Nexus Award for Epic and Other JH Data Sources

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What are the Translational Research Communities?

- Lead by Dr. Daniel Laheru, Co-Director, Skip Viragh Center for Pancreas Cancer, Associate Professor of Oncology
- Behavioral, Social and Systems Sciences
  - Felicia Hill Briggs, PhD, ABPP (Behavioral Medicine)
  - Jill Marsteller, PhD, MPP (Psychosocial Traits and Quality Improvement)
- Drugs/Devices/Biologics/Vaccines
  - Barbara Slusher, PhD, MAS (Drug Development)
  - Clifford Weiss, MD (Devices)
- Biomarkers and Diagnostic Testing
  - Marty Pomper, MD, PhD (Imaging)
  - Elizabeth Selvin, PhD, MPH (Biomarker Analysis; Epidemiology)

Overall Goals

- Improve quality, innovation and impact of translational research

- Increase the value of individual and team research and further their translational abilities

- Promote interdisciplinary research bringing multiple experts together to solve important problems

- Develop our next generation of translational researchers

The ABCs of TRCs

- Each span the entire translational pathway from basic discovery to full implementation in the community

- Each sponsor educational and networking opportunities to disseminate new approaches and methodologies that facilitate translational research

- Each community will bring together members from all JHU schools, industrial partners, technology licensing experts, and regulatory experts

Targeted Funding

- Each TRC has $100,000/yr in pilot funding to facilitate the initiation of multidisciplinary translational projects
- Each year the focus, theme or platform for Nexus will change
- Grants aim to bridge research gaps in a specifically identified areas of interest
- Awards will help investigators to advance along the translational pathway, bridging a pivotal moment in their work, propelling investigators forward
- Award provides teams with services provided by the Center for Clinical Data Analysis
- Priority for project selection will be given to projects that demonstrate how the results will lead to direct translation or future grant funding (R01 or similar)
- Projects will have higher priority if they have outcomes that benefit the larger research community

Nexus Award for Epic and Other Johns Hopkins Data Sources

Cosponsored by:

The ICTR Behavioral, Social and Systems Science Translational Research Community (TRC)

&

The Center for Clinical Data Analysis (CCDA)

Basic Information:

- **Deadline:** October 30, 2015 at 11:59pm

- **Eligibility:** All JHU faculty

- **Award Period:** Twelve months from start date as listed in award letter

- **RFA & web based application form available on the ICTR Connection Request page:** https://ictrweb.johnshopkins.edu/ictr/?ApplyNexus

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What is the Center for Clinical Data Analysis (CCDA)?

- Service to assist researchers with access to institutional data

- Overseen by the Johns Hopkins Data Trust, which assures that data access conforms to IRB regulations and Data Trust policies.

- Staffed by experienced data experts

- Can build one time or periodic extracts (e.g. monthly, quarterly)

New Data Trust website:
http://intranet.insidehopkinsmedicine.org/data_trust

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What is the Research Data Trust Sub Council?

- **Stuart Ray** – *Co-Chair, Professor of Medicine and Oncology*

- **Jennifer Kulynych** – *Co-Chair, Johns Hopkins Counsel for Human Research*

- Key Functions:
  - Solutions for research, informatics and analytics
  - Prioritize of major projects
  - Research data extracts
  - Data Access use
  - Data improvement contribution process
  - Research access auditing
  - Support and assistance

JHM Data Trust Council
Chair: Peter Greene

Budget Committee

Office of Data Trust

Key Council Functions:
- Implement JHM data governance program
- Secure enterprise support and funding
- Prioritize efforts through approval of Data Trust projects
- Review sub-council recommendations and policies
- Ensure coordination of sub-council activities
- Resolve issues and ensure progress
- Review requests for large data extracts involving third parties

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Data Stewardship Sub-Council
Chairs:
Amy Knight
Alan Coltri

Key Functions:
- Solutions for stewardship and architecture
- Prioritization of major projects
- Data definition, profiling, mapping
- Data quality assurance
- Data standardization
- Data integration
- Data architecture
- Funding mechanism

Clinical & Quality Data Sub-Council
Chairs:
Steve Kravet
Renee Demski

Key Functions:
- Solutions for clinical, quality, and operational reporting and analytics
- Prioritization of major projects
- Data access and use
- Data improvement contribution process
- Support and assistance
- Funding mechanism

Research Data Sub-Council
Chairs:
Stuart Ray
Jennifer Kulynych

Key Functions:
- Solutions for research, informatics, and analytics
- Prioritization of major projects
- Research data extracts
- Data access and use
- Data improvement contribution process
- Research access auditing
- Support and assistance
- Funding mechanism

Privacy & Security Sub-Council
Chairs:
Donald Bradfield
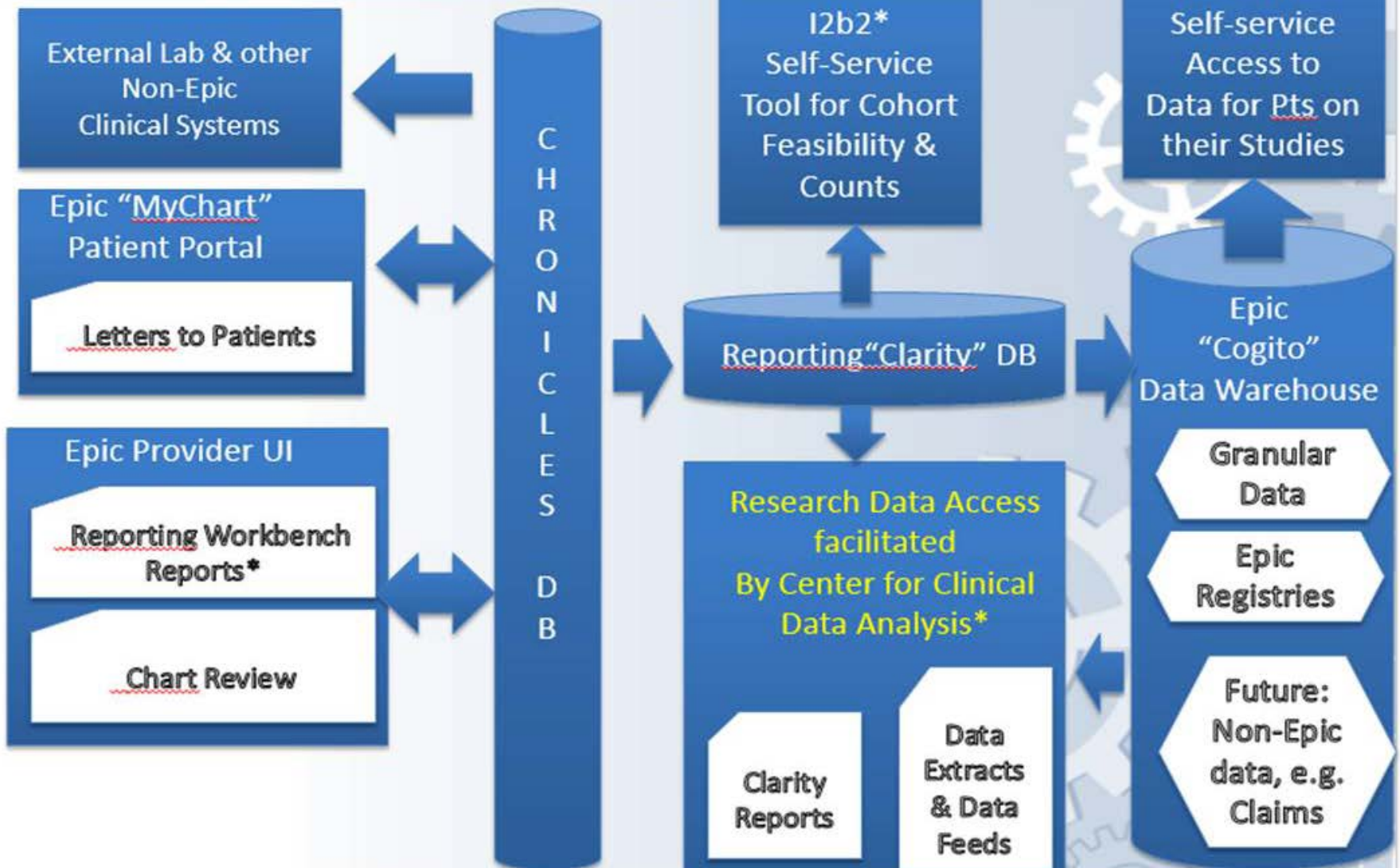Darren Lacey

Key Functions:
- Policy solutions for privacy and security, including:
  - Data access and use
  - Data and system security
  - Data auditing
- Prioritization of major projects
- Support and assistance to other sub-councils
- Funding mechanism

Research Data Trust Sub Council Members

- Theodore Abraham, *Associate Professor, Cardiology*
- Susan Bassett, *Associate Professor, Psychiatry and Behavioral Sciences*
- Kit Carson, *Sr. Research Associate*
- Chris Chute, *Chief Health Research Information Officer*
- Toby Cornish, *Assistant Professor, Medicine*
- Michael Crocetti, *Assistant Professor, Pediatrics*
- Neil Goldenberg, *Associate Professor, Pediatrics*
- Linda Dunbar, *VP, Population Health & Care Management*
- Peter Greene, *CMIO, Johns Hopkins Medicine*
- Diana Gumas, *Senior Director for Clinical Research Informatics*
- Joe Herman, *Associate Professor, Radiology & Oncology*

- Noreen Hynes, *Associate Professor, Infectious Diseases*
- Hadi H. K. Kharrazi, *Assistant Director, Center for Population Health Information Technology (CPHIT)*
- Harold Lehmann, *Professor, Health Sciences Informatics*
- Scott Levin, *Associate Professor, Emergency Medicine*
- Liz Martinez, *Sr. Research Nurse, Institute for Clinical and Translational Research*
- Joan Pettit, *Director, Institutional Review Board*
- Jim Potter, *Assistant Professor*
- Dave Thiemann, *Associate Professor, Cardiology*
- Sarah Wheelan, *Assistant*
- *Professor, Oncology-Bioinformatics*

Deep Dive into Types of Data in Epic

What data is available to researchers?

The CCDA primarily extracts data from large institutional data sources such as:

- Epic
  - John Hopkins Hospital ambulatory data since April 2013
  - Johns Hopkins Bayview ambulatory data since April 2013
  - Johns Hopkins Community Physician data since April 2013
  - Two community hospitals starting Fall 2013
  - Another community hospital starting 2014
  - Some lab data for JHH & JHBMC back to 2004

- Sunrise POE (the JHH inpatient EMR)
- EPR2020 (JHH outpatient EMR pre-Epic)
- CaseMix/Datamart – diagnosis data

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Overview of the Award

- Provide research teams focusing on behavioral, systems, or social sciences questions with access to clinical data housed in various institutional databases

- Preference will be given to applications that effectively show how the data mined using Nexus funds will be useful not only to the applicant, but to other Behavioral, Social and Systems Science researchers, or the larger Johns Hopkins research community

- Applications will be scored based on the merit of the data request, and the described data uses

- Awards should go to high impact, low cost projects.

Who May Apply?

- Eligible submissions may seek data for career development grant applications

- Investigators working on larger center-based studies are encouraged to apply

- Cross-departmental collaboration is encouraged

- No preference will be given to external collaborations, although they are acceptable.

- Any faculty member at JHU is eligible; Undergraduates, graduate students, and postdoctoral fellows are not eligible to apply as Principal or Co-Investigators for pilot grants, but can be incorporated as team members into any proposal

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Examples of Potential Projects

- Data requests for creating disease or other types of patient registries

- Patient lists for recruiting

- Case findings for chart review

- Preliminary, anonymous data for feasibility, grant applications and statistical sample-size estimates

*IRB-approval is required to obtain case-finding data to be used for study enrollment (mailings, phone solicitation, etc.), chart review, and cohort/case-control studies.

*Large integrated research data extracts from multiple institutional systems can be done one-time, weekly, monthly, or quarterly.

Required Application Materials

As well as the information provided on the **web-based form,** supplemental materials required to be submitted via the online application include:

- —5 page research plan containing specific aims; brief description/background; Explain how the data set will help address problem/research question.

- —4 page biosketch for PI & Co-PI(s)

- —Short paragraph describing role each study team member; or submit biosketches for study team members (no CVs)

- —If applicable, a document listing other funding sources used to cover costs associated with project; *Budgets may be submitted in Microsoft Excel format. NO FORMAL BUDGET IS REQUIRED.

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Approvals and Agreements

- Teams should submit institutional regulatory approvals when the Nexus Award application is submitted:
  - — IRB approval is required for anything other than counts or preliminary anonymous data
  - — A signed Data Trust "Use of Data" Agreement is required; Details to be discussed with Diana Gumas further into the application process
  - — For data from Johns Hopkins Community Physicians (JHCP), letter of approval from the JHCP Research and Projects Committee (RPC) required; Details pertaining to this will be discussed with second round potential awardees with Diana Gumas
- In order to share data outside of Johns Hopkins, it must be approved by Data Trust Research Sub-council, and Data Trust "Data Use" Agreement must be signed; Details to be discussed with Diana Gumas further into the application process

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Selection Process:

- Web-based applications will first be vetted for a scientific review by BSSS researchers

- Applications receiving top scores will be passed on to the CCDA. Potential awardees will be contacted by Diana Gumas, to schedule a consultation meeting, to obtain further information to better understand the data request, project feasibility and cost

- Diana Gumas and TRC Co-Leaders will meet to make final decisions

- Award letters to be circulated end of January, explaining the terms of the award; Decline letters will contain little feedback

- Project start-up to be done in February

- Tentative start date: March 1, 2016

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Award Period:

- After award letters have been issued, a month-long start-up period will begin in February. During this time, the CCDA will work with the investigator to refine project specifications. Once specifications have been agreed upon, the CCDA will be able to provide the study team with an approximate date when software development can begin. Once software development is completed, the CCDA will perform internal quality checks of the software. Then, the data will be securely delivered to the study team for their review and acceptance testing. Any errors should be reported to the CCDA to be fixed. Lastly, the final data set will be delivered to the research team.

- Projects should be completed within twelve months from the project start date as dictated by award letter

Special Considerations

The CCDA does not provide data management services (e.g. data analysis, database creation, data archiving etc.)

You may find information about these types of services and resources by contacting:

- The Johns Hopkins University Data Management Services (data management planning, data preservation and sharing)

- The ICTR Clinical Research Informatics Core (Clinical Research Management System)

- The Johns Hopkins Biostatistics Center (study design, data interpretation, statistical analysis, and reporting)

Questions? Contact:

- **Felicia Hill-Briggs (fbriggs3@jhmi.edu)**
- **Jill Marsteller (jmarste2@jhu.edu)**
- **Diana Gumas (dgumas1@jhmi.edu)**