BOARD OF REGENTS
UNIVERSITY OF MINNESOTA

Special Committee on Academic Medicine

May 2015

May 7, 2015

7:30 a.m. - 9:00 a.m.

West Committee Room, McNamara Alumni Center

CAM - MAY 2015

BOARD OF REGENTS
DOCKET ITEM SUMMARY

Special Committee on Academic Medicine **May 7, 2015**

Agenda Item: Medical School Strategic Plan: Progress Report

☐ **Review** ☐ **Review + Action** ☐ **Action** ☒ **Discussion**

☐ *This is a report required by Board policy.*

Presenter: Brooks Jackson, Dean of the Medical School and Vice President for Health Sciences

Purpose & Key Points

The Medical School's Strategic Vision for 2025 was developed by Medical School faculty in 2013 and delivered to President Kaler in July 2013. It has served as the basis of Dr. Jackson's and the Medical School's work in developing and sustaining a world-class medical school and academic health system that ranks in the top decile nationally. The work focuses on building a culture of excellence across the three missions of research, education and clinical care.

The presentation will share a progress report and related metrics on the Medical School's efforts to enhance:

1. Scholarship
2. Research
3. Education
4. Clinical care
5. Financial sustainability
6. Diversity

Background Information

The committee reviewed the Medical School's Strategic Plan and its implementation and metrics at its October 2014 meeting.

Medical School Strategic Plan: Progress Report

Brooks Jackson, M.D., M.B.A.
Dean of the Medical School
Vice President for Health Sciences

Special Committee on Academic Medicine
May 7, 2015

Medical School Strategic Plan

- Developing and sustaining a world-class Medical School and an academic health system in top decile nationally
- Building a culture of excellence in research, education and clinical care
- Goals and metrics in six areas:
  - Scholarship
  - Research
  - Education
  - Clinical Care
  - Financial Sustainability
  - Diversity

Goal 1: Enhancing Scholarship

Impact is far reaching:

- National reputation
- Attracting top students
- Retaining and recruiting top faculty
- Securing NIH and other funding
- Basis for national awards and leadership positions

Scholarship: Raising the Bar

- Increase percentage of faculty who publish annually in peer reviewed publications
- Set clear expectations for scholarship
  - Tenure track
  - Non tenure track
- One first/last author published paper a year is a baseline
- Align incentives for faculty and department chairs around scholarship
- New portal for tracking scholarship

Medical School Faculty Publications CY 2014

Clinical Science Dept	Total Faculty	Total # of Faculty Published	(%)	First/Last Author	(%)
Anesthesiology	33	8	(24%)	6	(18%)
Dermatology	13	10	(77%)	7	(54%)
Emergency Med	2	1	(50%)	0	(0%)
Family Med – Duluth	10	2	(20%)	2	(20%)
Family Med - TC	93	42	(45%)	31	(33%)
Lab Med & Pathology	61	45	(74%)	32	(53%)
Medicine	265	214	(81%)	115	(43%)
Neurology	34	25	(74%)	12	(35%)
Neurosurgery	9	7	(78%)	6	(67%)
Ob-Gyn	27	10	(37%)	7	(26%)
Ophthalmology	23	15	(65%)	7	(30%)
Orthopaedic Surgery	35	25	(71%)	21	(60%)
Otolaryngology	18	12	(67%)	11	(61%)
Pediatrics	155	104	(67%)	69	(45%)
Physical Med & Rehab	27	13	(48%)	8	(30%)
Psychiatry	56	33	(59%)	26	(46%)
Radiation Oncology	15	15	(100%)	8	(53%)
Radiology	67	39	(59%)	19	(28%)
Surgery	65	39	(60%)	27	(42%)
Urology	18	11	(61%)	7	(39%)
TOTAL:	**1026**	**670**	**(65%)**	**421**	**(41%)**

Basic Science Dept	Total Faculty	Total # of Faculty Published	(%)	First/Last Author	(%)
Behavioral Health & Population Sci – Duluth	7	5	(71%)	5	(71%)
Biomedical Sci - Duluth	24	12	(50%)	10	(42%)
Biochem, Molec Biol, & Biophysics	20	10	(50%)	9	(45%)
Genetics, Cell Biol & Dev	25	20	(80%)	14	(56%)
Integrative Biol & Physiology	15	9	(60%)	7	(44%)
Microbiology	17	11	(65%)	6	(35%)
Neuroscience	31	21	(68%)	17	(55%)
Pharmacology	19	17	(89%)	11	(58%)
TOTAL:	**158**	**105**	**(66%)**	**79**	**(50%)**
Medical School Total	**1184**	**775**	**(65%)**	**500**	**(42%)**

Wall of Scholarship

- Phillips-Wangensteen Building 2nd Floor
- First or last author papers with 1000+ Citations
- 25 current faculty members represented

Goal 2: Enhancing Research
NIH Rankings 2014

Rank	Name	School of Medicine
1	UNIVERSITY OF CALIFORNIA, SAN FRANCISCO	$480,483,692
2	JOHNS HOPKINS UNIVERSITY	$428,953,771
3	UNIVERSITY OF PENNSYLVANIA	$410,231,644
4	WASHINGTON UNIVERSITY	$353,931,278
5	STANFORD UNIVERSITY	$348,960,661
6	YALE UNIVERSITY	$328,073,531
7	UNIVERSITY OF PITTSBURGH AT PITTSBURGH	$317,319,224
8	UNIVERSITY OF WASHINGTON	$301,997,394
9	UNIVERSITY OF CALIFORNIA SAN DIEGO	$295,372,126
10	VANDERBILT UNIVERSITY	$293,981,233
11	DUKE UNIVERSITY	$293,221,537
12	UNIVERSITY OF MICHIGAN	$282,337,836
13	UNIV OF NORTH CAROLINA CHAPEL HILL	$267,415,566
14	UNIVERSITY OF CALIFORNIA LOS ANGELES	$265,253,297
15	COLUMBIA UNIVERSITY HEALTH SCIENCES	$252,609,169
16	NEW YORK UNIVERSITY SCHOOL OF MEDICINE	$245,023,387
17	ICAHN SCHOOL OF MEDICINE AT MOUNT SINAI	$234,933,311
18	EMORY UNIVERSITY	$224,254,440
19	MAYO CLINIC ROCHESTER	$205,330,761
20	BAYLOR COLLEGE OF MEDICINE	$191,407,545
21	HARVARD MEDICAL SCHOOL	$186,473,965
22	NORTHWESTERN UNIVERSITY AT CHICAGO	$179,322,644
23	OREGON HEALTH & SCIENCE UNIVERSITY	$171,821,248
24	UNIVERSITY OF COLORADO DENVER	$167,326,343
25	ALBERT EINSTEIN COLLEGE OF MEDICINE	$156,694,942
26	UNIVERSITY OF ALABAMA AT BIRMINGHAM	$156,324,620
27	UNIVERSITY OF WISCONSIN-MADISON	$156,223,268
28	UNIVERSITY OF CHICAGO	$155,633,475
29	UT SOUTHWESTERN MEDICAL CENTER	$155,430,778
30	**UNIVERSITY OF MINNESOTA**	**$144,859,250**
31	CASE WESTERN RESERVE UNIVERSITY	$142,104,883
32	UNIVERSITY OF CALIFORNIA AT DAVIS	$127,222,806

Source: Blue Ridge Institute for Medical Research, 2014

NIH Funded Research Awards
Rankings by Department

Rank	Department	Funding
3	Family Medicine	$ 3,966,283
8	Pediatrics	$26,434,062
12	Pathology	$11,954,531
13	Neurology	$11,257,545
13	Physical Medicine	$911,733
14	Radiology	$7,449,406
14	Surgery	$6,791,073
16	Biochemistry	$9,103,727
17	Neurosciences	$6,581,251
23	Otolaryngology	$876,160
26	Genetics	$5,909,164
26	Psychiatry	$9,173,660
30	Emergency Medicine	$301,328

Rank	Department	Funding
30	Pharmacology	$5,363,541
32	Dermatology	$364,002
36	Internal Medicine	$29,115,469
41	Orthopedics	$137,727
45	Microbiology	$4,651,460
54	Ophthalmology	$874,245
NA	Physiology	$2,461,161
NA	Duluth Campus	$596,068
NA	Miscellaneous	$736,725
NA	Anesthesiology	$0
NA	Neurosurgery	$0
NA	Obstetrics and Gynecology	$0
NA	Urology	$0

Awards October 1, 2013 – September 30, 2014
Source: Blue Ridge Institute for Medical Research, 2014

Medical School FY 2015 Grant Applications Through March 31, 2015

	Number of Applications	Number of Faculty Submitting*	% of Faculty Submitting*
All New Grant Applications	994	506	45%
New Federal Grant Applications	407	283	25%
New NIH Grant Applications	357	264	23%

* Out of 1137 Faculty

Building Critical Research Infrastructure

Clinical and Translational Science Institute: One of 60 NIH funded centers

- Development of a comprehensive clinical data warehouse for research:
  - Housing Fairview and UM Physicians clinical data
- Development of health informatics tools and services
- Expansion of bio specimen repository
- Project development teams to support early stage translational research
  - 39 Medical School investigators supported since program began in 2012
- Training of early career clinical/translational researchers:
  - 12 Medical School faculty currently in program
  - 18 senior Medical School faculty currently serving as mentors
- Development of AHC-wide clinical trial management system
- Provision of clinical trial services for faculty:
  - 4336 patients enrolled in clinical trials by Medical faculty (CY 2014)
  - 1076 patients in first quarter of CY 2015

Goal 3: Enhancing Education

- Redesigning the Curriculum
  - Greater focus on educational outcomes
  - Greater emphasis on student research and scholarship
  - Incorporating interprofessional education into the curriculum
  - Piloting new courses and clerkships:
    - Nine-month integrated clerkship at VA focused on interprofessional teamwork, quality improvement, and the medical home model
    - EPAC - Education in Pediatrics Across the Continuum
      - Testing the feasibility of medical education and training based on outcomes rather than on time, beginning early in Medical School and running through completion of residency

Enhancing Education: Innovation

- Developing a 7 year BS-MD program in Twin Cities:
  - Reduced timeline and debt load while also increasing pipeline with focus on diversity.

- Strengthening the MD/Ph.D. Program:
  - Developing plans for continuous career advising and mentoring of MD/PhD students
  - MD/PhD program received “Outstanding” evaluation from NIH site visit. Panel recommended an increase in training grant slots during the next 5 year funding cycle.

Education: Recruiting the Best Students

Application/Acceptance Ratio

	2014	2013
• Twin Cities Campus		
– Applications (secondary):	2,308	2,133
– Acceptance Rate:	11.74%	12.75%
• Duluth		
– Applications (secondary):	781	833
– Acceptance Rate:	12.55%	9.96%
• MD/PhD		
– Applications (secondary):	263	213
– Acceptance Rate:	8.75%	16.43%

Education: Progress on Tuition and Student Debt

- Currently ranked 18th highest tuition among public Medical Schools ($34,716/year)
- Froze tuition and fees in FY 2015. Plan to continue freeze in FY 2016
- Changes in recruitment scholarships
  - Awarded over four years vs. one year
  - Smaller awards consolidated into larger awards
  - Two full tuition scholarships awarded

Goal 4: Enhancing Clinical Care

- Strength of clinical enterprise is vital to:
  - Research
  - Education
  - National reputation
  - Bringing the best care to all Minnesotans

University of Minnesota Health

- University of Minnesota Health's Strategic Plan
  - Earn provider-of-choice status
  - Advance reputation as a breakthrough treatment destination for clinical care, research and education by investing in programs of distinction
  - Continuously innovate and optimize patient care models
  - Generate margins to continually reinvest in clinical, education and research needs

University of Minnesota Health

Enhancing the Patient Experience

- Working toward top-decile performance by 2017
  - Physician communication/coordination of care
  - Nursing/pharmacy communication
  - Improved access
  - Improved patient satisfaction
  - Affordability of care
- Outcomes
  - Achieve ANCC Magnet status by 2018
  - Improved mortality observed/expected ratio
  - Improve 30-day readmission rates
- 2014 US News Hospital Ranking: University of Minnesota Medical Center ranked 4th in Minnesota

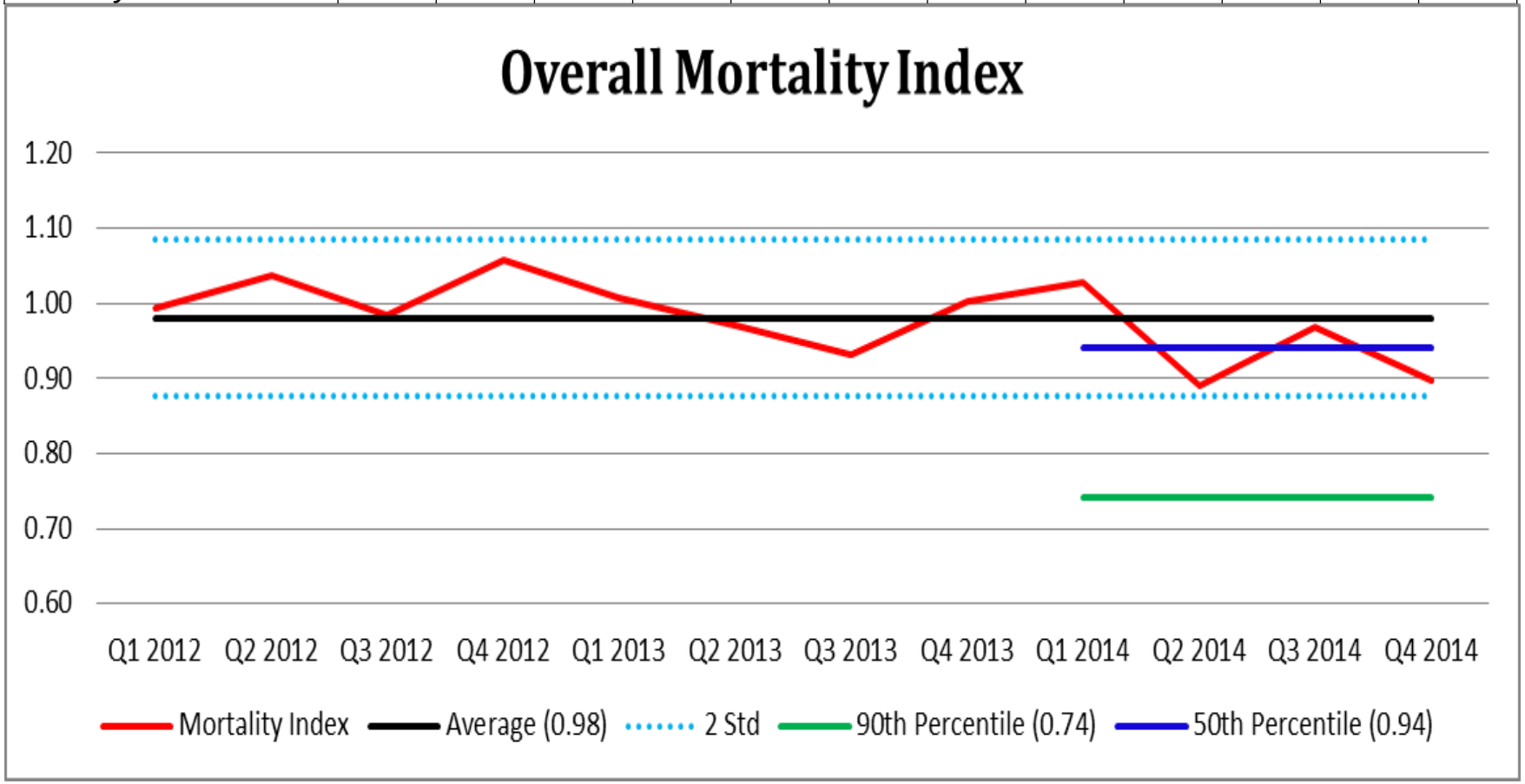
University of Minnesota Health Clinical Metrics

- M Health Strategic Plan focuses efforts to become a top decile academic medical center.
- Goals for each metric have been set at:*
  - 2015: median performance
  - 2016: 75th percentile performance
  - 2017: 90th percentile performance
- Additional patient satisfaction and safety metrics are regularly measured, such as:
  - Outpatient Patient Satisfaction metrics
  - Reportable events, hospital acquired infections, etc.

**Compared to benchmark, which includes similar academic medical centers across the country*

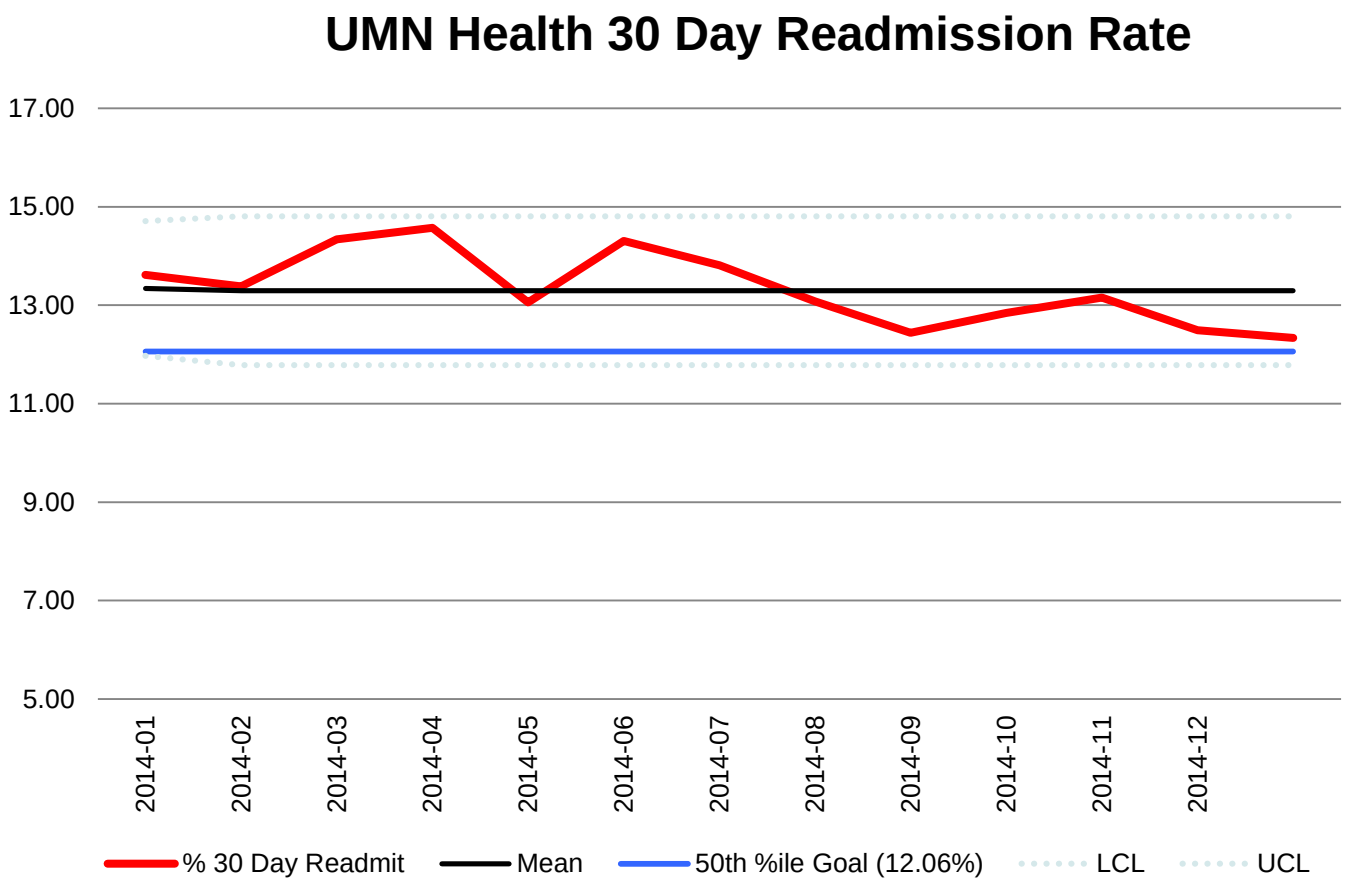
Mortality

	Q1 2012	Q2 2012	Q3 2012	Q4 2012	Q1 2013	Q2 2013	Q3 2013	Q4 2013	Q1 2014	Q2 2014	Q3 2014	Q4 2014
Mortality Index	0.99	1.04	0.99	1.06	1.01	0.97	0.93	1.00	1.03	0.89	0.97	0.90



Readmissions

2014-01	2014-02	2014-03	2014-04	2014-05	2014-06	2014-07	2014-08	2014-09	2014-10	2014-11	2014-12
13.62	13.39	14.34	14.57	13.05	14.31	13.81	13.08	12.44	12.85	13.16	12.49



- Early win, reducing readmissions for five data points to 3-year low

Patient Satisfaction Indicator: MD and Nurse Communication

MD Communication	Q4 2013	Q1 2014	Q2 2014	Q3 2014	Q4 2014	Goal
Adult (IP)	77.20%	79.90%	77.80%	77.60%	78.50%	79.90%
Peds (IP)	74.35%	79.84%	78.78%	70.23%	78.33%	81.06%
Nurse Communication	**Q4 2013**	**Q1 2014**	**Q2 2014**	**Q3 2014**	**Q4 2014**	**Goal**
Adult (IP)	72.10%	75.10%	77.70%	75.90%	76.90%	78.10%
Peds (IP)	80.33%	80.94%	77.32%	75.62%	78.25%	80.42%

IP = In Patient

Patient Satisfaction
Inpatient and Outpatient

	Q4 2013	Q1 2014	Q2 2014	Q3 2014	Q4 2014	Goal
Overall Rating of Hopsital (Adult IP)	61.20%	65.80%	69.30%	68.90%	66.80%	70.30%
Overall Rating of Hospital (Peds IP)	86.20%	81.20%	77.90%	68.40%	78.50%	78.90%
Outpatient Clinic Satisfaction (Would You Recommend this Clinic?)	90.00%	89.00%	90.00%	90.00%	n/a	87.00%
Outpatient - MD Communication Domain	91.00%	91.00%	91.00%	91.00%	n/a	87.00%

Goal 5: Financial Sustainability

Net Operating Income

Fiscal Year	Med School (in 000s)	UMP (in 000s)	Combined (in 000s)
2011	39,120	2,287	41,407
2012	46,414	4,278	50,692
2013	37,788	11,197	48,985
2014	7,905	21,761	29,666
Budget 2015	(1,622)	5,621	3,999
Forecast 2015	12,937	9,365	22,302

(February 2015)

Financial Sustainability: Philanthropy

- University of Minnesota Foundation Gifts:
  - FY 2012 $ 41.6 million
  - FY 2013 $ 58.1 million
  - FY 2014 $ 55.1 million
  - FY 2015 $ 36.2 million (through March 31, 2015)

- Additional Philanthropy
  - Minnesota Masonic Charities - $25 million for the Children's Hospital
  - Lifetime support from Masonic Charities is now more than $125 million

Goal 6: Enhancing Student Diversity

- Record number of diverse students chose the University of Minnesota Medical School this year

Twin Cities Campus	2014	2013	2012	2011	2010
Multicultural	53	41	41	35	38
Percentage of Class	31%	24%	24%	21%	22%
Underrepresented In Medicine (UIM)	32	18	15	16	14
Percentage of Class	19%	11%	9%	9%	8%
Duluth Campus	**2014**	**2013**	**2012**	**2011**	**2010**
Multicultural	5	6	8	3	7
Percentage of Class	8%	10%	13%	5%	12%
Underrepresented In Medicine (UIM)	5	5	8	3	7
Percentage of Class	8%	8%	13%	5%	12%

- Long-term goal is to train physician leaders who reflect the diversity of our state

Goal 6: Enhancing Faculty Diversity

	Male	Female	Total Faculty
October 2013	63%	37%	1047
March 2014	61%	39%	1031
March 2015	61%	39%	1083

Gender

	American Indian/ Alaska Native	Asian	Black/ African American	Hispanic/ Latino	Native Hawaiian/ Pacific Islander	Not Specified
October 2013	< 1%	17.0%	< 2%	< 2%	< 1%	< 1%
March 2014	.5%	16.6%	1.4%	2.4%	.1%	1.0%
March 2015	.6%	16.0%	1.4%	2.3%	.1%	1.3%

Ethnicity

December 2014	Male	Female	White	Minority	Unspecified
Professor	77%	23%	85%	15%	0%
Associate Professor	68%	32%	80%	20%	0%
Assistant Professor	48%	52%	75%	23%	2%
Instructor	52%	48%	78%	22%	0%

By Faculty Rank

BOARD OF REGENTS
DOCKET ITEM SUMMARY

Special Committee on Academic Medicine **May 7, 2015**

Agenda Item: Clinical and Translational Health Research at the University

☐ **Review** ☐ **Review + Action** ☐ **Action** ☒ **Discussion**

☐ *This is a report required by Board policy.*

Presenter: Bruce Blazar, Associate Vice President for Clinical and Translational Science and Director of the University's Clinical Translational Science Institute (CTSI)

Purpose & Key Points

The presentation will provide an overview of clinical and translational health research at the University of Minnesota's Academic Health Center, covering the following topics:

- Definition and scope of clinical and translational research
- Purpose and status of NIH Clinical and Translational Science Award (CTSA)
- Programs of University of Minnesota's Clinical and Translational Science Institute (CTSI)
- Representative case studies
- Opportunities and challenges

Background Information

In June 2011, as part of the Clinical and Translational Science Awards (CTSAs) program, the National Institutes of Health awarded the University of Minnesota $51 million over five years. With this award, the University joined a network of 61 CTSA institutions to translate and accelerate scientific discoveries into treatments for patients and improved human health, engaging communities in research, and training a new generation of clinical and translational researchers.

Clinical Translational Research
Bruce Blazar

Board of Regents
Special Committee on Academic Medicine
May 7, 2015

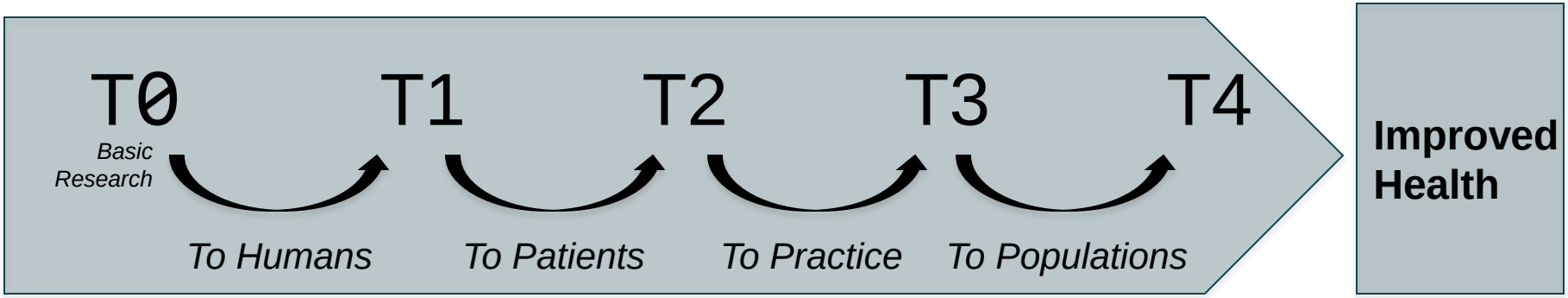
UNIVERSITY OF MINNESOTA

Clinical and Translational Science Institute

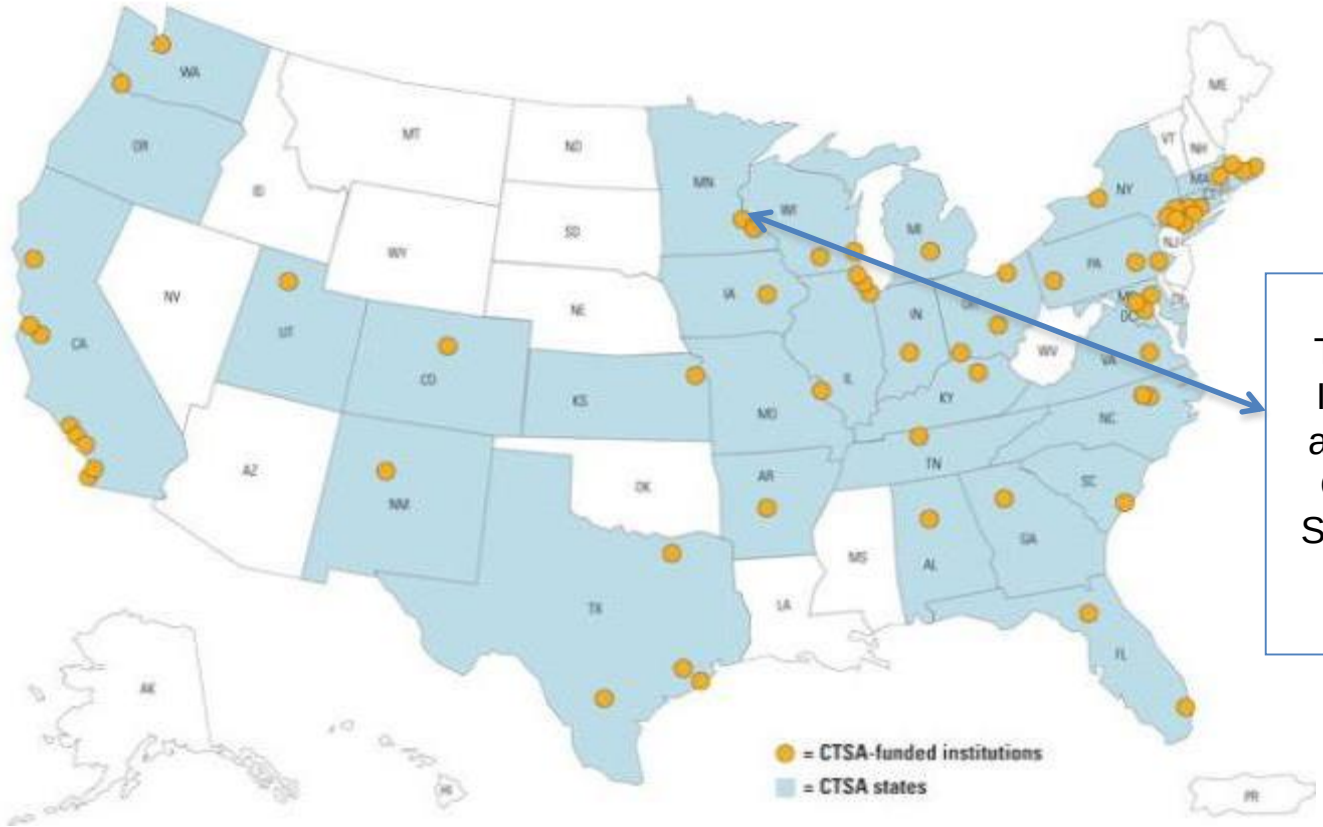
Driven to Discover℠

The Spectrum of Translational Research

- **Early-stage research**
- **Clinical research**
- **Community-engaged research**



UMN Clinical Translational Science Institute (CTSI) is working with 61 other CTSAs to increase the efficiency and speed of clinical and translational research



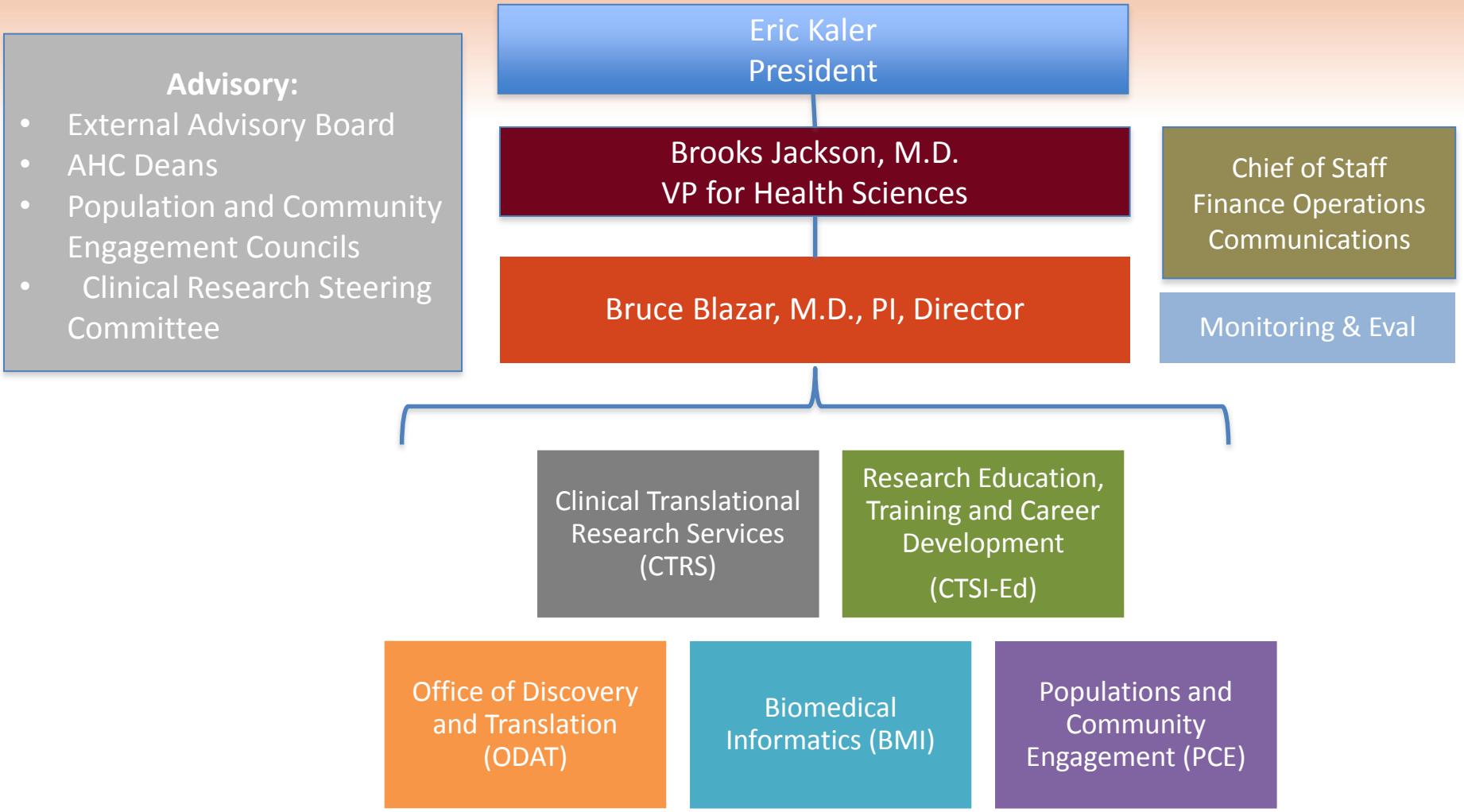
The Clinical and Translational Science Institute (CTSI) is the academic home of the Clinical Translational Science Award (CTSA) at the University of Minnesota

Vision for Clinical Translational Science Institute (CTSI)

- A world-class integrated clinical research enterprise, advancing health at the forefront of discovery

CTSI Goals:

- Provide **quality infrastructure –** standardize processes, services, and tools for efficiency, effectiveness and consistency
- Strengthen faculty **mentoring** programs
- Foster and support **team science**
- **Speed translation** of research into clinical practice
- Expand clinical research throughout Fairview **system**, not just on this University campus


Advisory:
External Advisory Board
AHC Deans
Population and Community Engagement Councils
Clinical Research Steering Committee
Eric Kaler
President
Brooks Jackson, M.D.
VP for Health Sciences
Chief of Staff
Finance Operations
Communications
Bruce Blazar, M.D., PI, Director
Monitoring & Eval
Clinical Translational Research Services (CTRS)
Research Education, Training and Career Development
(CTSI-Ed)
Office of Discovery and Translation (ODAT)
Biomedical Informatics (BMI)
Populations and Community Engagement (PCE)

UMN Clinical Translational Science Award (CTSA) - $51.2M over Five Years

- 5th year of five-year award began March 1, 2015
- Annual UMN award has been $10.2M ($7.16M Direct plus $3.09 Indirect)
  - $8.89M for UL1 Clinical Research
  - $1.36M for KL2 Scholars
- Anticipate new RFA ~ August – Sept 2015
- Re-application anticipated ~ Oct – Jan 2016
- Revised NIH funding formula (2.5% of all UMN NIH awards) reduces annual award amount by $3.5 - 4.0M

Evolving approach of the NIH's National Center for Advancing Translational Science (NCATS)

OFFICE OF DISCOVERY AND TRANSLATION (ODAT)

Focus: New products & treatment approaches

Translational Grant Programs	**Identify and support basic research discoveries with translational potential**
Project Development Teams	**Provide expertise and project management to accelerate translation of research discoveries into patient benefit**
Pediatric Device Development Committee	**Identify, develop, and enhance commercial potential of novel pediatric devices**
Committee for Pharmaceutical Development	**Identify, develop, and enhance commercial potential of novel therapeutics**
Mayo Partnership Program	**Partnership with Mayo Clinic to advance potential commercialization projects**

Goal: ODAT awards

Support projects with the *primary goal* of developing new products and treatment approaches that will benefit patients.

Outcomes: ODAT awards

- Facilitated submission and review of nearly 300 applications
- Funded +65 projects and provided project team support to 44 projects
- Worked with 160 unique Project Development Team and development committee members
- Significantly expanded available project funding ($2.75M in new dollars) and expert pool through new partnership initiatives
- Projects supported through ODAT team programs continue to advance along the translational spectrum

Outcomes are from 2011-2015

Wells, S.M., Rebuffoni, J.F., LeBien, T.W. Novel Team-Based Approaches to Advance Academic Translational Research. *Clin Transl Sci.* 2014; 7(6): 427-429.

Accomplishment: Project advancement

- **43** projects receiving team support (since 2012)
  - **3 technologies have been licensed** with several others in process
  - **2 projects are preparing for initial clinical trials**
  - **5 ODAT team-supported technologies** (out of 44 total) have spun out into start-up companies
  - **+50% of the supported projects have advanced** at least one technology development stage

Example: Valerie Pierre, PhD, Associate Professor of Chemistry

•Siderophore aptasensors for immediate point-of-care diagnosis of urinary tract infection

•Received initial ODAT funding in 2012 – project milestones met

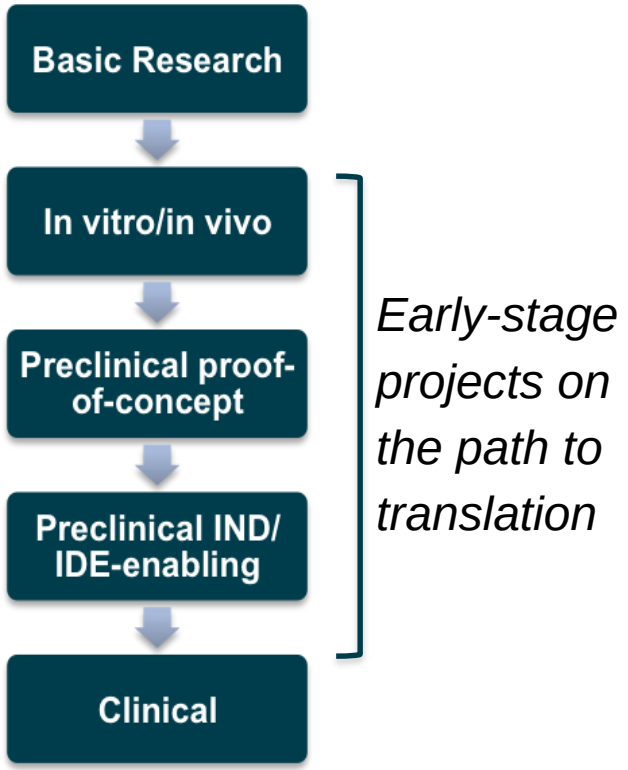
•Developed second generation technology – new IP

•Forming start-up company and submitted SBIR

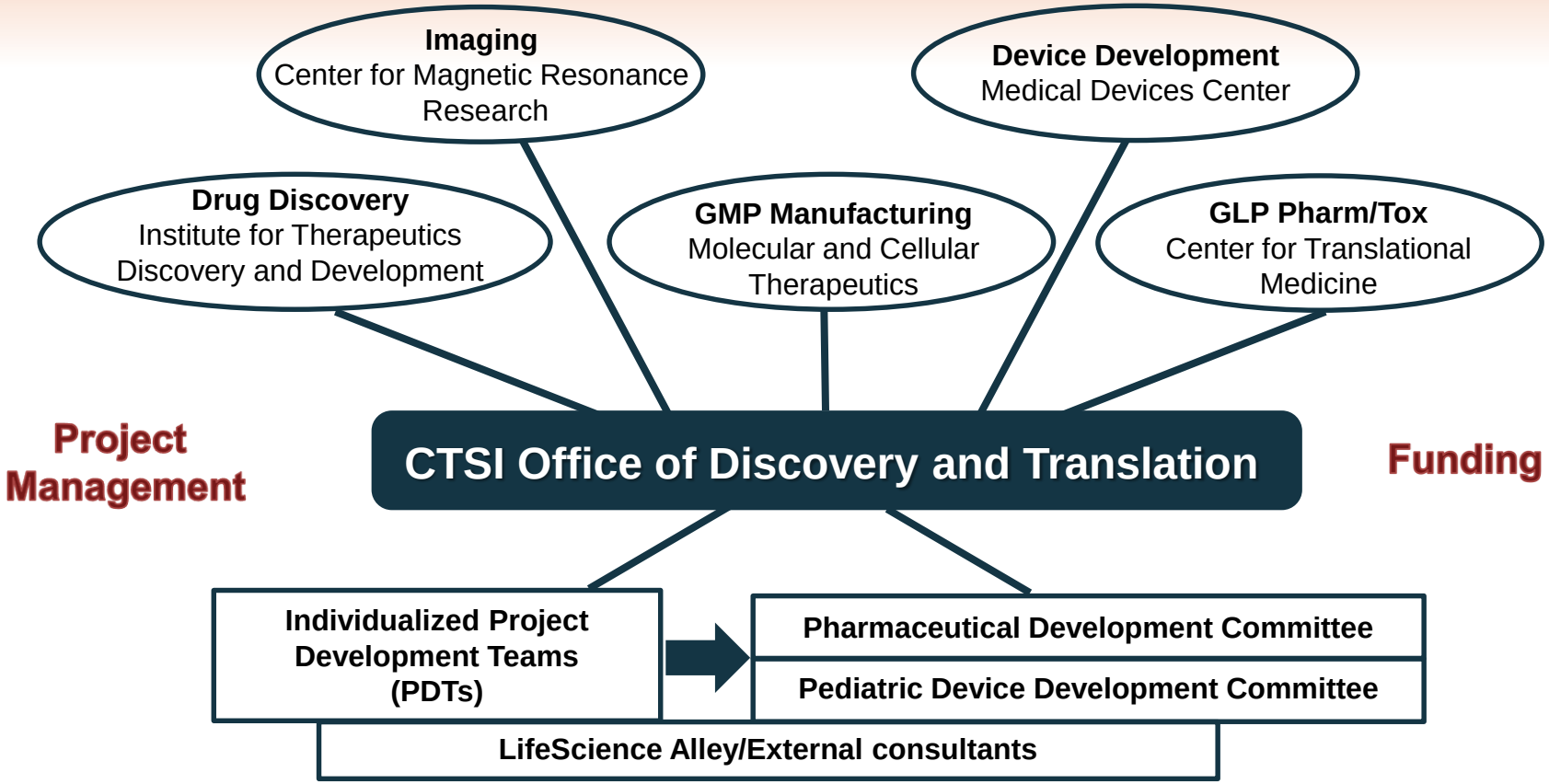
•Awarded funding through the CTSI/CCaTS new Mayo Partnership program for further development – partnership with Robin Patel, MD, at Mayo Clinic

ODAT builds project development teams to support projects in the early stages of translation

- **Offer specialized assistance to move discoveries into the next stage of translation**
  - Teams are created from a pool of 125+ experts
- **Approach has been leveraged nationally**
  - Inter-CTSA partnerships w/ UW-Madison & Mayo

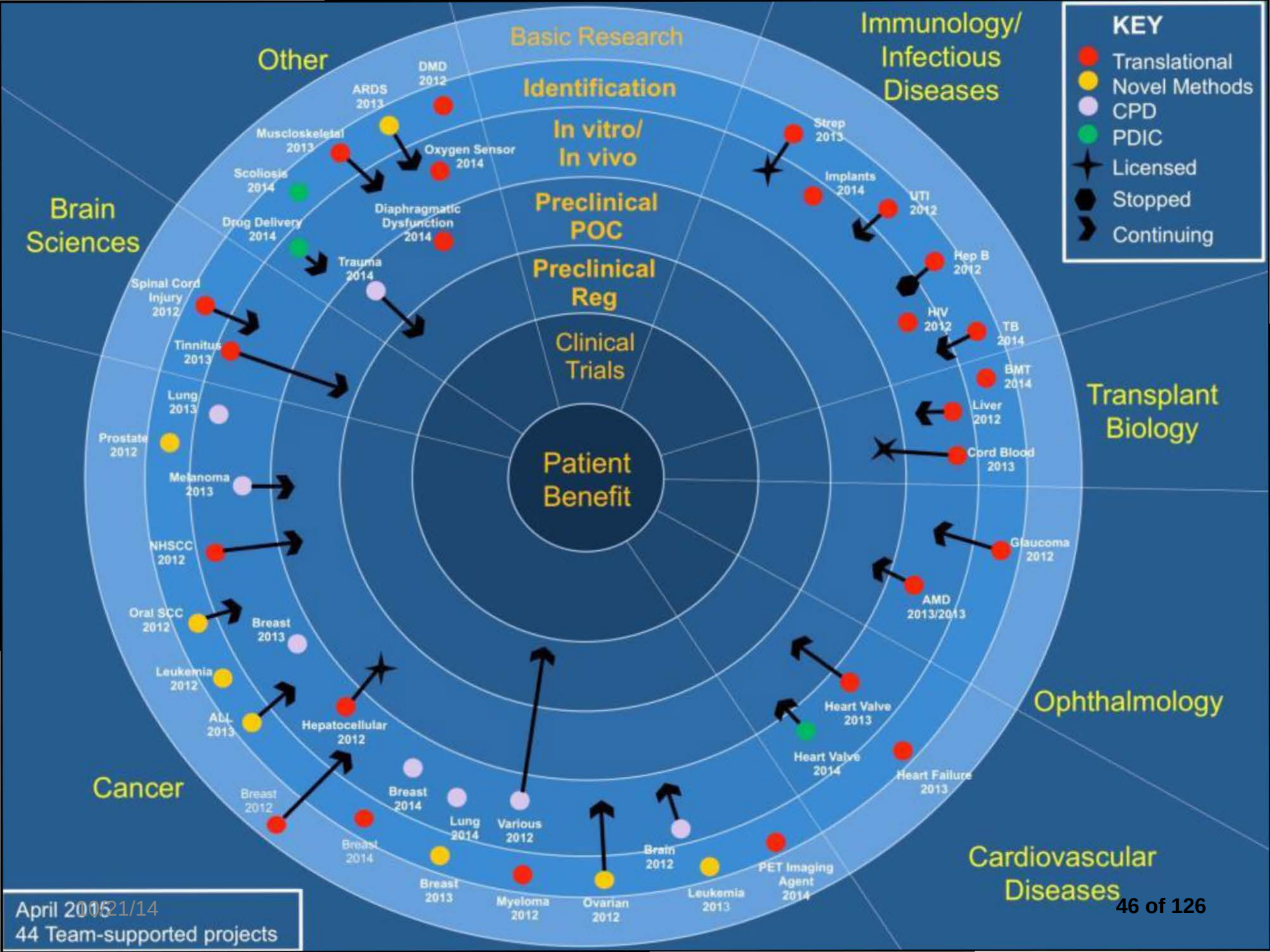


UMN Capabilities



Development-focused Teams and Expertise

Discovery | **Product definition** | **Preclinical Development** | Clinical



April 2006
44 Team-supported projects

CLINICAL TRANSLATIONAL RESEARCH SERVICES (CTRS)

Management, coordination, & regulatory support

- **Study management** (research project managers)
  - Protocol development
  - Grants, budgets, and contracts
  - Study closeout
- **Study coordination** (clinical research coordinators)
  - Protocol implementation
  - Participant visits
  - Administrative management
- **Regulatory support**
  - Project planning
  - Assist with IND and IDE application submissions
  - Clinical trial monitoring

Clinical research facilities and support staff

- **Facilities**
  - Three clinical research facilities and a processing laboratory
- **Clinical research support staff**
  - Clinical research coordinators, nurses, and clinical support staff
  - Support for patient care, study management and other study aspects
- **Procedures**
  - Glomerular filtration rate, glucose and body composition tests, IV/medication administration, blood draws, specimen processing, and more

CTSI operates the Delaware Clinical Research Unit, which features an exam room for children and free parking.

CTSI has one of the only iDXA machines in Minnesota.

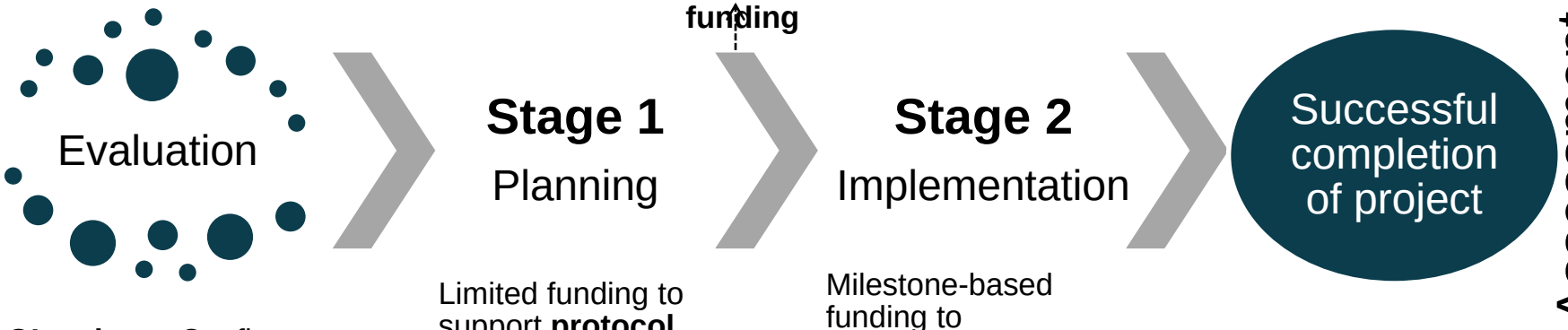
Clinical Translational Research Services (CTRS) pilot awards

2015 RFA:

22 LOIs received

12 invited to submit proposals

Project plans successfully completing Stage 1 are **eligible for Stage 2 funding**



LOI review – Confirm applicant eligibility and ensure project scope is appropriate.

Proposal review – Select projects based on overall strategy and probability of successful completion.

Limited funding to support **protocol development and study planning**

$2,500-$5,000 for 4-6 months

Milestone-based funding to **implement pilot study**

$25,000-$75,000 for 12-18 months

Research Project Manager

Feasibility Committee

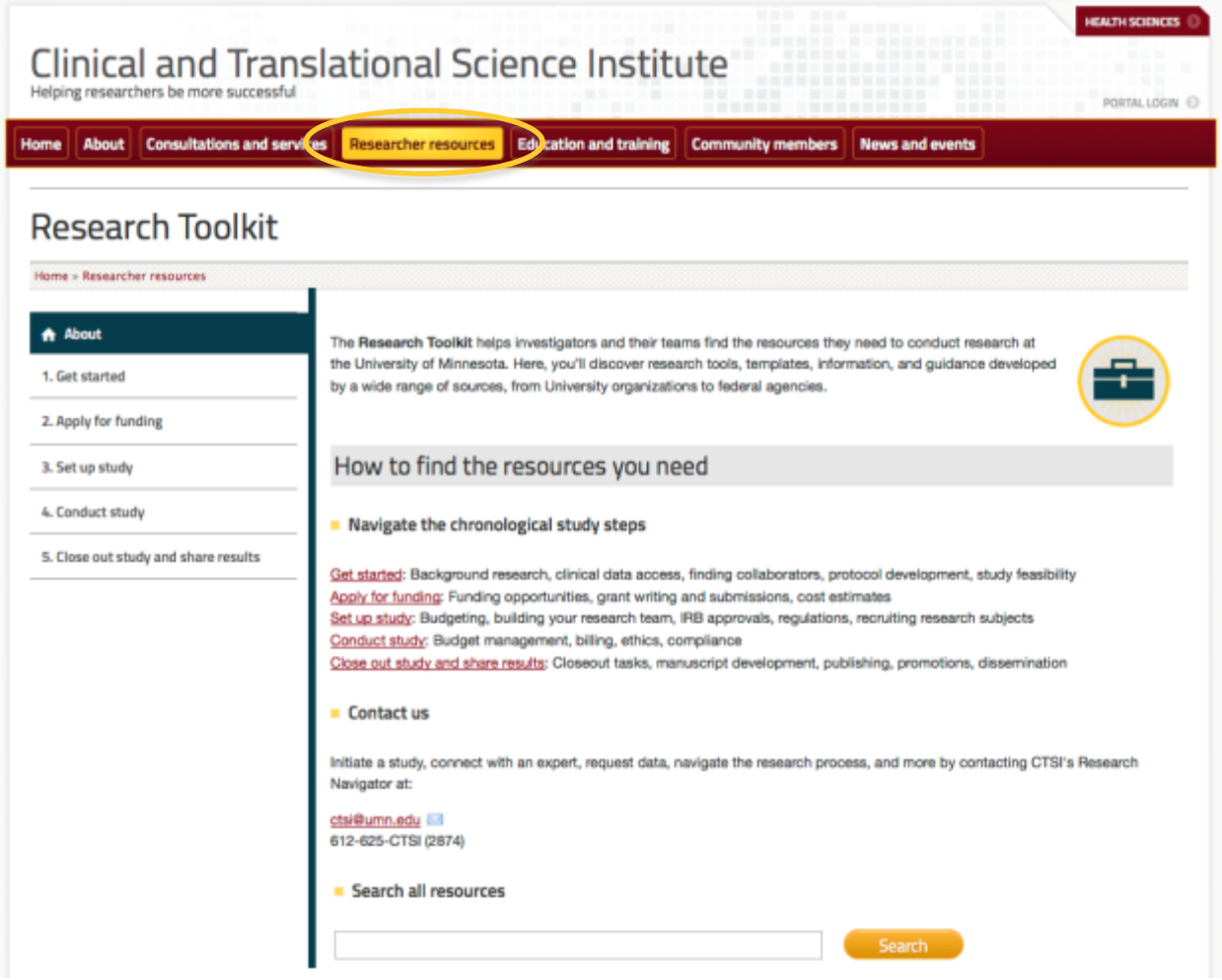
Recruitment build-out

- Built StudyFinder.umn.edu
  - A kiosk website which will help potential participants easily find and connect with U studies that need volunteers
- Pilot of kiosk at Minnesota State Fair and in Delaware Clinical Research Unit lobby
- Universal consent at IRB for review
  - Two parts:
    - Research registry consent
    - Bio-specimen registry consent
  - Consenting will occur during the patient registration process and be distributed throughout entire Fairview system
    - Believed to be the first time that Fairview will be offering a research consent to all of its patients

The Research Toolkit is a new online resource to support U of M research

Curated tools, information, and guidance for every step of the research process

- Applying for funding
- Setting up your study
- Conducting research
- Sharing results
- ...and much more



z.umn.edu/researchtoolkit

Bio-specimen program

Bio-specimen & Laboratory Services (BLS):

- Fairview Operating Room policy now requires CTSI oversight for procurement of research specimens
- Construction of the freezer farm (in process), which has the capacity for:
  - 8 large liquid nitrogen storage tanks (94,000 2cc vials each)
  - Up to 30 freezers (-80 degrees)
  - Licensed BioSpecimen Inventory (BSI) software, a product of Information Management Services, Inc.

A bio-specimen repository facilitates a clinic-wide system where every patient can be a research subject

- Goal of creating a personalized medicine infrastructure
- Link bio-specimen data to clinical trials in enterprise CTMS
- Link to genomic/proteomics data with bioinformatics support
- Link to electronic health records at our hospitals and clinics
- Store specimens off-site with a comprehensive inventory management system
- Pre-existing repositories, so investigators know what samples are potentially available on site

Biostatistics, design and analysis core (BDAC) expertise

- 9 AHC department contracts
  - Statisticians establish ongoing relationships with researchers, often leading to future grant proposals
- BDAC faculty mentored 20 funded scholars
  - Translational Research Development Program (TRDP), Pre-K, KL2, K to R01
- 4 projects with local healthcare system Hennepin County Medical Center (HCMC)
- 101 external & 53 internal grant submissions: funding rates of 40% and 48% respectively
- 89 publications with team members as co-authors
- Inter-CTSA grant proposal
  - Recommended for funding for a three-year R21 project that will allow the team to learn more about clinician stress from the electronic medical record and successful strategies for mitigating that stress
  - U of New Mexico, U of Colorado, Stanford, and HCMC (MN) collaboration

COMMUNITY ENGAGED RESEARCH AND POPULATION HEALTH

Mission and goals

Mission: Transform research relationships between UMN and community to ensure that clinical and translational science research is highly relevant to the health needs of communities.

Goals:

- **Integrate community engagement** across the spectrum of basic, clinical, and population research to ensure translation
- **Strengthen mutual trust and respect**
- **Promote engaged scholarship** in collaboration with community partners to:
  - Carry out research that matters to the community
  - Ensure reciprocal use of research knowledge and resources
  - Increase dissemination and implementation of research results

Goals: PCE award programs

Collaborative Grant awards

- Create solid and sustainable relationships between the community and university
- Incorporate community-based knowledge and expertise, and link these perspectives with the skills of researchers/evaluators
- Generate long-term research projects that will leverage additional funds
- Develop more efficient translation of evidence-based strategies

Dissemination awards

- Translate evidence-based research findings to specific audiences and communities in partnership with communities

Populations and Community Engagement

COMMUNITY IMPACT

Highlights include:

- A **Minnesota law** passed in 2014 helps care for pregnant, incarcerated women and their babies.
- A new **statewide policy** is screening new refugees for mental health issues.
- **Legislation** expanded home-based medication management services, which was previously limited.

NEW PARTNERSHIPS

90% of funded partnerships are new collaborations

UNIVERSITY IMPACT

19 peer-reviewed journal publications

98 presentations

45% of awards disseminated findings through peer-reviewed journal publications

75% of awards disseminated findings through presentations *(n=98; 64% local; 30% national; 6% international)*

Evolution: PCE award programs

- **New review process for Community Collaborative Grants increases community voice**
  - Two-step selection process: scientific review, then community panel reviews and decides on funding

- **New grant programs**
  - Driven to Discover Community Health Research Grants
  - Dissemination & Implementation Awards program
  - Child Health Collaborative Grant Award

Accomplishment: High-impact pilot awards

7:1 RETURN ON INVESTMENT

$792,304
PCE Collaborative Grant Funding (2010-2012)

$5,568,369
Resulting follow-on funding

COMMUNITY IMPACT

Partner-reported project results:

- **59%** Organizational policy changes
- **54%** Community organization funding
- **27%** Government policy changes

RESEARCH FOCUS

55% underserved populations

40% child health

18% hard to reach/rural populations

PARTNERSHIPS

Integrating community expertise: Community partners reported active engagement in design (71%), implementation (81%), and dissemination (83%).

Sustainable collaborations: 65% of community-University partnerships continue to collaborate.

Accomplishment: Engaging grad students

- **Providing evaluation assistance**
  - Teams of graduate students from a School of Public Health Evaluation Course responded to requests of 8 community organizations for evaluation assistance (2014-15)
    - Recruited 4 community organizations seeking evaluation assistance
    - Organizations served as sites for teams of 4-5 graduate students (total: 18 students)
- **Collaborating on writing projects**
  - Students collaborated with Westside Community Health Services' SoLaHmo (Somali/Latino/Hmong Partnership for Health) to co-write and submit a manuscript on an ethics training pilot.
    - Manuscript, "Ethical Issues in Community-Engaged Research: Human Subjects Research Training" was submitted to *Progress in Community Health Partnerships: Research, Education, and Action*.
- **Supporting community-University research collaborations**
  - Examples: Driven to Discover State Fair, Community Health Collaborative Pilot Grants, and Little Earth Health and Wellness Project/Wellness International/Stairstep Foundation

Accomplishment: Research at the State Fair

DRIVEN TO DISCOVER BUILDING

- **9,000** participants recruited for **29** studies over **12** days (2014)

6 CTSI-FUNDED INVESTIGATORS (2014)

- **100%** of projects recruited sufficient sample to complete projects
- **67%** exceeded recruitment targets

WHAT WE HEARD

"It is unlikely that families would have been willing to travel to the University to give two samples of bacteria from their hands and fill out a 5-10 minute survey [without this award]."

"Implementing our study at the State Fair provided easy access to many willing participants in a short period of time."

"We successfully recruited families and they provided thoughtful feedback that will help us address comments from NIH reviewers and strengthen our revised R01 grant application."

"The benefit of implementing research at the State Fair was really the time-saving aspect of recruiting bio-specimens from participants."

Accomplishment: Community capacity

The **Community Research Institute (CRI)**

- Six-week workshop trains community groups in research methodology, empowering them to be more involved in health research or conduct their own studies.
- Attracted 67 participants from 29 community organizations (2012-14)

RESULTING COMMUNITY RESEARCH

Since participating in the CRI one year ago:

9% have received funds for research

26% have worked on or completed a research project; examples include:

- Resiliency training for urban students and teachers
- Healthy eating and exercise (focus: minority children)
- Autism in Somali communities
- Hormone access for trans-identified individuals
- Annual community health survey

WHAT WE HEARD

"Our research project that we started through CRI has been instrumental in our most recent strategic planning process, as well as seeking and securing funding for projects and programs.

"Our project was to create an evaluation framework for our long term community health project. That still guides us."

"Our community is continuing to do research and implement strategies, programs and create partnerships."

Accomplishment: Rural health collaboration

- **14% of awards focus on rural issues**
- **Presence at 2015 MN Rural Health Conference,** which will reach +500 Minnesota clinicians, researchers, health systems representatives, and policy makers
  - "Engaging Communities in Collaborative Research to Improve Health in Rural Populations," breakout session featuring a collaborative between CTSI, Essentia Health, UMD Department of Biobehavioral Health & Population Sciences, and Stratis Health
  - "Collaborating for Improved Community Health: Health Providers and Researchers in Partnerships" interactive learning session moderated by CTSI's Dr. Sheila Riggs
  - Sponsored exhibit booth
- **Expanding collaboration with UMN-Duluth Medical School**
  - Partnering on Rural Health Conference
  - Increasing role with CTSI (e.g., pilot and State Fair grantees, proposal reviewers, steering committee members)

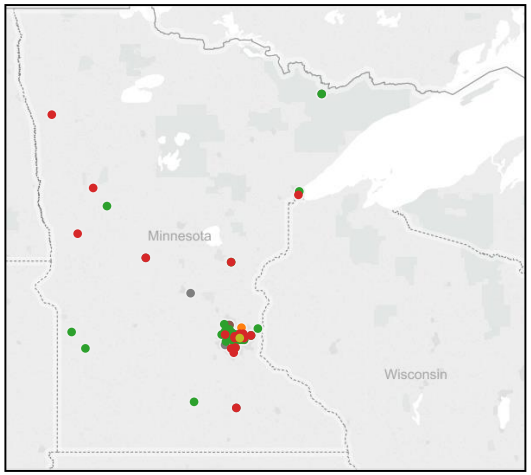


**Chart depicts mock data*

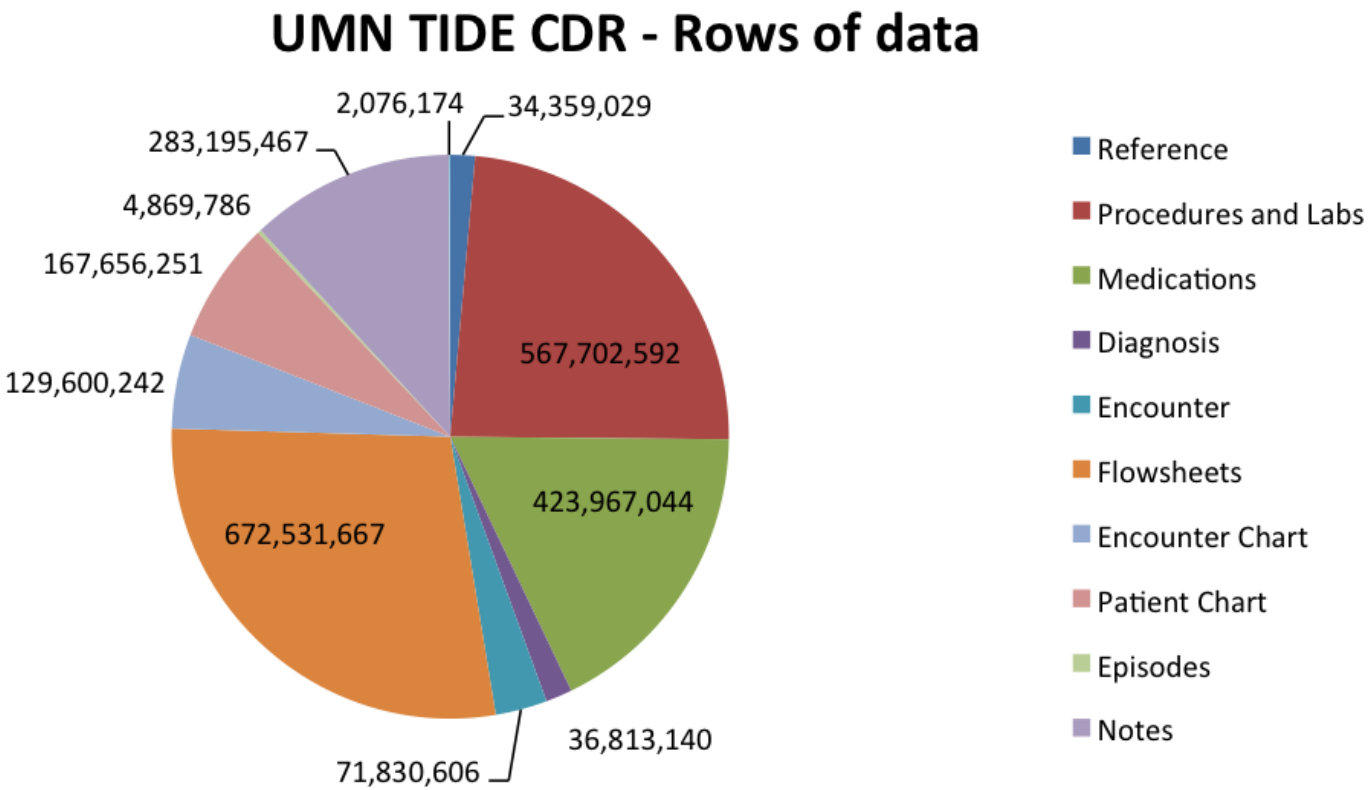
BIOMEDICAL HEALTH INFORMATICS

Biomedical informatics infrastructure

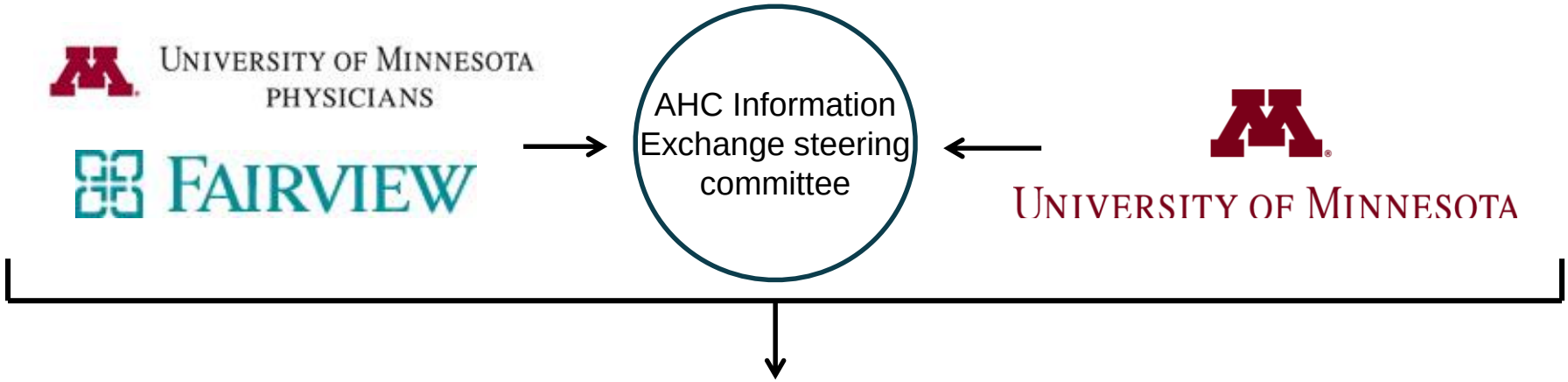
- **Comprehensive clinical health data repository**
- **Informatics Consulting Service (ICS)**
  - Natural language processing (NLP) service for researchers
- **Comprehensive access to imaging**
  - Center for Magnetic Resonance Research
- **Comprehensive access to bio-specimens**
  - CTSI's Bio-Specimen and Laboratory Services initiative
- **Genotype-phenotype mapping**
- **Robust big data grants**

The Information Exchange platform houses Fairview EMR data for more than 2.1M patients

- Clinical data repository houses 2.8B lines of data
- Data are transferred from 8 hospitals and 40+ clinical settings



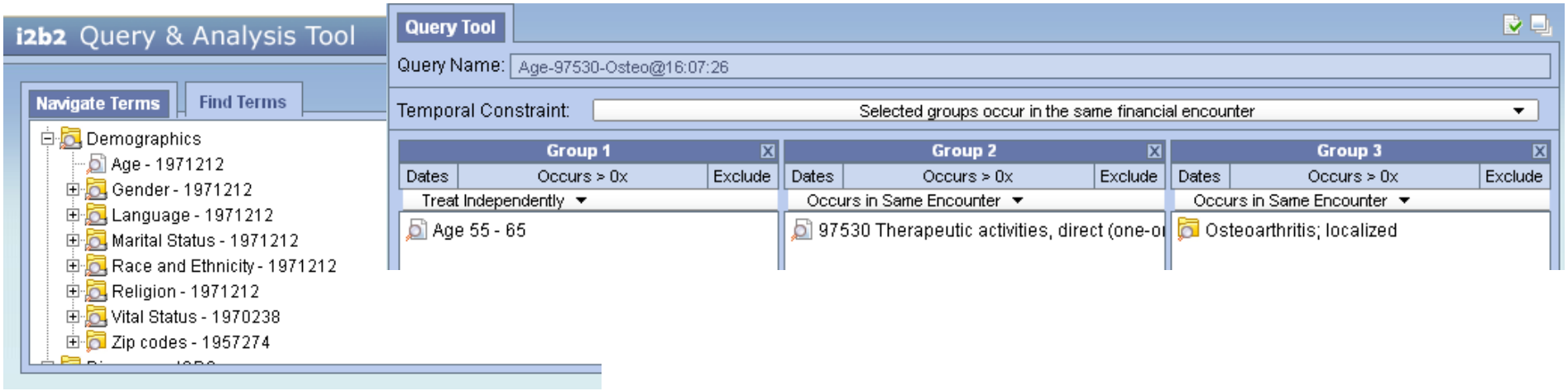
Data governance model



- **MOU** that supports collaboration, shared leadership, and data access usage
- **Collaborative leadership approach** on policy and resource decisions
- **Robust data shelter** supported by data security, policies, SOPs, and audits

Self-service informatics tools

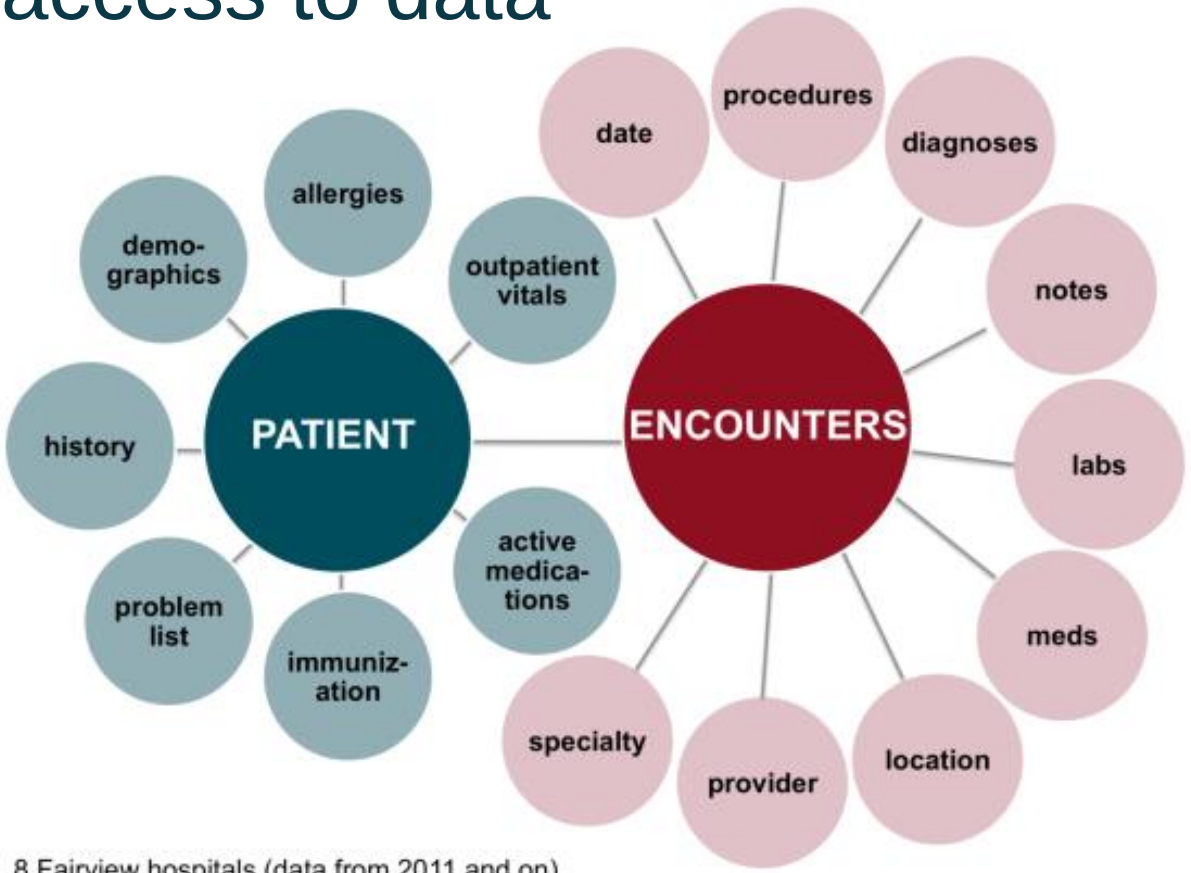
- **I2b2 cohort-discovery tool**
  - Access data from the clinical data repository to:
    - Determine how many patients match study criteria
    - Understand study feasibility
  - Doesn't require IRB approval (data are de-identified and are number queries only)



Find tools at ctsi.umn.edu/biomedical-informatics

Clinical data repository and death records database gives UMN researchers unprecedented access to data

- **Clinical data repository**
  - Houses electronic health records of +2M patients
- **Minnesota death records database**
  - Minnesota Dept. of Health



8 Fairview hospitals (data from 2011 and on)
40+ Fairview (from 2005) and UMP clinics (from 2011)

Capacity for big data

- **Minnesota Supercomputing Institute (MSI)**
  - Access to supercomputers that meet high-performance computing needs for advanced computation and scientific visualization
- **Minnesota Population Center**
  - Access to U.S. census data back to 1790 for the U.S., as well as data from 75 countries
  - Technical expertise to support strong empirical orientation for large-scale data analysis, geospatial analysis, and policy-relevant research
- **Optum Labs partnership**

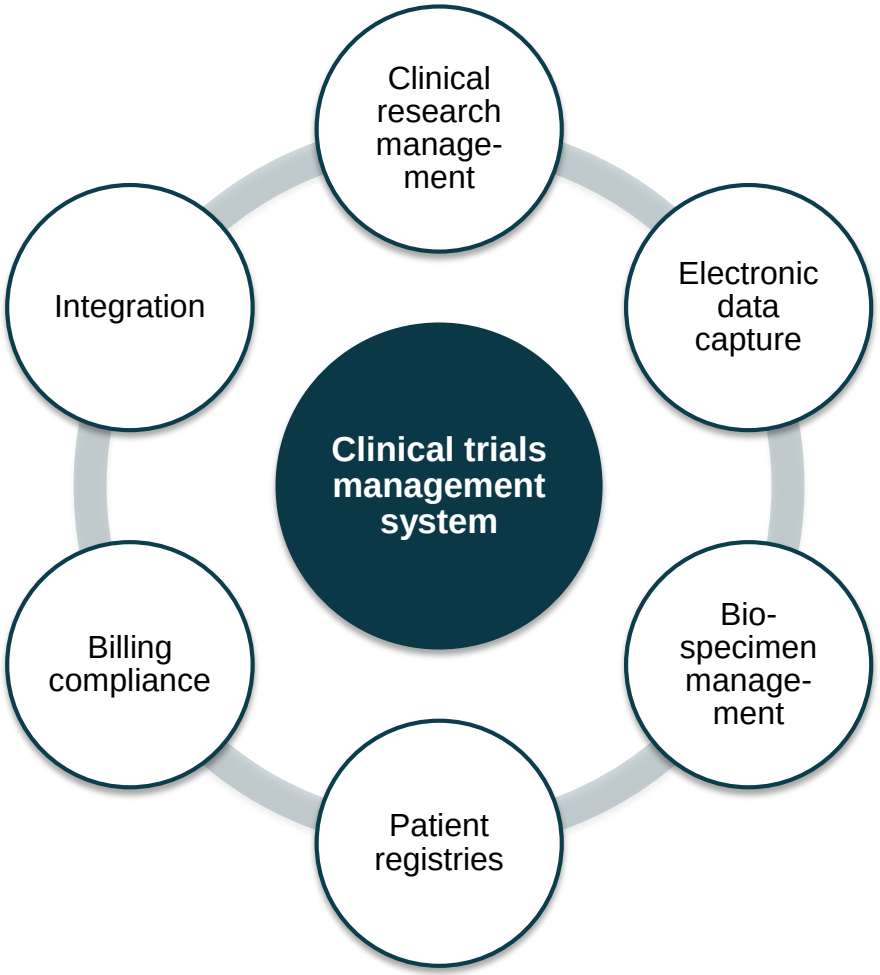
New Clinical Trials Management System (CTMS) better supports a broad range of clinical research

- A single, centrally supported system (OnCore) will enhance the efficiency and quality of health research at the U of M by:
  - Reducing costs via the elimination of redundant processes
  - Consistently capturing data needed to manage trials
  - Increasing the capability to provide meaningful reports & data
  - Improving regulatory compliance

Enterprise OnCore clinical trials management system (CTMS)

An enterprise-wide deployment of OnCore enables:

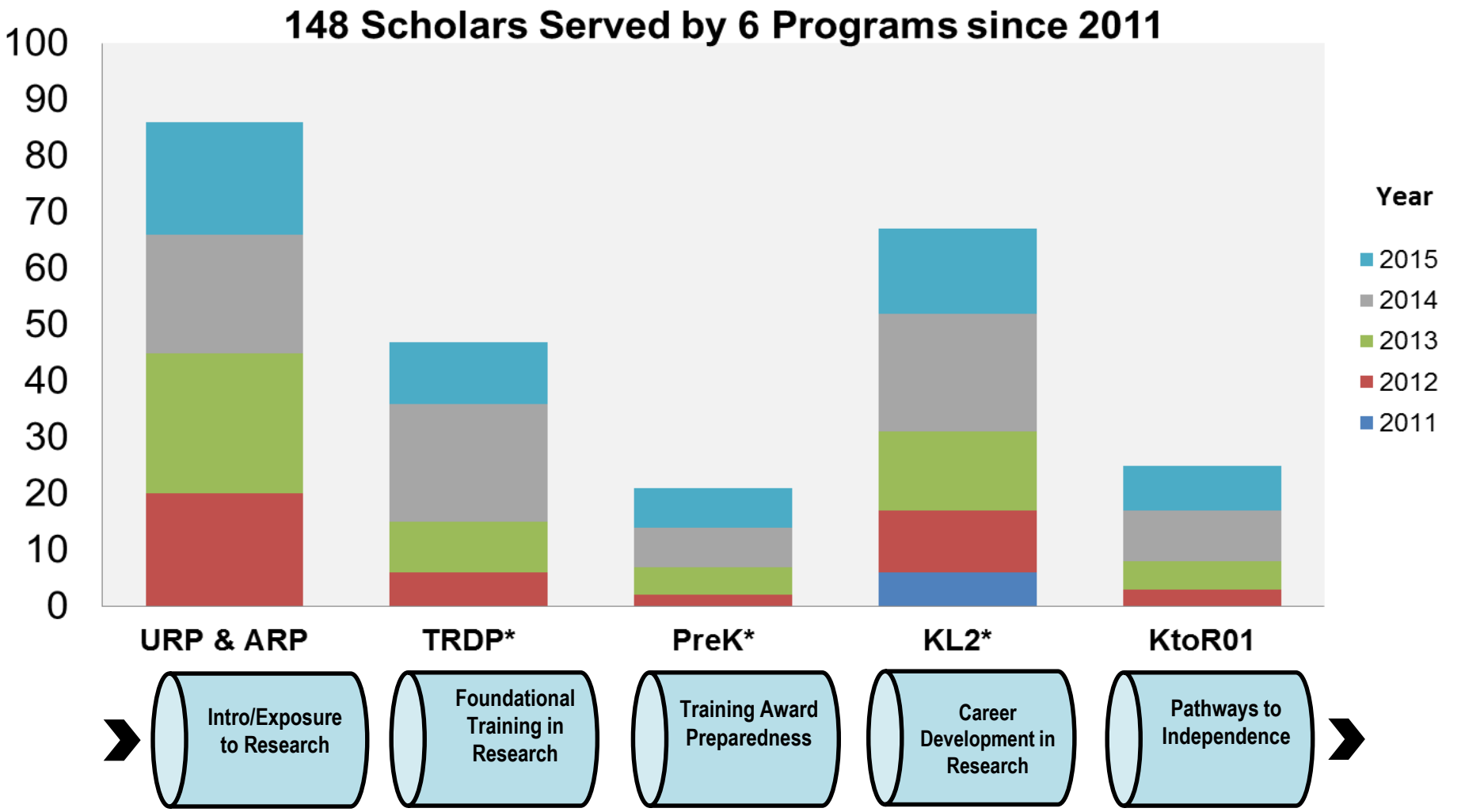
- **Clinical research management**
  - Protocol and subject life cycles
  - Subject safety data
  - Scheduling of subject visits
  - Regulatory tracking and reporting
  - Electronic data capture
- **Financial management**
  - More efficient budgeting and pricing (e.g., replaces TASCS for current users)
  - Invoicing of sponsors
  - Post-award financial activities



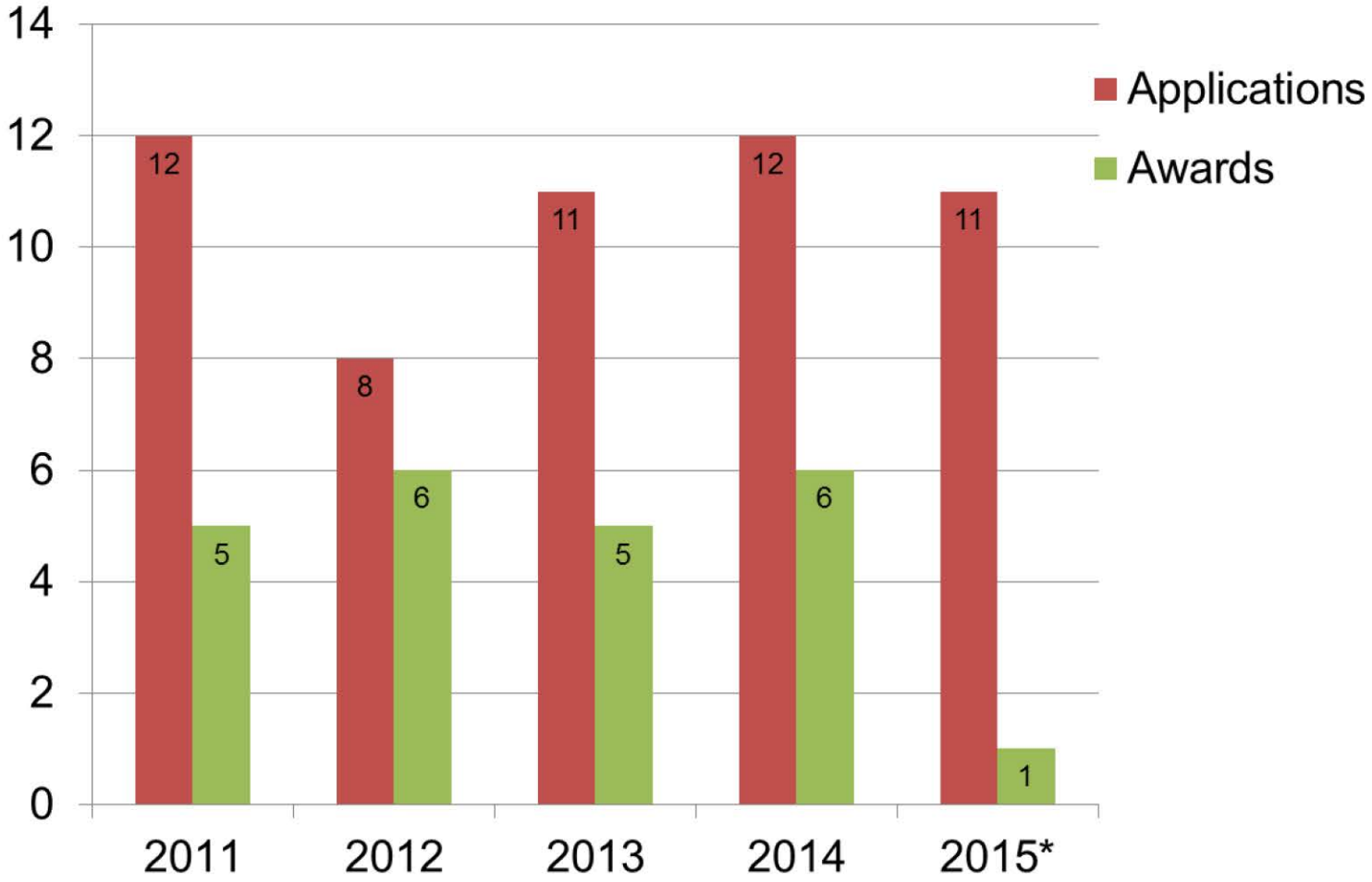
CLINICAL RESEARCH EDUCATION AND CAREER DEVELOPMENT

Training the next generation

Accomplishment: Building scholar pipeline



KL2 applications by year



Career development events

- **Five ongoing seminar series**
  - K Scholar Multidisciplinary Seminar (weekly): For CTSI faculty scholars, Women's Health K12 scholars (BIRCWH), Pediatric K12 scholars (CHRCDA), and select individual K awardees
  - Career Development Seminar (bi-monthly): For UMN faculty, students, and staff
  - Translational Research Development Program Seminar (monthly): Pre- & postdocs
  - Advanced Research Program (ARP) Seminar: For doctoral or professional health sciences students (PhD, DDS, DNP, MD, PharmD)
  - Undergraduate Research Program (URP) Seminar: For undergraduate students
- **Two annual training events**
  - "Write Winning Grants" day-long workshop
  - CTSI's annual all-scholar poster session

Creating a mentoring culture

- **All training programs include a mentoring component**
  - 30 trainees; 50 mentors
- **Required mentor-mentee compact**
- **Mentoring for Mentors online training** is completed by trainees and all mentors
- **K scholars receive training on mentorship and are offered the opportunity to mentor** CTSI URP and ARP summer scholars.
  - 9 K scholars mentored 15 summer scholars
- **Outstanding junior and senior mentors recognized annually**
- **63 multidisciplinary mentoring teams created** for TRDP, Pre-K, KL2, and K to R01 scholars
- **Joint mentoring activities with Mayo KL2 and the National Research Mentoring Network (NRMN)**, a nationwide consortium focused on training and career development
  - Mayo KL2 scholars visited CTSI-Ed on April 1 for a lunch hosted by UMN scholars and a K Scholar Multidisciplinary Seminar on mentoring from UMN's NRMN site PIs
- **Coordinating activities across the Medical School** with Office of Faculty Affairs
  - Associate Dean for Faculty Affairs created a collaborative group – which includes CTSI – to coordinate mentoring and faculty development activities, expand opportunities of faculty development and mentoring, avoid redundancy, maximize impact of external visitors, and collaborate to advance scholarship.

Workforce training

Overview

- **Online training system created in partnership** with CTRS and key research managers in the clinical domains
- **Comprehensive year-long orientation for research staff**
  - Covers everything the training development committee felt needed to be covered within the first year for a new clinical research coordinator (CRC) to be successful.
- **"One-stop-shop" for coordinator training needs**
  - Houses all of the links to trainings and information for CRC training whether or not it was developed by CTSI to save them the considerable and confusing work of trying to find the necessary training.
- **106 participants since the October 2013 release**

Courses developed

1. **New CRC Checklist**: Questions to ask and trainings to take for new CRCs
2. **Research 101:** Broad overview of the research process and the role of the CRC
3. **Navigating Research @ UMN**: Seven major phases of clinical research and how to navigate each
4. **UMN & Fairview Research Policies:** Overview of policies at both institutions, plus UMN Physicians
5. **Role of CRC Certification:** Brief overview of the role of CRC certification
6. **Participant Recruitment & Retention:** Provides common, realistic examples of the process
7. **Research Budgeting Overview:** Provides a broad view of the budget process for a clinical trial

Scholars are succeeding

447 **publications**

7 **faculty promotions**

- 3 to Assistant Professor
- 4 to Associate Professor

6 **faculty degrees obtained***

- 2 PhDs
- 4 Masters

** While in our programs*

18 external grants awarded to KL2s*, totaling

+$15.4 million

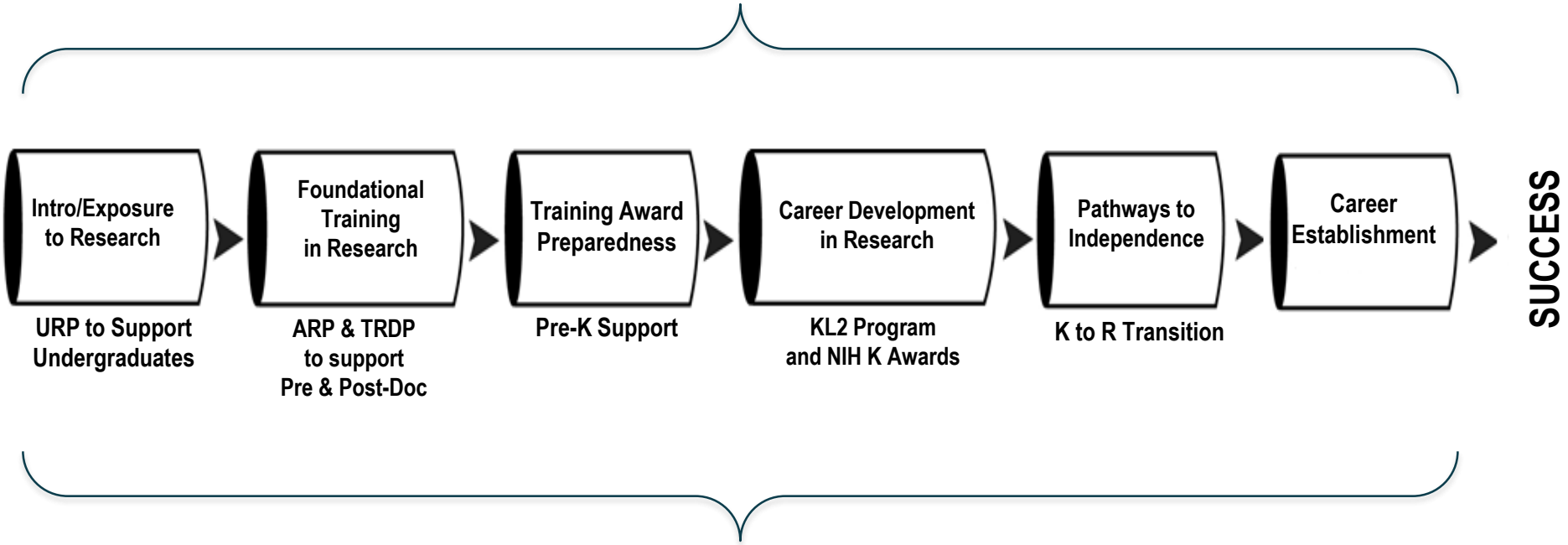
4 RO1s	1 K23
3 RO3s	1 K01
1 R56	1 PCORI
1 R21	1 Federal (UK)
1 U01	4 foundation

**As PI (>$50K) since 2011 (n=23)*

Metric (2011-15)	All CTSI scholars (n=157)	KL2 only (n=24)
Publications	447	227
Promotions	3 Postdoc to Assistant Professor (TRDP, N=9)	4 Assistant to Associate Professor
First Authorship	139	86

A full pipeline for career development, with mentoring at all levels

Programs run the gamut from undergraduates to junior faculty



Mentoring occurs at all levels

Senior faculty are paired with KL2s, KL2s with student scholars, etc.

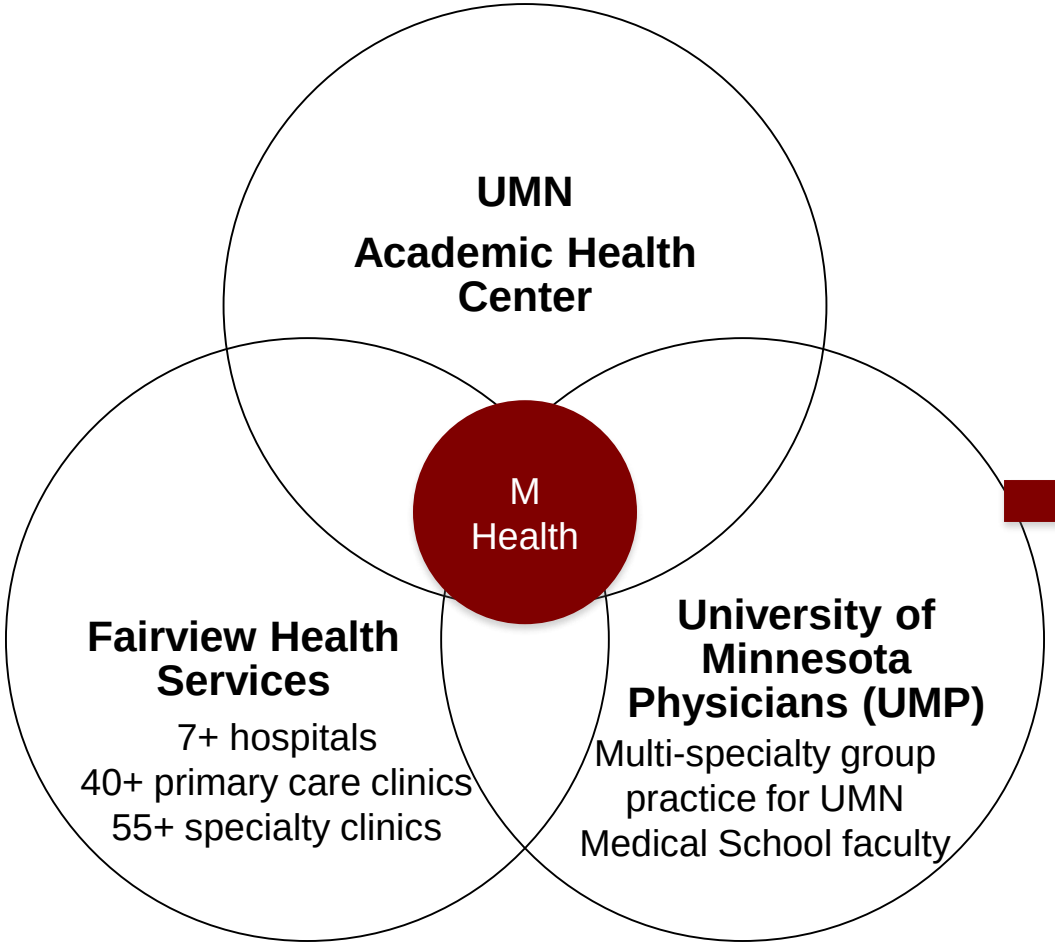
UNIQUE OPPORTUNITIES PROVIDED BY CTSA NETWORK

Changing NIH Funding Landscape

- Without a CTSA award, certain clinical research opportunities will be out of reach
- Examples of exclusive CTSA enabled opportunities:
  - Cooperative Agreements with NIH Centers and Institutes for which CTSA designation is requirement
  - Mayo Clinic Inter-CTSA collaborations
  - Midwest Area Research Consortium for Health (MARCH)
  - Greater Plains Collaborative (Patient-Centered Outcomes Research Institute: PCORI) and other PCORI applications dependent upon CTSA infrastructure
  - Midwest Consortium for Drug Discovery and Development
  - NCATS supplemental awards (numerous)

OUR CLINICAL PARTNERS

University of Minnesota Health: Key Players



HEALTH
UNIVERSITY OF MINNESOTA

Research opportunities

- Enhanced recruitment
- Establish and support bio-repository and lab services
- Staffing model efficiency
- Phase I capabilities

Engagement with University of Minnesota Physicians (UMP) and Fairview Health Services

- Recruitment – Patient Kiosks and Other Strategies
- Flexible Space for Clinical Research Activities - ACC
- Phase I Capability – Hybrid Approach
- Research Rates: Labs & Experimental Pharmacy Services
- Bio-Specimen Procurement and Consent Process
- Electronic Health Records – Information Exchange
- Joint RFA on Patient Health Outcome Studies
- Ongoing brain-storming to optimally leverage bi-directionally CTSI and UMHealth

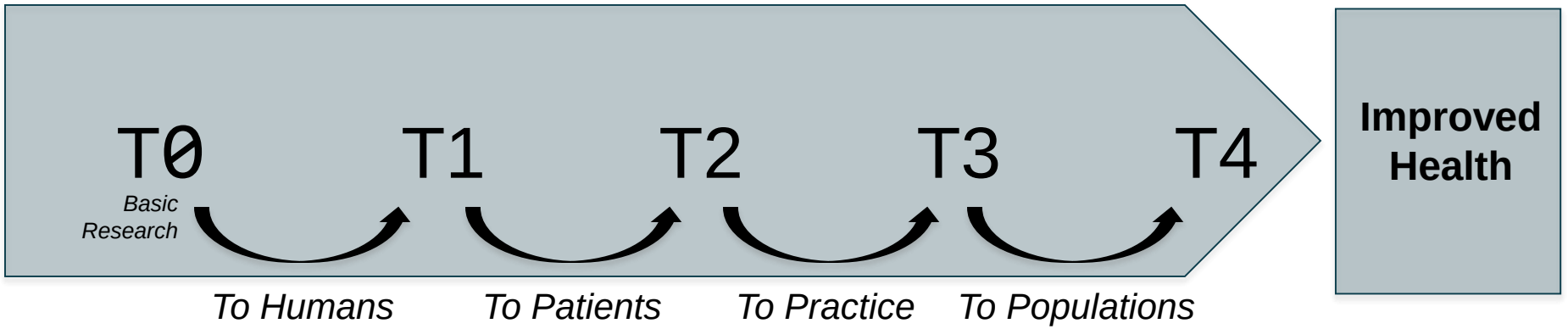
Cumulative Service and Impact Data

- **$6.8M** in research funds to support **145+** faculty
- **850+** investigators representing **13** schools and colleges have used clinical service offerings
- **$2.7M** in research funds to support **60+ early-stage** translational research projects
- A network of **125+** University and industry experts provided project-specific guidance on translational research projects, as part of **30+** individual project teams and **2** standing committees
- **50+** community-University research teams formed
- **100+** clinical data repository requests (July 2013-Sept. 2014)
- **100+** investigators and research staff used i2b2 (since July 2013)
- Trained **50+** UMN faculty members and **70+** trainees via our career development programs

Unless noted otherwise, figures are cumulative from 2011 -- when CTSI joined the CTS consortium -- to July 2014

The Spectrum of Translational Research

- **Early-stage research**
- **Clinical research**
- **Community-engaged research**



An Example: Triptolide → Minnelide

Example - Translating technologies into therapies

- Triptolide:
  - Diterpenoid triepoxide extract from Chinese herbal plant used to treat inflammatory and autoimmune disorders
  - Potent antitumor agent in preclinical pancreatic cancer studies; solubility, narrow TI, lack of IP limit clinical & commercialization potential.

AHC capabilities to develop triptolide into therapeutic for pancreatic cancer:

Institute for Therapeutics Discovery and Development (ITDD)	**Center for Translational Medicine (CTM)**	**CTM Partner Program**	**Molecular and Cellular Therapeutics (MCT)**
Medicinal chemistry, small molecule synthesis, & scale-up	Preclinical testing, (POC through GLP toxicology), program development and management, regulatory & IND filing support	Access to development expertise, services and resources necessary to advance technologies into the clinic (scope & model similar to TRND's)	GMP manufacturing facility

*ITDD and CTM approved as TRND service provider

Example - Developmental pathway for Triptolide/Minnelide

- ITDD synthesizes Minnelide, a highly water-soluble analog of triptolide
- Studies in multiple models provide POC and support improved TI
- CTM conducts/directs completion of ADME, safety and toxicology studies to support IND & commercialization (13 conducted internally)
- GMP manufacturing completed by ITDD at MCT facility
- Pharmacology/toxicology, CMC & clinical sections of IND completed
- CTM expends ~$3M for preclinical development

Summary

- IND-enabling toxicology studies completed <3 years after first in vivo study initiated (and completed within budget)
- Minnelide licensed to start-up
- Clinical trial for patients with advanced GI tumors ongoing at UMN Masonic Cancer Center and TGen/Virginia Piper Cancer Center

QUESTIONS

BOARD OF REGENTS
DOCKET ITEM SUMMARY

Special Committee on Academic Medicine **May 7, 2015**

Agenda Item: Institutional Review Board Primer

☐ **Review** ☐ **Review + Action** ☐ **Action** ☒ **Discussion**

☐ *This is a report required by Board policy.*

Presenters: Brooks Jackson, Dean of the Medical School and Vice President for Health Sciences
Joanne Billings, Assistant Professor, and Executive Institutional Review Board Chair

Purpose & Key Points

The purpose of the presentation is to educate Regents on the review and approval process for clinical research that involves human subjects, specifically how research projects are reviewed, assessed, approved or not approved. Key points will include understanding the roles and accountabilities of the investigator, institution and the Institutional Review Board (IRB); processes and procedures; history of human subjects research and the evolution of protections; involved authorities and resources; and the current level of review activity happening at the University. The presentation will also provide an overview of IRB responsibilities and approval criteria, informed consent procedures, review of research that involves vulnerable subjects, and risk and review levels.

Background Information

The presentation will provide context for understanding the current recommendations and changes underway for advancing human subjects research at the University. An external review panel and the Legislative Auditor made the recommendations in recent reports that examined the human subjects research review process at the University, particularly when it involves people with limited capacities. The same presentation is being made to the Audit Committee.

The Review and Approval Process for Human Subjects Research

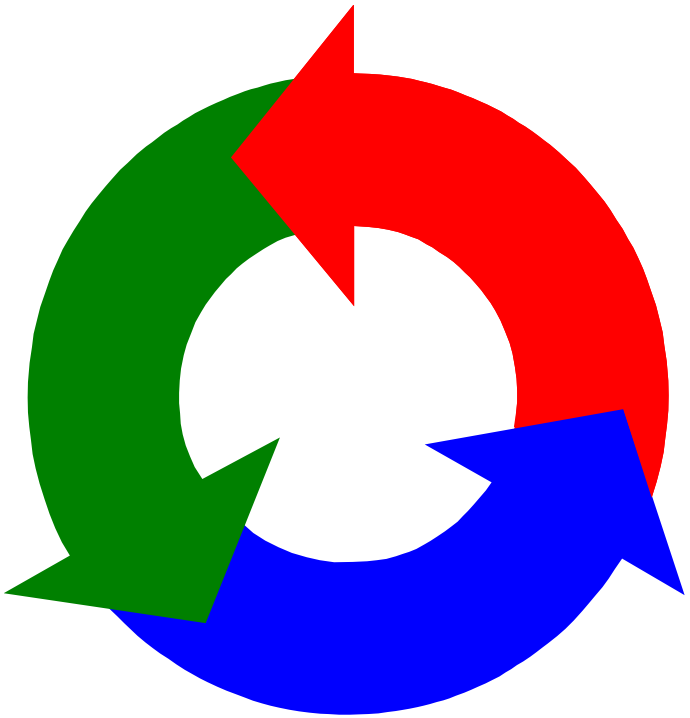
Joanne Billings, M.D., Chair
IRB Executive Committee

Board of Regents
Special Committee on Academic Medicine
May 7, 2015

UNIVERSITY OF MINNESOTA
Driven to Discover℠

Human Subjects Protection is a Shared Responsibility

IRB



Investigator/
Researcher

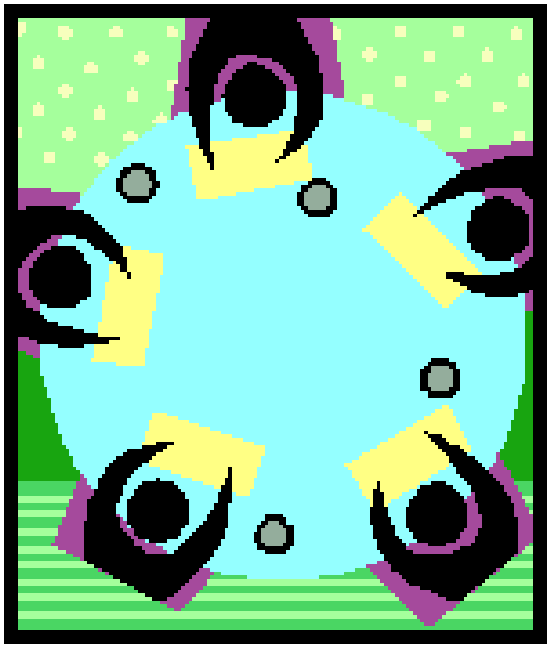
Institution

What does an IRB do with a Protocol?

- Approve, disapprove or modify
- Conduct continuing review
- May observe or perform additional review
- May suspend or terminate approval

Institutional Review Board (IRB)

- Four boards at U of M
- Minimum of five people required at each meeting
  - Technical experts on the types of research under review
  - Non-scientific member
  - Non-affiliated community representatives



Components of Initial Human Subjects Review

- Institutional requirements
- Fairview requirements
- Scientific review
- Researcher education and training
- Conflict of interest management
- Bio safety review
- Regulatory status of investigational products
- Grants and contracts
- Communication with prospective subjects/participants

Federal Regulations and Policy

45 CFR 46 – DHHS Policy for Protection of Human Research Subjects- Subpart A

"The Common Rule" – Federal Policy for Protection of Human Subjects – applies to all research involving human subjects conducted, supported, or otherwise subject to regulation by any federal department or agency which makes the policy applicable to such research.

Federal Regulations and Policy

Additional Protections Included in 45 CFR 46:

- **Subpart B -** Additional DHHS protections pertaining to research, development, and related activities involving pregnant women, fetuses and neonates (non-viable and those of uncertain viability)
- **Subpart C -** Additional DHHS protections pertaining to biomedical and behavioral research involving prisoners as subjects
- **Subpart D** - Additional DHHS protections for children involved as subjects in research
- There is no subpart providing additional DHHS protections for vulnerable adults

Federal Regulations and Policy

FDA

U.S. Department of Health and Human Services
Food and Drug Administration

Authority

- Federal Food, Drug, and Cosmetic Act (1962)

Regulations

- IRB: 21 CFR 56
- Informed Consent: 21 CFR 50
- Investigational Drugs: 21 CFR 312
- Investigational Devices: 21 CFR 812

Other Relevant Authorities

- Privacy regulations (HIPAA)
- FERPA and PPRA (education research)
- Applicable state laws pertaining to research, research subjects, records, privacy, etc.
- Institutional policies and codes
- Professional associations and licensure requirements

Belmont Report

- The Belmont Report (1974) summarizes three basic ethical principles relevant to research involving human subjects.
  - Respect for persons
  - Beneficence
  - Justice

IRB Responsibilities 46.109

- Review and approve, require modifications or disapprove all *covered* research
- Require that informed consent is in accordance with regulations
- Require documentation of informed consent or may waive documentation in accordance with regulations
- Notify investigators in writing of decisions
- Conduct continuing review of research no less than once per year

IRB Risk Responsibilities

- Identify risks
- Determine that risks are minimized
- Determine that “risks to subjects are reasonable in relation to anticipated benefits”
- Determine that subjects are adequately informed about “any reasonably foreseeable risks or discomforts”

Criteria for IRB Approval

46.111

- Risks to subjects are minimized
- Risks are reasonable in relation to anticipated benefits
- Selection of subjects is equitable
- Informed consent is sought from each subject
- Informed consent is appropriately documented

When appropriate

- data collection is monitored to ensure subject safety
- privacy and confidentiality of subjects is protected
- additional safeguards are included for vulnerable populations

Criteria for IRB Approval

46.111

BENEFICENCE

Risk/Benefit analysis
Data safety
Experimental design
Qualifications of PI

JUSTICE

Subject selection
Inclusion/exclusion
Recruitment

RESPECT FOR PERSONS

Informed consent
Surrogate consent
Assent

Privacy & Confidentiality
Vulnerable populations

Respect for Persons

- Individuals should be treated as autonomous agents
- The investigator must ensure that the subject has received a full disclosure of the nature of the study, the risks, benefits and alternatives, with an extended opportunity to ask questions.
- Persons with diminished autonomy are entitled to protection
- Persons with diminished autonomy (e.g., prisoners, students, children, etc) should not be coerced to participate in a research

Beneficence

- Maximize possible benefits and minimize possible harms
- The investigator should give forethought to the maximization of benefits and the reduction of risk that might occur from the research

Justice

- Fairness in distribution
- Justice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly
- Equitable selection of participants

Informed Consent

- Consent process should empower subjects to make their own determination about risk
- Risks should be explained in terms to which the subjects can relate - everyday life experiences
- Vulnerable subjects consent especially complicated with little federal regulation
- Main focus of external review panel and OLA reports

Informed Consent
Basic Elements

46.116(a)

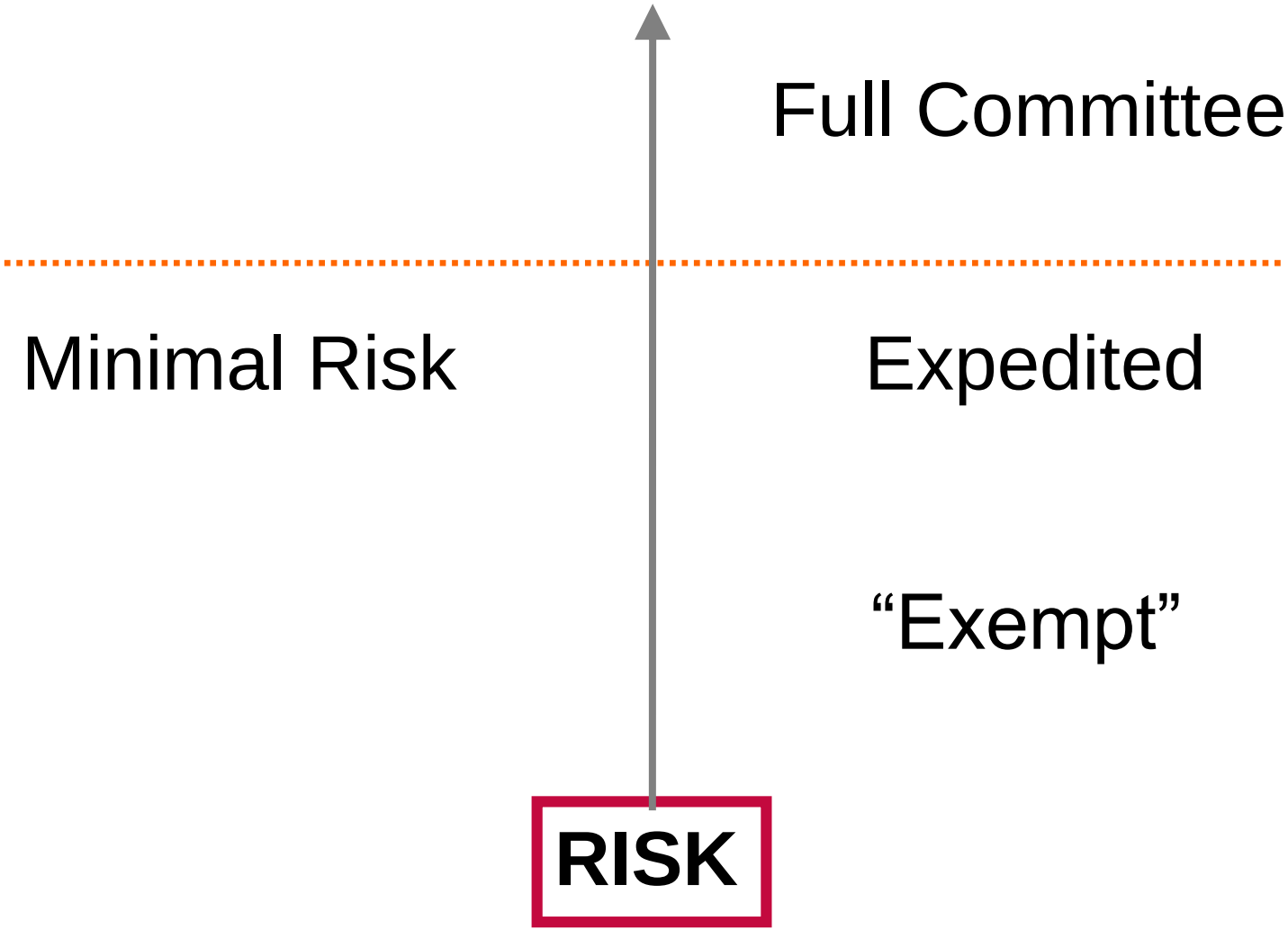
- Research
  - Purpose/Duration
  - Procedures
  - Experimental
- Risks
- Benefits
- Alternatives

- Confidentiality
- Compensation for injury
- Whom to contact
- Right to refuse or withdraw

Informed Consent Additional Elements 46.116(b)

- Currently unforeseeable risks
- Termination of participation
- Additional costs to subjects
- Consequence of withdrawal
- Informing of new findings
- Number of subjects

Level of Risk Determines Level of Review



Vulnerable Populations

- Cognitive vulnerability
- Institutional vulnerability
- Deferential vulnerability
- Medical vulnerability
- Economic vulnerability
- Social vulnerability

Continuing Review

An IRB shall conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, ***but not less than once per year***, and shall have authority to observe or have a third party observe the consent process and the research.

21 CFR 56.109

45 CFR 46.109

Components of Post-Approval Human Subjects Review

- Change in protocol
- Add/remove personnel
- Add/remove funding
- Reportable events
- Continuing/continuous review
  - Post approval monitoring
- Study inactivation

IRB Report Form

UNIVERSITY OF MINNESOTA

Report Form

For the prompt submission of information to the IRB

Submission instructions:

Use this form to report events, including Unanticipated Problems Involving Risks to Subjects or Others (UPIRTSO), which fit the definition of promptly reportable events. See section 1 below for description of events that require prompt reporting. The IRB defines "prompt" to be **within 5 business days** of discovery of the event. See the Reporting Unanticipated Problems webpage for additional guidance

If an event does not meet the criteria outlined below, report it to the IRB in summary form, using a table or spreadsheet, at the time of continuing review. A spreadsheet template is available in the templates section of the IRB forms page

This section for IRB use only

Electronic Submission (preferred):
Submit to: irb@umn.edu
PI must submit request using University of Minnesota e-mail Account.

U.S. Mail Address:
Human Research Protection Program
MMC 820
420 Delaware St. SE
Minneapolis, MN 55455-0392

For more information please visit our website
http://www.research.umn.edu/irb/index.html
Contact our office
Phone: 612-626-5654
Email: irb@umn.edu
Fax: 612-626-6061

IRB Protocol Information

IRB Study Number:	
Principal Investigator:	
Primary Study Title:	
Report Date:	(reference this date on all subsequent submissions including Changes in Protocol related to this event)

Section 1 Reportable Events - Report Type

Events listed below require prompt reporting to the IRB. Indicate the type of information the PI is reporting.

- ☐ Unexpected death of a locally enrolled subject whether considered related to the research or not. Death is considered unexpected if the risk of death is not listed in the consent form or is not listed in the Investigator's Brochure.
- ☐ New or increased risk (For example, publications indicating a new risk, new risk in an investigator brochure, FDA black box warning, new risk identified in a data safety monitoring report, information or change that adversely affects subject safety, or information or change that adversely affects the conduct of the research)
- ☐ Adverse events or safety reports that indicate a potential increase in risk or reduction of benefit (such as those that may prompt a change to the protocol or consent form)
- ☐ Protocol deviation due to the action or inaction of the investigator or research staff
  Those deviations that do NOT affect the scientific soundness of the research plans or the rights, safety or welfare of human subjects can be reported at the time of continuing review.
- ☐ Protocol deviation that harmed a subject or placed subject at risk of harm
- ☐ Protocol deviation made without prior IRB approval to eliminate an immediate hazard to a subject

- ☐ Audit, inspection, or inquiry by a federal agency
- ☐ Written reports of federal agencies (e.g., FDA Form 483)
- ☐ Written reports of study monitors, Data Safety Monitoring Board reports or other sponsor reports (e.g. FDA non-approval letters).
- ☐ Allegation of investigator or study team noncompliance or finding of investigator or study team noncompliance
- ☐ Unauthorized disclosure of confidential information
- ☐ Unresolved subject complaint
- ☐ Suspension or premature termination by the sponsor, investigator, institution or other IRB
- ☐ Incarceration of a subject enrolled in a research study not approved to involve prisoners
  Complete Appendix C "Research including Prisoners" and submit with this report form
- ☐ State medical board or hospital medical staff actions
- ☐ Unanticipated adverse device effect
- ☐ Other information that the PI determines is related to the research and indicates that participants or others might be at increased risk of harm; or that may affect a subject's willingness to continue to participate.

Section 2 Summary of Event/Report

Provide all relevant details of the event.

2.1 Describe the problem/event/report.

Include in the summary the nature and severity of the problem

☐ **This submission includes a report that does not communicate a potential new or increased risk to subjects or others. Go to Section 3 - Attachments. Do not check this box if reporting a protocol deviation or complaint.**

2.2 Date event occurred:

Date event was discovered/report received:

If reporting outside of the required reporting time, explain why the delay occurred and how prompt reporting will be assured in the future.

2.3 Where did this event occur?

☐ **on-site (under UMN/Fairview/Gillette PI oversight)** ☐ **off-site (under oversight of PI at another institution/site)**

2.4 Indicate whether this is an initial or follow up report.

☐ **initial**

☐ **follow up - date of initial report:**

IRB Report Form

2.5 Indicate below which criteria of the regulatory definition [45 CFR 46.103(b) (5) and 21 CFR 56.108(b) (1)]of Unanticipated Problem Involving Risks to Subjects or Others (UPIRTSO) are met by this event:

Is the problem/event unanticipated? Unanticipated problems/events are those that are *not* already described as potential risks in the consent form, *not* listed in the Investigator's Brochure or *not* part of an underlying disease.

☐ Yes ☐ No

Is the problem/event at least possibly related to research procedures?

☐ Yes ☐ No

Does the problem/event potentially reflect new or increased risk to subjects or others?

☐ Yes ☐ No

The IRB will make the final determination regarding whether this event meets the regulatory definition of UPIRTSO.

2.6 Describe the likely impact of the event on risk to the study subjects or others?

☐ **No impact**

2.7 What actions, if any, have been taken to address the situation? If none, check the box below.

☐ **None**

2.8 What actions are proposed to be taken?

☐ **Change in protocol**

☐ **Change(s) to the consent form – include updated consent forms (tracked changes and clean versions) with submission**

☐ **Notification to enrolled research subjects, including those who have completed the study**

Describe proposed actions:

☐ **None. Justify below**

Section 3 - List of Attachments

Submit with this report any relevant interim reports or information, including but not limited to: clinical trial monitoring reports, interim safety reports, interim data analyses, or data safety monitoring board reports. Any proposed change in protocol must be documented on a Change in Protocol form and included with this submission. Also include with this submission all proposed notification(s) to subjects, changes to the consent form or changes to any other previously approved study materials.

3.1 What attachments, if any, will be included with this report?

☐ Notification to subjects
☐ Change in Protocol form
☐ Revised consent form (both clean and with changes tracked)
☐ Study monitoring or data safety monitoring board reports
☐ Other(s). List:
☐ No attachments

Original Signature of Principal Investigator

The current PI's signature is required unless submitting via email. Forms sent by email must be emailed from PI's UMN x.500 email account. The Principal Investigator assures the information contained on this form is true and accurate.

Principal Investigator Signature (enter PI UMN x500 if submitting via email)	**Date**

FORM-POST-004_Report Form Page 4 of 4

IRB Membership and Compensation

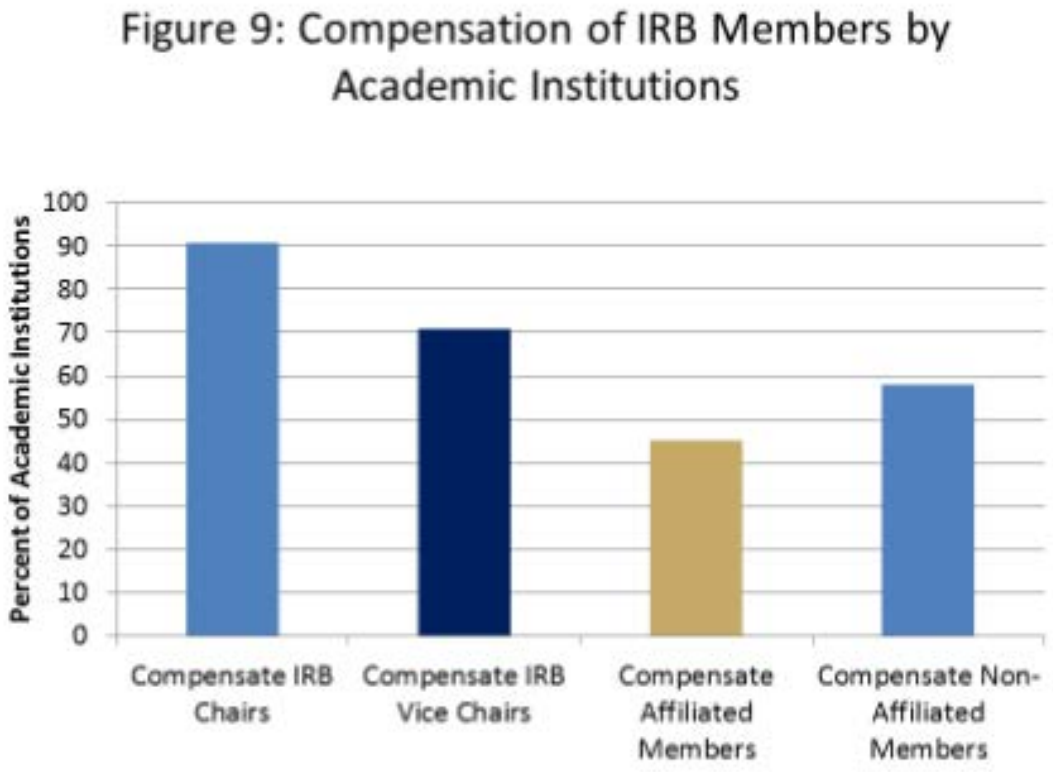


Figure 9: 90.6% of academic institutions Compensate IRB Chairs, 71% Compensate IRB Vice Chairs, 45.2% Compensate Affiliated Members, and 58.1% Compensate Non-Affiliated Members.

IRB Workload and Staffing

Table 1: IRB Staffing and Funding Levels

Protocol Category	Median Number of Staff	Median Number of Protocols	Median Protocols per FTE	Median Dollars Budgeted for IRB
All	14	1821.5	130.1	1,400,000
1-100	-	-	-	-
101-500	3.1	398.0	128.4	$225,000
501-1000	8.5	916.5	107.8	$236,714
1001-2000	11.3	1,453.0	128.6	$1,017,439
2001-4000	22	3056.5	138.9	2,023,199
4000+	30.0	4,943.0	164.8	$3,024,830

University of Minnesota			
Number of protocols	**Number of staff**	**Protocols per FTE**	**Annual budget**
5814 protocols	22 staff members (3 open positions)	264 protocols	$2,182,123

Challenges

- IRB membership and compensation
- IRB workload and staffing
- Scientific assessment
- Identification and management of perceived and real conflicts of interest
- IRB member and staff retention during period of intense scrutiny

Questions & Answers

For more information visit: research.umn.edu/subjects

References

OHRP: http://ohrp.osophs.dhhs.gov/

FDA: http://www.fda.gov/

PRIM&R: http://www.primr.org/

2013 Metrics on HRPP Performance for Academic Institutions: http://aahrpp.org/apply/resources/metrics-on-hrpp-performance

Elizabeth A. Bankert and Robert J. Amdur: Institutional Review Board: Management and Function

Dunn CM, Chadwick G: Protecting Study Volunteers in Research

Levine, RL.: Ethics and Regulation of Human Research, Second Edition

Beauchamp, TL, Childress JF.: Principles of Biomedical Ethics, Fourth Edition

UNIVERSITY OF MINNESOTA

Driven to Discover℠