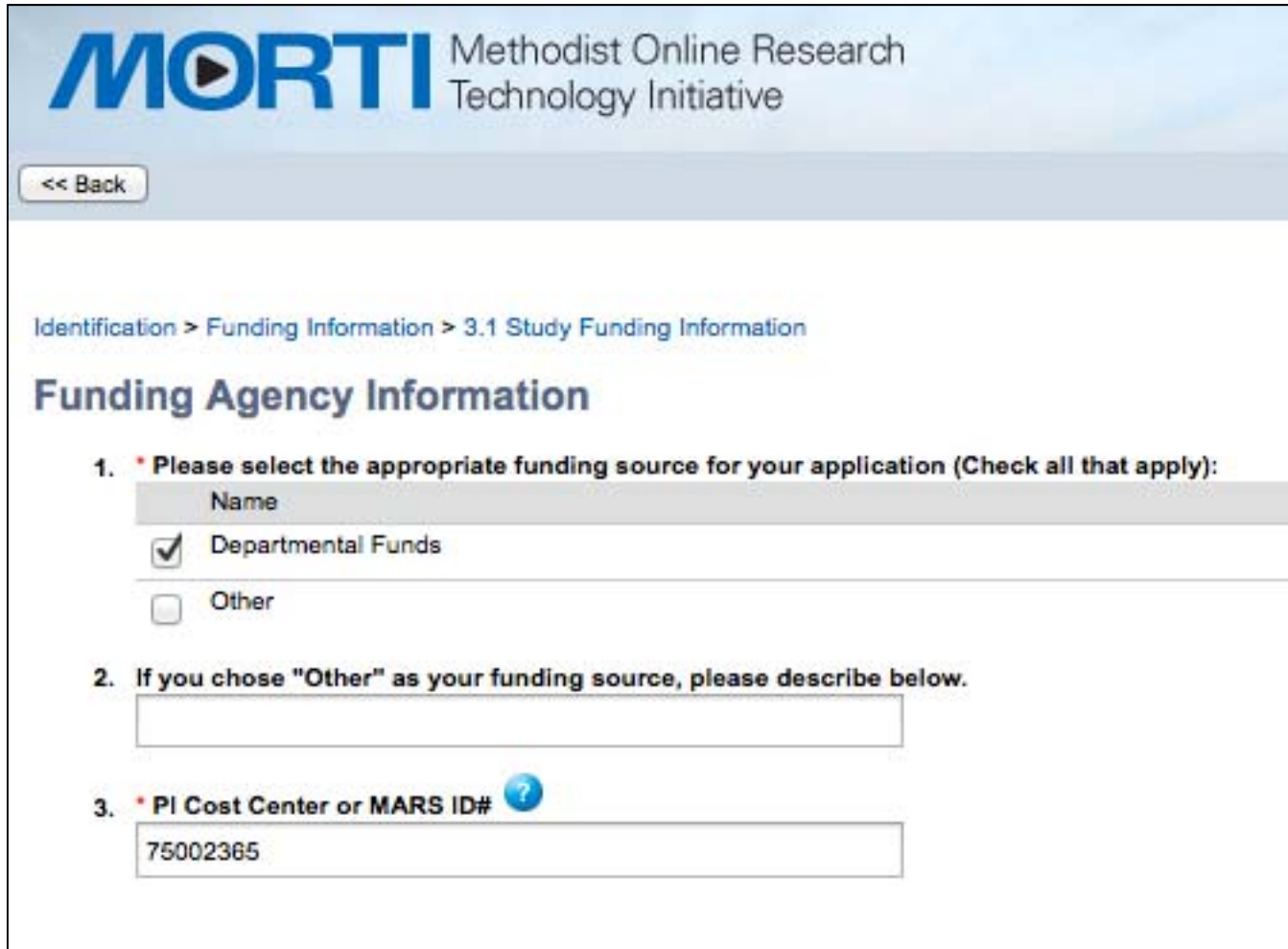# OVERVIEW: EXAMPLE TRAINEE RESEARCH PROJECT

Fill out required information:
- Title
- Brief/Lay Description
- Principal Investigator (typically the mentor with whom you are working)
- Study Coordinator (you can put yourself)
- Primary Study Contact
- Proposed Project Period (when you will have finished the research)

And then there will be ~ 2 more pages of questions
Answer based on the scope/goals of your project

OVERVIEW: EXAMPLE TRAINEE RESEARCH PROJECT

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Research Category

1.0   * Is this project investigator-initiated? ⓘ
     ● Yes   ○ No   Clear

2.0   * Does this project involve: ⓘ

Name	Description
☐ Human Clinical Trial	Research activities involving human subjects and a therapeutic intervention, such as investigational or approved drugs, biologics and devices or other human subject research
☑ Clinical Research	Research that DOES NOT INVOLVE THERAPEUTIC INTERVENTION, poses only minimal risk, either directly involves a person or group, or uses materials from humans, su
☐ Basic (Bench) Research	Research activities occurring within a laboratory environment (e.g., in vitro studies), and/or involving animals.
☐ Education	Support for instructional activities for employees of HMRI, HMPO or other HM corporation.
☐ Public Service	Support for community service programs and other activities designed to provide beneficial services to the general public, e.g, community service programs, conferences, and

Research that DOES NOT INVOLVE THERAPEUTIC INTERVENTION, poses only minimal risk…or uses materials from humans that can be linked to a particular living person.

OVERVIEW: EXAMPLE TRAINEE RESEARCH PROJECT

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Special Categories of Research (check all that apply): ⊘

Name
☐ One Time Emergency Use of Investigational Device or Drug
☐ Drugs or Biologics
☐ Devices (Includes FDA approved devices, investigational devices, and humanitarian use devices (HUD))
☑ Medical Records / Protected Health Information
☐ Radioactive Materials / X-Rays / Lasers. Requires review by the Radiation Safety Officer
☐ Recombinant or Synthetic DNA, RNA, Nucleic Acids, Gene Therapy – Requires Institutional Biosafety Committee review
☐ Select Agents (Click Here to see a list from the CDC website)
☐ Stem Cell for Therapeutic Human Clinical Trials
☐ Hazardous Agents (Biological agents BSL-2 or higher, Hazardous Chemicals, or other Hazards not listed) Requires review by the Hazardous Substances Committee
☐ Research use or collection of any human serum or tissue (This does not include samples that are routinely sent to clinical laboratories for analysis)

OVERVIEW: EXAMPLE TRAINEE RESEARCH PROJECT

Houston Methodist Hospital Services

1.0   Does this study require Houston Methodist Hospital services:
(Examples: Lab Work, Diagnostic Imaging or Pharmacy **(including the IDS)**)
◯ Yes ◉ No Clear

2.0   If yes, does this study involve human subjects?
◯ Yes ◯ No Clear

3.0   If you answered yes to question 2.0, considering your delineated schedule of events attached in section
◯ Yes ◯ No Clear

- Typically your answer will be "no"
- Most trainee projects use histology, which is considered internal

OVERVIEW: EXAMPLE TRAINEE RESEARCH PROJECT

Based on your answers, the ARAF will be sent to the appropriate reviewers

Required Reviews and Additional Information

1.0	**Required Department Approvals:**	
	Department Name	
	Pathology & Genomic Medicine	
2.0	**Required Facility Approvals:**	
	Name	
	There are no items to display	
3.0	**Required Ancillary Approvals:**	
	Available Committees	
	Biorepository	
	Core Pathology Lab	
	Investigator Initiated ANC	
4.0	**Provide any additional comments about your proposed study:**	

Next Steps:

1. Fill out accompanying IRB that will be generated once the ARAF is submitted

2. For Biorepository samples, once your ARAF and IRB are approved, contact Pam McShane (PMcShane@houstonmethodist.org)

3. Fill out the form she sends you

4. You <u>will only have access</u> to what you requested in the ARAF and IRB

What does this mean?

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- If you requested completely de-identified, anonymous samples (exempt), then that is what will be provided
  - retrospective chart reviews
  - analyses of discarded pathological specimens without patient identifiers

- If you need linked patient information, then it falls under expedited
  - studies of existing pathological specimens with patient identifiers

- If what you need changes, then you need to file an amendment to your approved protocol

OTHER CONSIDERATIONS

- It takes a lot less time if you fill the forms out completely and correctly the first time

- Check frequently (1-2x/week) to make sure your ARAF and IRB protocol are not held up at any stage of the review/approval process

- There is no such thing as retroactive approval!

Core Facilities

*H*ouston Methodist Research Institute has core support capabilities for both basic and clinical research. These core resources enhance access to cutting-edge technology and data analysis for a wide variety of projects. For more information, contact Brenda Hartman, bkhartman@houstonmethodist.org.

Houston Methodist Research Institute is now using iLab, an online system to streamline the process of ordering and billing for core service requests. All facility users are now required to use the iLab system in order to initiate service requests, which requires a one-time registration as discussed below. Once you are registered, the system will enable you to place service requests, provide required approvals, and monitor progress.

More online scheduling modules for our other cores will be added in 2013.

- Academic Office of Clinical Trials
- Advanced Cellular & Tissue Microscopy (iLab)
- Biomedical Informatics Support (iLab)
- Center for Biostatistics (iLab)
- cGMP Manufacturing (iLab)
- Comparative Medicine
- Cyclotron & Radiopharmaceutical cGMP (iLab)
- Electron Microscopy (iLab)
- Event Services (iLab)
- Flow Cytometry (iLab)
- Genomic Sequencing (iLab)

- Magnetic Resonance Imaging (iLab)
- Machine Shop (iLab)
- Molecular Diagnostics (iLab)
- Nanochips-Peptidomics (iLab)
- Nanoparticles (iLab)
- PET Center (iLab)
- Platelet Lab (iLab)
- Preclinical Catheterization Laboratory (iLab)
- Preclinical Imaging (iLab)
- Proteomics (iLab)
- Research Pathology (iLab)
- RNAcore (iLab)
- Serum & Tissue Biorepository

To register for an iLab account:
1. Complete the registration form on the sign-up page.
2. Receive a Welcome Email from iLab (typically within one business day) with login credentials.

To request access to the core:
1. Once you have received your log in credentials, navigate to the sign-in page and log in: http://tmhricores.methodisthealth.com
2. You will be taken to your homepage. On the left-hand side, under *Core Facilities*, click *List all cores*.
3. Enter your core name.
4. Add an additional note, or just click the Send access request button.
You will then be notified once the core manager has given you access to use the core.

To Create a Service Request:
1. Click the (iLab) link next to the core you wish to access.

Serum and Tissue Bank

*T*he serum and tissue biorepository is a large, general-purpose tissue bank and associated database of pre-selected and randomly selected specimens for use by researchers within The Methodist Hospital Research Institute and their collaborators. All collection activities are conducted in a manner that will ensure that priority is given to accurate pathologic diagnosis, that the patient confidentiality is protected, and that investigators have appropriate authorization for tissue use.

For more information, visit our public website.

The TMHRI serum and tissue repository offers the following services:

1. Collection and storage of fresh, snap-frozen human tissues from surgical pathology specimens resected at The Methodist Hospital.
2. Collection and storage of paraffin embedded tissue and slides made from tissue.
3. Collection and storage of human blood components and other body fluids collected from patients undergoing specific surgical procedures as well as associated control groups from similar dates and procedures.
4. Harvesting and initial preparation of tissue samples according to established protocols. Snap freezing, controlled freezing, and formalin fixation with subsequent paraffin embedding are routinely performed. Blood products are separated and then frozen.
5. Maintenance of a patient database for harvested tissue. The repository maintains interfaces with the patient history records to provide accurate clinical and pathological information. Only tissues collected with patient's informed consent according to HIPAA guidelines are available for use. Most collected tissue will be de-identified before release to investigators to protect patient confidentiality.
6. Oversight by the Tissue Bank committee that reviews and approves requests for tissue. Because these materials are available only to approved investigators, researchers who want to use this resource are required to submit an appropriately designed research protocol that has been independently reviewed and approved by the IRB. Requests for tissue must include the types of tissue needed, the minimum useful amounts of tissue required, how the tissue is to be supplied, as well as IRB, informed patient consent, and other approvals.

Contact

Pam McShane, Tissue Bank Coordinator
The Methodist Hospital Research Institute
phone 713-441-2113
pager 713-768-1808

DEPARTMENT MICROGRANTS

- Designed to foster innovation and expansion of clinical service
- Budgets of $5,000 to $15,000
- Work must be started and completed in 3-4 months max
- Applications must include IRB-approved protocols
- Criteria include (but not limited to):
    - Clinical need
    - Potential for significant return on investment
    - Involvement of residents and/or fellows and multiple faculty
    - Likelihood of leading to a peer-reviewed publication

DEPARTMENT MICROGRANTS

ANYONE can apply – Excellent opportunity to get involved in research

Applications accepted until July 15th, 2014

Next round in mid-late August

Association of histologic and immunophenotypic features of cervical dysplasia with infection by various HPV genotypes
- Dr. Yimin Ge and colleagues (Drs. Steve Zhou, Christi Perez, Dina Mody, and Michael Deavers)

Prognostic and predictive biomarkers in metastatic rectal adenocarcinoma
- Dr. Suzanne Crumley and colleagues (Drs. Mary Schwartz, Alexandria Phan, Randall Olsen, and Bryce Portier)

GETTING STARTED

Additional information/tools to help
with your research:

1. The light purple "Getting Started" cheat sheet

2. Reference manager software

3. The OAD website "Resources" page

- "Getting Started" cheat sheet
  - A step-by-step guide to getting started with your research project
  - Contact information
- Keep it available for frequent reference

Use for your manuscripts - ALWAYS

Two main reference managers available through Methodist: EndNote and RefWorks

EndNote
- IT can push a copy onto your workstation
- Student copy available for ~$100

REFWORKS

- Also free and available on the HMH Intranet site
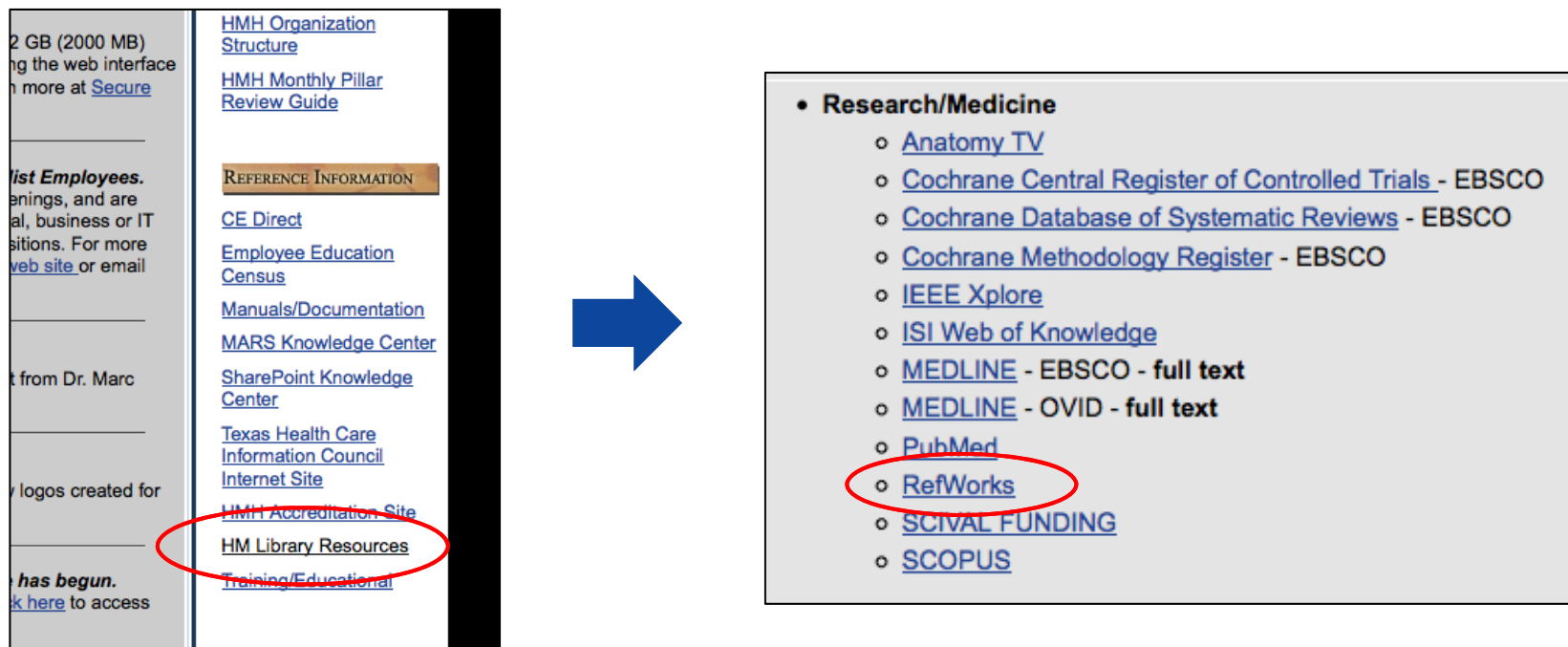
- Step-by-step instructions posted on the OAD website

OFFICE OF ACADEMIC DEVELOPMENT

http://www.houstonmethodist.org/OAD

RESOURCES: OAD WEBSITE

CONTACT INFO

Contact Information:

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"OFFICE HOURS": Tuesdays, 4:30 – 5:30, B5-029

QUESTIONS?