Improving People's Lives Through Innovations in Personalized Health Care

Medical Student Research Opportunities

September 21, 2015

Ginny L. Bumgardner MD PhD FACS
Associate Dean for Research Education

The Ohio State University
Wexner Medical Center
Topics

- Finding a Research Mentor
- Basics of Medical Student Research Success
- Medical Student Research Funding Opportunities
- Faculty Alumni Perspectives
- Student Alumni Perspectives
Basics of Medical Student Research Success

- Find a Great Research Mentor
- Identify an Interesting Research Project
- Seek Medical Student Research Funding
- Prepare a High Quality Application
- Apply to Multiple Funding Sources!
  - Applications are competitive
  - Intramural funds are limited
- Prepare a timeline to meet application due dates
Finding the “Right” Research Mentor
http://medicine.osu.edu/go/mdsr

Research Trainees

Resources for Medical Students

The Medical Student Research Office strives to connect interested medical students with quality basic, clinical, or translational research experiences and projects with a College of Medicine faculty member.

There are several ways to find a faculty mentor to conduct research. The interested medical student, who starts early, communicates often, and thoroughly investigates a faculty member’s research areas of interest will be most successful in getting a quality experience.

- **How to find a Research Mentor** - Tips for what to do and how to find a COM Faculty Research Mentor.
- **Research Opportunities** - Listing of previously funded opportunities through the office of Medical Student Research.
- **Scholarship Opportunities** - Listing of scholarship and grant opportunities for medical students.
- **FAQ’s** - commonly asked questions and answers.
Where to Start Your Search

http://www.medicine.osu.edu/research_ed/medical_students/resourcesformedicalstudents/pages/index.aspx
How to Find a Faculty Research Mentor

Checklists, Useful Documents, and Events

- **Medical Student Research Scholarship Application Checklist (PDF)** - a quick checklist of important tips and documents to share with prospective mentors

- **Landacre Honor Society Mentor Search Tips (PDF)** - Landacre Research Honor Society Mentor Search Tips and Tricks

- **List of Previous Medical Student Scholarship Mentors (PDF)** - Many students have been very successful connecting with mentors who have had previous Roessler, Bennett, or Watts scholarship recipients in their labs

- **Annual Research Opportunity Fair (October 15th, 4-6pm)**
  Fair where interested faculty members are available to talk with Medical Students looking for research experiences and mentors
How to Find a Faculty Research Mentor

Sources to Faculty Research Mentor Profiles

- **List of Current/Past MDSR Mentors** — COM Faculty postings
- **Faculty Researcher Profiles** — a listing of COM faculty by their research area.
- **Listing of Faculty by Departmental/Center** — The OSUMC Departmental websites can be especially helpful when trying to narrow down multiple mentors in a research area. There are clinical departments and COM Basic Science departments.
- **Center Faculty** — for example...
  - Comprehensive Cancer Center
  - Heart Lung Research Institute
  - Center for Microbial Interface Biology
  - OSU Center for RNA Biology
How to Prepare for Research Mentor Meeting

Before meeting with your mentor:

- Check the medical student research program (MDSR) website
- Read the Landacre Honor Society Medical Student Research Guide
- Prepare an NIH style Biosketch outlining your interest/motivation in pursuing research and prior research experience, research skills, presentations, publications, etc.
- Review Mentor and Mentee Compact agreements
- Questions to Consider:
  - Time period for pursuing research
  - Time commitment
  - Potential interest in continuing the research project beyond the summer
- Determine if you might be interested in continuing the research for a longer time period
- Contact potential mentors (or their lab contact)
- Research your potential mentor’s publications
How to Prepare for Research Mentor Meeting

- Read **PI publications** and prepare some questions
- Provide **your Biosketch** and discuss research goals and prior experience
- Discuss your **dates & time commitment**
- Attend a **lab meeting**
- Learn where the **lab environment** is located
- Determine **who will supervise the work** in the laboratory
- Determine what is the **desired outcome** of this research
How to Prepare for Research Mentor Meeting (cont.)

- Determine if the project you would be working on already has IRB/ILACUC approval.

- **Attend a lab meeting** to meet the other lab members, hear about ongoing research etc.

- Ask your mentor about medical student mentored research grants

- Determine if your potential mentor could provide funding for your stipend if you do not receive a scholarship or other sources of sponsorship
How Your Research Mentor Can Help…

- Clarify learning objectives, your role, meeting frequency, timeline for completion, realistic outcomes
- Introduce you and your role to the team
- Provide research resources
- Identify important research seminars you can attend
- Guide your awareness of other research projects
- Identify extramural grant funding opportunities
- Get to know you as a person, research team member, research potential and interests
How to Fund Your Research Project?
Research Funding Opportunities  
(Scholarships and Grants)

- **BE ALERT to funding opportunities**
  - Weekly MD2B emails
  - Medical Student Research Program [Website Listings](#)
  - Department specific opportunities
  - Center specific opportunities (CCTS, CCC-Pelotonia)
  - National Associations in specific areas (e.g., American Heart Association, American Cancer Society, ….)

- **Resources for Information**
  - Research Mentors and laboratory team
  - Websites of Professional Medical Associations
  - Other medical students

  - **BE AWARE of Scholarship Deadlines & Commitments**
Internal Funding Sources Summer
The Medical Student Research Scholarship (MDSRS)

2 Phase Application process

Phase 1 = Due 5:00PM December 14th
Phase 2 = Due 5:00PM January 8th
Phase 1 of the MDSRS Application

1. MEDICAL STUDENT RESEARCH APPLICATION COVER PAGE
2. NIH BIOSKETCH OF STUDENT
3. IRB/ILACUC PROTOCOL APPROVALS
4. SIGNED STUDENT COMPACT
5. SIGNED MENTOR COMPACT
6. CATEGORIZATION OF RESEARCH PROPOSAL (complete online)
Phase 2 of the MDSRS Application

1. COVER PAGE (include Student, mentor name)
2. MENTOR LETTER
3. ABSTRACT (150 words)
4. TRAINEE PERSONAL STATEMENT (150 words)
5. TRAINING PLAN
6. RESEARCH PLAN (3 pages)
   a. SPECIFIC AIMS
   b. BACKGROUND INFORMATION
   c. PRELIMINARY STUDIES
   d. EXPERIMENTAL DESIGN & METHODS
7. ENVIRONMENT & RESOURCES (150 words)
8. EXPERIMENTAL DUTIES ON PROJECT (150 words)
9. TIMETABLE (specific dates, weeks of duties)
10. REFERENCES (1 page)
11. NIH BIOSKETCH OF MENTOR
2016 Medical Student Research (MDSR) Research Scholarship Application Timeline

- Funding Sponsors: Roessler/Bennett/Barnes/COM
- Phased Application Submission
  - Application Opens: **October 2nd, 2015 - 9:00 AM**
  - Phase 1 Due: **December 14th, 2015 – 5:00 PM**
  - Phase 2 Due: **January 8th, 2016 – 5:00 PM**
- Award Notification:
  - **April 4th, 2016 by email**

- Apply via the MDSR website: [http://medicine.osu.edu/go/mdsr](http://medicine.osu.edu/go/mdsr)
2016 Carolyn L. Kuckein Student Research Fellowship

•Research support for a continual period of a minimum of 8-10 weeks, 30 hrs/week, or an average of 4 hrs/wk for 12 months over 1-2 years.

•Supports clinical investigation, basic laboratory research, epidemiology, social science/health services research, leadership or professionalism.

•Students DO NOT have to be AOA members in order to apply. All 1st, 2nd, and 3rd year medical students are eligible to apply. (PhD or MD/PhD candidates are NOT eligible)

•Award is $5000, one half paid on announcement of award, one half on approval of final report. Up to an additional $1000 reimbursed for travel to present on research at a national meeting.
2016 Carolyn L. Kuckein Student Research Fellowship

• OSU students submit their application to the OSU chapter of AOA, and then the committee selects one application to send to the national office for consideration. **50** Fellowships are granted nationwide.

• Applications are due to OSU chapter by **December 31, 2015** and must include a 3 page summary of the proposed research project, the applicants CV, a letter of support from the faculty supervisor, the mentor's biographical sketch, and the completed application form with checklists.

Date of award announcement: **on or about April 15, 2016**

More information, contact **aoa@osumc.edu**, all application information may be found at **www.alphaomegaalpha.org/student_research.html**
Internal Funding Sources
Year-Long
OSU Pelotonia Fellowship Program

The Pelotonia Fellowship Program provides one-year research fellowships for up to two of the best and brightest OSU medical students who want to help cure cancer.

- To be eligible, an applicant must:
  - Be an outstanding OSU medical student
  - Propose a cancer related project
  - Participate in Pelotonia

- Applications for the next Medical Student Pelotonia Fellowships are due in February for Medical Students starting July 1.

- Applications will be scored on the following criteria:
  - Applicant strengths and research potential
  - Mentor/advisor qualifications and training record
  - Innovativeness and impact of

Jeff Mason, Program Director

Pelotonia Website
jeffrey.mason@osumc.edu
CCTS TL1 Awards

- The OSU Center for Clinical and Translational Science (CCTS) is pleased to announce a call for graduate student (PhD, post-doctoral, pre-professional, post-professional resident and fellow trainees) applicants to receive research funding from the National Institutes of Health (NIH) sponsored TL1 Mentored Clinical Research Training Program (CCTS-TL1). The CCTS-TL1 program is part of a comprehensive program at OSU to advance research education and training in multidisciplinary clinical and translational investigation targeted at the improvement of human health. Pre-professional students such as MEDICAL STUDENTS are eligible and encouraged to apply.

- Objectives of the TL1 program include:
  - Recruitment and selection of highly qualified applicants who will develop a career in multidisciplinary clinical and translational research.
  - Completion of a mentored research project.
  - Didactic training in team science and interdisciplinary and translational research.
  - Shared educational experiences with student and faculty scholars from other training programs.

- Please visit the [CCTS TL1 award website](http://ccts.osu.edu/) for more information.
External Funding Sources
Summer
The HHMI Summer Medical Fellows Program provides an 8–10 week research experience for medical, dental, and veterinary students in the laboratories of HHMI investigators, early career scientists, HHMI professors or Janelia researchers. This fellowship program is primarily aimed at those students who wish to use the summer research experience to explore continuing research through a year-long research training program. Subsequent applications to the year-long Medical Research Fellows Program are not limited to the laboratory in which the summer experience was obtained. Students from all medical, dental and veterinary schools in the U.S. are encouraged to apply for this beneficial educational opportunity. Up to 20 fellowships will be awarded in 2015.
2015 HHMI Summer Medical Fellows Program

Program Dates

**November 3, 2014** - Online application opens

**February 17, 2015** - Application deadline

**March 20, 2015** - Award notification

**March 27, 2015** - Award acceptance deadline

**Summer Program Information**

**Summer Program Highlights**

**Summer Program Mentors**

http://www.hhmi.org/programs/medical-research-fellows-program
NIH Summer Internships

- The NIH Clinical Center (CC) Summer Internship Program offers summer internships to students who are U.S citizens or permanent residents and are currently enrolled in high school, college, graduate programs, and health professional schools including nursing and medicine.

- Each year, more than 7,000 students apply to the National Institutes of Health Summer Internship Program. From this pool, approximately 50 students are selected to participate in the Clinical Center's internship experience. At the Clinical Center— the nation's largest hospital devoted entirely to clinical research—students work with mentors who are researchers and health professionals; participate in the NIH Research Poster Day with results generated by their work in this summer program; and attend weekly lectures presented by NIH investigators.
2016 Summer Internship Experience
The start date for the 2016 program is June 13, 2016. The summer internship is 40 hours a week for 8 weeks. Selected students must participate in the program for eight, uninterrupted weeks, leaving no earlier than August 5, 2016.

Apply to the NIH Summer Internship Program: November-March 1
Applications are accepted from late-November through March 1 each year. Apply on-line using the NIH-wide application and specify your interest in the 'Clinical Center.' Students will receive notice of application acceptance by early April.

For more information, please email the CC Summer Internship Program staff.

http://www.cc.nih.gov/training/students/summer_internships.html
External Funding Sources
Year-long
Year-Long NIH Medical Research Fellows Program

Overview

- Student scholars engage in a closely mentored basic, clinical, or translational research project on the main NIH campus in Bethesda, or nearby NIH facilities, that matches their research interests and career goals.

Eligibility

- The MRSP is designed for U.S. citizens and permanent residents currently enrolled in an accredited medical, dental, or veterinary program who have completed their core clinical rotations. This does not exclude students with strong research interests from applying prior to having completed their clinical rotations.

- Medical and osteopathic students: participation in the MRSP is recommended after you have completed your first year of clinical rotations (i.e., third year of medical school).

- Dental and veterinary students: due to the integrated nature of the third and fourth (clinical) years, participation in the MRSP is recommended after you have completed your second or fourth year in school.
Year-Long NIH Medical Research Fellows Program

- NIH Medical Research Scholars Program (MRSP) is a comprehensive, year-long research enrichment program (replaced CRTP and NIH-HHMI)
  - Read about other student projects @ link below!
  - The MRSP application cycle for 2015-2016 will open on October 1, 2015
  - Deadline is **January 31, 2015**

HHMI Medical Research Year-Long Fellows Program

- Students select mentor at any academic or nonprofit research institution in the United States (excluding NIH)
- Students work with Mentor to develop a research project proposal
- Working with HHMI PI encouraged but not required

[HHMI investigator, early career scientist, or HHMI professor](http://www.hhmi.org/programs/medical-research-fellows-program/year-long-program)
HHMI Medical Research Year-Long Fellows Program

Medical Fellows conducting research in the following areas may be supported by organizations partnering with HHMI:

- Epilepsy research (Partner: Citizens United for Research in Epilepsy)
- Inherited retinal degenerative disease research (Partner: Foundation Fighting Blindness)
- Duchenne muscular dystrophy research (Partner: Duchenne Research Fund)
- Parkinson's disease research (Partner: Parkinson's Disease Foundation)
- Preclinical research in interventional radiology (Partner: Society of Interventional Radiology Foundation)

http://www.hhmi.org/programs/medical-research-fellows-program/year-long-program
Year-Long Medical Research Fellows Program at Janelia

- Janelia Research Campus
- Students interested in neuronal network function or imaging at the cellular and molecular level are encouraged to apply for fellowship positions at HHMI’s Janelia Research Campus.
- Fellows at Janelia take part in cutting-edge research and work with small, interdisciplinary teams of chemists, biochemists, neurobiologists, geneticists, physicists, computer scientists, mathematicians, and engineers from around the world in a collaborative, creative, resource-rich environment.
- This intense research training experience is targeted to highly talented students with a proven track-record of research accomplishment and a commitment to a basic research field being pursued by Janelia investigators.

Life at Janelia includes:
- A full agenda of seminars, conferences, and journal clubs;
- A chance to interact with outside faculty speakers, HHMI investigators, and other renowned researchers;
- State-of-the-art laboratory and conference facilities;
- Well-appointed on-campus housing; and many other amenities.
Year-Long Medical Research Fellows Program at Janelia

Two-step application process:

Prescreening application deadline - November 2, 2015

Late November/early December - Interviews for selected candidates

December 11, 2015 - Interviewees notified of outcome

March 18, 2016 - Award notification

March 25, 2016 - Award acceptance deadline

Summer 2016 - Fellowship begins between May 1 and September 1

http://www.hhmi.org/programs/medical-research-fellows-program/year-long-program-at-janelia
Year-Long Medical Research Fellows Program, K-RITH

- **K-RITH**
- Students interested in conducting research in HIV, TB, or co-infection in a state-of-the-art research institute at the heart of the TB and HIV epidemics should apply for fellowship positions at K-RITH.
- Fellows will spend the year living and working in Durban, South Africa.
- Students should have previous research experience and a strong interest in infectious disease.
Year-Long Medical Research Fellows Program, K-RITH

Applications will be accepted on a rolling basis.

REVIEW PANEL - Each application will be reviewed by a committee of scientists based at K-RITH and the Ragon Institute of MGH, MIT and Harvard. 90 awards will be made over a 5-year period (18 per year).

APPLICATION DOCUMENTS - In order to complete your application the following supplemental documents need to be submitted along with your Application Form:
1. Three letters of recommendation: one should be from your current mentor. If you will be visiting a different institution, you will also need to submit a letter of support from your host. All individuals should be familiar with your work.
2. Budget and Budget justification
3. CV
4. If attending a course or conference please provide details of content of the event
Failure to submit a complete and accurate application will result in removal of the application from the selection process.
Please email Victoria Kasprwicz (K-RITH Director of Training and Education) or Marylyn Addo (Ragon Institute Director of International Programs) on connectafricascholarships@gmail.com for further information.

http://www.k-rith.org/connect-africa-scholarships/application-details
The Sarnoff Fellowship Program offers research opportunities for outstanding medical students to explore careers in cardiovascular research. Applicants must be enrolled in accredited U.S. medical schools. Sarnoff Fellows conduct intensive work in a research facility, located in the United States, for one year. Prior research experience is not a prerequisite.

What makes Sarnoff unique is our lifetime commitment to the Fellow. A member of our Scientific Committee guides the Fellow during the research year and throughout the Fellow's career. The Fellow interacts with other Fellows, Scholars and Foundation leaders at the Sarnoff Foundation's Annual Scientific Meetings, Sarnoff-sponsored regional events, and at other scientific conferences.
Sarnoff Medical Student Research Fellowship Program

The Sarnoff Fellowship Program offers research opportunities for outstanding medical students to explore careers in cardiovascular research.

- Sarnoff Fellows conduct intensive work in a research facility, located in the United States, for one year.
- Prior research experience is not a prerequisite.

**Timeline:**

- January 6, 2016, 3:00 pm ET - Application deadline
- February 5, 2016 - Finalist notification via e-mail
- February 25-February 28, 2016 - Finalist interviews in Boston, MA
- March 11, 2016 - Award notification via e-mail
- March 18, 2016, 1:00 pm ET - Award Acceptance Deadline
- Summer/Fall 2016 - Fellowship begins between May 1 and October 1

- Current Scholars
- [http://www.sarnofffoundation.org/](http://www.sarnofffoundation.org/)
- [https://sarnofffoundation.site-ym.com/?page=Fellowship_App](https://sarnofffoundation.site-ym.com/?page=Fellowship_App)

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**Rohit Mital - 2012-13 Fellow**

Med School: Ohio State
Sponsor: Clay Marsh, MD
Host Inst: Rockefeller University
Preceptor: Sohail Tavazoie, MD, PhD
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What’s Next?
Monday, Oct. 12
12:00 – 1:30 PM
Medical Student Research Funding Opportunities Information Session
160 Meiling

Thursday, Oct. 15
4:00-6:00 PM
Medical Student Research Opportunities Fair
Meet faculty from OSU COM and NWCH
115 BRT
Medical Student Research Program
Internal Review for HHMI, Sarnoff etc

- Assistance with internal review of NIH, HHMI and Sarnoff applications
- Internal review due date **November 23rd, 2015**
- E-mail to research.education@osumc.edu
- E-mail subject “Internal Review for …. Fellowship”
Resources

- Medical Student Research Program Office
  - Reach us by email: research.education@osumc.edu
  - Phone: 685-9106
  - In person: 1190A Graves Hall

- Medical Student Research Program Website
  - [http://medicine.osu.edu/go/mdsr](http://medicine.osu.edu/go/mdsr)
  - MDSR Newsletter

- Landacre Research Honor Society Executive Board
  - Vlad Manko, President

- Landacre Interest Group
  - Now taking applications
Medical Student Panel

Priyanka Chablani, Med IV
- priyanka.chablani@osumc.edu
- Research LOA
- External Funding
- Research ACAE

Volodymyr Manko, Med III
- priyanka.chablani@osumc.edu
- Finding a Mentor
- Landacre

Maya Armstrong, Med II
- Maya.Armstrong@osumc.edu
- Finding a Mentor
- How to prepare a successful MDSRS Application

Courtney Yong, Med IV
- Courtney.Yong@osumc.edu
- Research ACAE
HIPAA/HITECH: Medical Student Access to PHI for Research Purposes

Frank White, MS, JD
Director of Research Compliance

College of Medicine
Office of Research

The Ohio State University
Wexner Medical Center
Outline

- HIPAA
  - Clinical Practice
  - Research
- Research Regulations
- Definitions
- Access Requirements
- Scenarios
- Summer Funding Deadlines
What is HIPAA?

- Not HIPPAA
- Not HIPPO
- Not HIPPA
  - HIPAA

HIPAA Is Powerful And Awesome
What is HIPAA/HITECH?

- **HIPAA**: Healthcare Insurance Portability and Accountability Act
  - Applies to Covered Entities (CE)
  - Creates various standards for Protected Health Information (PHI)
    - Privacy
    - Security
    - Coding Standards

- **HITECH**: Health Information Technology for Economic and Clinical Health Act
  - Strengthens HIPAA
    - Adds additional obligations for CE
    - Increase monetary fines ($1.5M per violations)
HIPAA Privacy: Clinical Practice

- TPO: Allowed to view protected health information for Treatment, Payment, and Healthcare Operations
  - Treatment
    - Provision, coordination, or management of health care and related services among health care providers...
  - Payment*
    - Various activities to obtain payment
  - Operations*
    - Certain administrative, financial, legal, and quality improvement activities, and education

*Minimum necessary applies: CE must develop and implement policies that reasonably limit the use/disclosure of PHI to the minimum necessary amount required to complete the function
Overlapping Regulations

- **Human Subject Protections**

  - Research involving:
    - Interaction or intervention with a living individual; or
    - Individually identifiable, private information about living individuals
What is PHI?

- PHI?
  - Protected Health Information
    - Individual’s past, present, or future physical or mental health or condition,
    - Provision of health care to the individual, or
    - Past, present, or future payment for the provision of health care to the individual,
    - and that identifies the individual or for which there is a reasonable basis to believe can be used to identify the individual.

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<th>Examples of PHI</th>
<th>Examples of non- PHI</th>
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<td>• Laboratory report</td>
<td>• Non-identifying aggregate data</td>
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<td>• Hospital bill</td>
<td>• Information not linked to health condition, payment, care</td>
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HIPAA/Research Terminology

- **Research**
  - Systematic investigation, including research development, testing, and evaluation, designed to contribute to generalizable knowledge

- **Prospective study**
  - Enrolls subjects who receive services according to schedule of events

- **Retrospective study**
  - Uses medical record information that has already been collected

- **Subject**
  - Volunteer enrolled in a research study
HIPAA/Research Terminology

- **IRB**
  - Institutional Review Board
  - Approves and reviews research studies

- **WIRB**
  - Western Institutional Review Board
  - Approves and reviews industry sponsored research studies

- **Privacy Board**
  - A review body that may be established to act upon requests for a waiver or an alteration of the authorization requirement under the HIPAA Privacy Rule for uses and disclosures of PHI for a particular research study
  - At OSU, IRB is the Privacy Board for non-exempt research
    - Separate board reviews exempt research
HIPAA/Research Terminology

- **Research Informed Consent Form**
  - Written document describing the risks and benefits of the research study along with acknowledging subject’s voluntary participation

- **Principal Investigator**
  - Individual (usually a physician, but sometimes other clinician) who conducts the research study

- **Key Personnel**
  - Research personnel who are directly involved in conducting research with study participants or who are directly involved with handling private information related to study participants during the course of a research project.
HIPAA/Research Terminology

- **Authorization**
  - Consent form that focuses on privacy risks and the use or disclosure of PHI (similar to Informed Consent)

- **Waiver of Authorization**
  - A document that has been signed and dated by an individual, most likely the research subject, who authorizes the use and disclosure of PHI for research purposes
  - Permission from IRB/Privacy Board required

- **Partial Waiver**
  - Allows limited viewing of PHI for recruitment purposes
HIPAA/Research Terminology

- **Minimum Necessary**
  - Reasonably limitation in the use/disclosure of PHI to the minimum necessary amount to complete the function

- **Preparatory to Research**
  - Review of medical records without IRB approval to determine feasibility. MIM requires following forms:
    1. Request for Research Access to Medical Records
    2. Access to PHI without IRB Approval
    3. Researcher Statement of Confidentiality
Limited Data Set

Health Information from which “direct” identifiers have been removed such as:

- Names, street addresses (other than town, city, state and zip code), telephone numbers, fax numbers, e-mail addresses, Social Security numbers, medical records numbers, health plan beneficiary numbers, account numbers, certificate license numbers, vehicle identifiers and serial numbers, including license plates, device identifiers and serial numbers, URLs, IP address numbers, biometric identifiers (including finger and voice prints), and full face photos (or comparable images).

Information that can remain in includes:

- Dates such as admission, discharge, service, DOB, DOD, city, state, five digit or more zip code, and ages in years, months or days or hours.

Separate agreement required
HIPAA Research Terminology

- HIPAA De-Identified Data
  - Data set in which all 18 HIPAA delineated identifiers have been removed

1. Names (including initials);
2. Street address, city, county, precinct, zip code, and equivalent geo-codes;
3. ALL elements of dates (except year) for dates directly related to an individual and all ages over 89 (this would include procedure dates, date of admission, date of lab work, etc.);
4. Telephone numbers;
5. Fax numbers;
6. Electronic mail addresses;
7. Social security numbers;
8. Medical record numbers;
9. Health plan ID numbers;
10. Account numbers;
11. Certificate/license numbers;
12. Vehicle identifiers and serial numbers, including license plate numbers;
13. Device identifiers/serial numbers;
14. Web addresses (URLs);
15. Internet IP addresses;
16. Biometric identifiers, incl. finger and voice prints;
17. Full face photographic images and any comparable images; and
18. Any other unique identifying number, characteristic, or code.
HIPAA Privacy and Research

- HIPAA/Research: What do you need to use/disclose the research subject PHI?
  - **Without patient authorization**
    - Waiver:
      - IRB/Privacy Board approval
  - **Limited Data Set:**
    - IRB Exemption/Approval
    - Separate agreement
  - **Preparatory for Research:**
    - OSUWMC requirements

- **With patient authorization**
  - Privacy Board approves the language of authorization
Special Cases

- **De-identified data**
  - No Specific Requirements
  - Cannot access identified data to obtain de-identified data without IRB approval

- **“Honest Broker” Program**
  - IW is pre-approved to share LDS and de-identified information

- **I2B2**
  - Generates de-identified information from PHI

- **Decedent Information**
  - Protected for 50 years after death
  - Not covered under Human Subject Protections
    - IRB approval not required
    - HIPAA authorization/waiver is required
The Recruitment Issue

- Clinicians view their patients’ information to identify subjects for research studies
  - HIPAA states this is Preparatory to Research
  - HSP regulations state that this is research and requires IRB approval
  - HHS guidance says that there are exceptions for individuals who are in a treatment relationship with the patient

- **Best Practice**
  - Obtain a partial waiver for identification/recruitment
What can you look at?

- Depends on why you are looking at the information

  - **Treatment/Education**
    - Clinical relationship with patient
    - Training
    - Fewer restrictions apply

  - **Research**
    - Authorization/Waiver/Partial Waiver
    - Minimum Necessary

- **What about IHIS access?**
  - Can you use it?
  - Still need authorization/Waiver/Partial Waiver
  - Need to modify account for research purposes
Scenario #1

- Investigator views clinic schedule to identify eligible patients for recruitment purposes. Staff approach to introduce the study.

  - Is there PHI?
    - Yes

  - Reason for Access
    - Recruitment

  - What is needed
    - Partial Waiver for viewing the records
    - Authorization for enrollment
Scenario #2

- Researcher matches State of Ohio Department of Rehabilitation data with Medical Center Medicaid enrollment files to create de-identified dataset

- Is there PHI?
  - Yes

- Reason for Access
  - Retrospective Review

- What is needed
  - Full Waiver
Scenario #3

- Clinicians inform participants introducing a study. Patients/subjects agree to passing name to investigator. Investigator contacts participants by phone to determine eligibility prior to visit.

- Is there PHI?
  - Yes

- What is needed
  - Clinicians:
    - Viewing
      - Nothing
    - Disclosure to investigator
      - Partial Waiver
  - Investigator
    - Viewing/contacting
      - Partial waiver
  - Enrollment
    - Authorization
Scenario #4

- Researcher is conducting analysis of data using past research records from a study conducted on a population of individuals with bipolar disorder. The data was collected in 1990. The researcher is accessing the records and creating a new data set for analysis purposes. Among the items are diagnosis information and social security numbers.

- Is there PHI?  
  - Yes

- What is needed?  
  - Waiver
Three groups of projects
- Projects with IRB approval
- Projects that are pending approval
- Projects that have not been submitted

Summer Funding: Key Dates

Dec 14th
- Phase 1: Funding Deadline

Jan 8th
- Phase 2: Funding Deadline
- Submit IRB (if required)

March 18th
- Review complete: Must have IRB approval
- Request to be added as key personnel

May 1st
- Request account modification after IRB approval and added as key personnel

June:
- Begin Research
Summer Research Requirements:

- Bianca will have a handout showing how to request to modify your IHIS account
- COMOR website will have a link with instructions
- Contact information
  - Frank White, Director of Clinical Research Compliance, Frank.White@osumc.edu, 614-685-1734
  - Abby Larsen, Regulatory Manager, Abigail.Larsen@osumc.edu, 614-685-1739