TRIAL INNOVATION NETWORK

Universal Consent

May 24, 2017

This pdf contains three presentation given by:

#1 Mandy Morneault, ITHS, University of Washington

#2 Peter Iafrate, University of Florida

#3 Kate Wilkinson, University of Texas Southwestern

#1 Mandy Morneault, ITHS, University of Washington

Universal Consent

Mandy Morneault
vicka@uw.edu
Manager, Regulatory Knowledge & Training
Institute of Translational Health Sciences, University of Washington

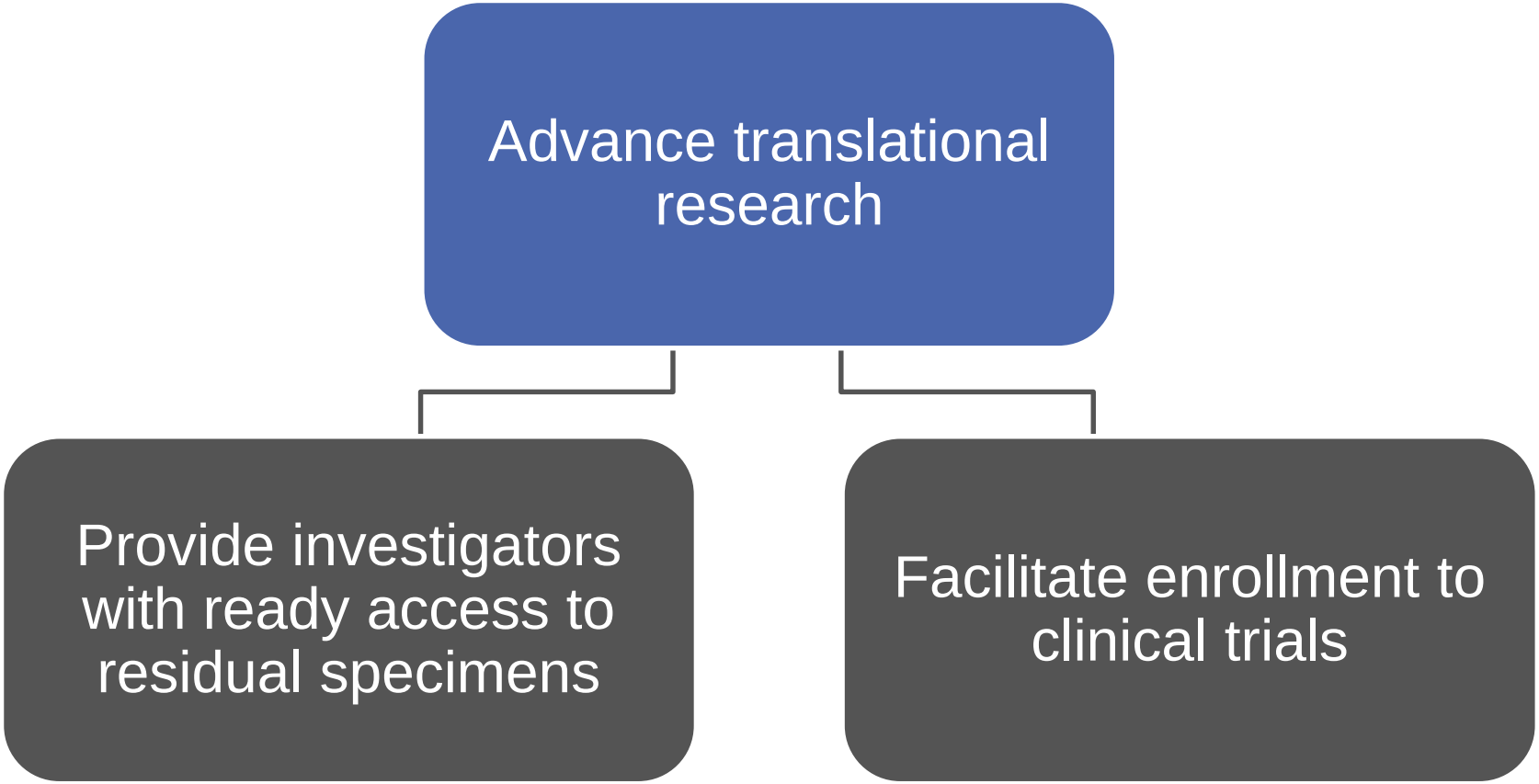
ITHS | Institute of Translational Health Sciences
Accelerating Research. Improving Health.

Universal Consent Vision

Give patients the opportunity to be involved in health research

Honor their decisions about use of their specimens and health information

Universal Consent Research Goals



Universal Consent Timeline

2010

Gather institutional stakeholders to prepare infrastructure grant application

2011-2012

Two-year grant support to build institutional infrastructure

2013

Pilot (and iterate) consenting process

2014-Present

Rollout consenting process

Universal Consent Approach

- ✓ Training in research consent process with clinic check-in staff
- ✓ 1-pg consent form for each question + FAQ brochure
- ✓ Epic decision & signature capture

Patient Opt-in

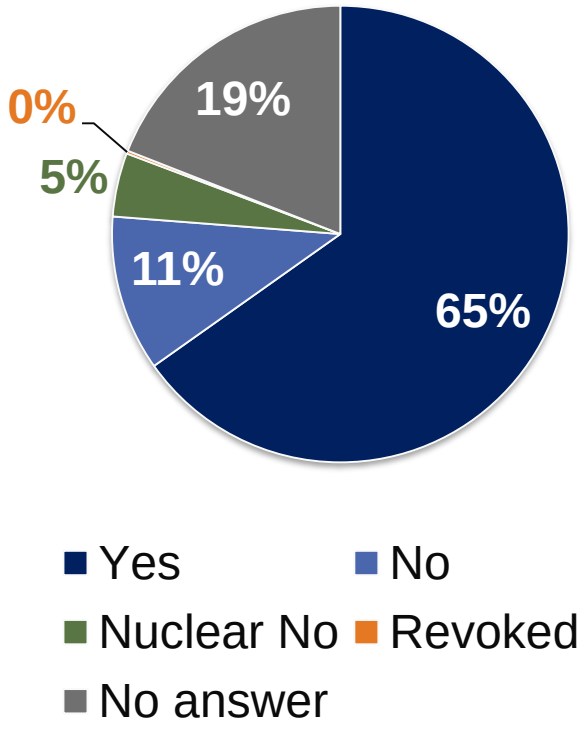
- ✓ Researchers can request patient specimens or contact information after registering through an intranet site
- ✓ The backend “pull” system discards data from patients who have said “no”

Researcher Acquisition

Universal Consent Enrollment

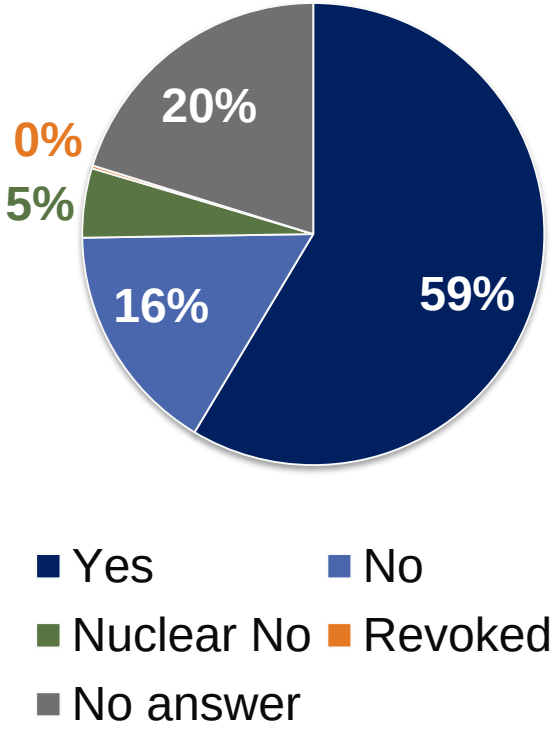
Use of Residual Specimens

21,681 patients approached



Contact for Future Research

21,232 patients approached



Universal Consent Lessons Learned

SUCCESSES

New process streamlined universal consenting at cancer clinics

Lower volume clinics more easily incorporated consenting process

+

CHALLENGES

Clinical responsibilities are the priority

Most staff stopped approaching patients early on after training

Some staff left out research and voluntariness of consent

Staffed lobby consent kiosks for 3 months but clinic staff did not refer patients to the kiosk

=

OVERALL

Clinic staff must have **high motivation** to incorporate a research consent process into their workflow

Next Step: Patient self-registration?

#2 Peter Iafrate, University of Florida

Consent2Share

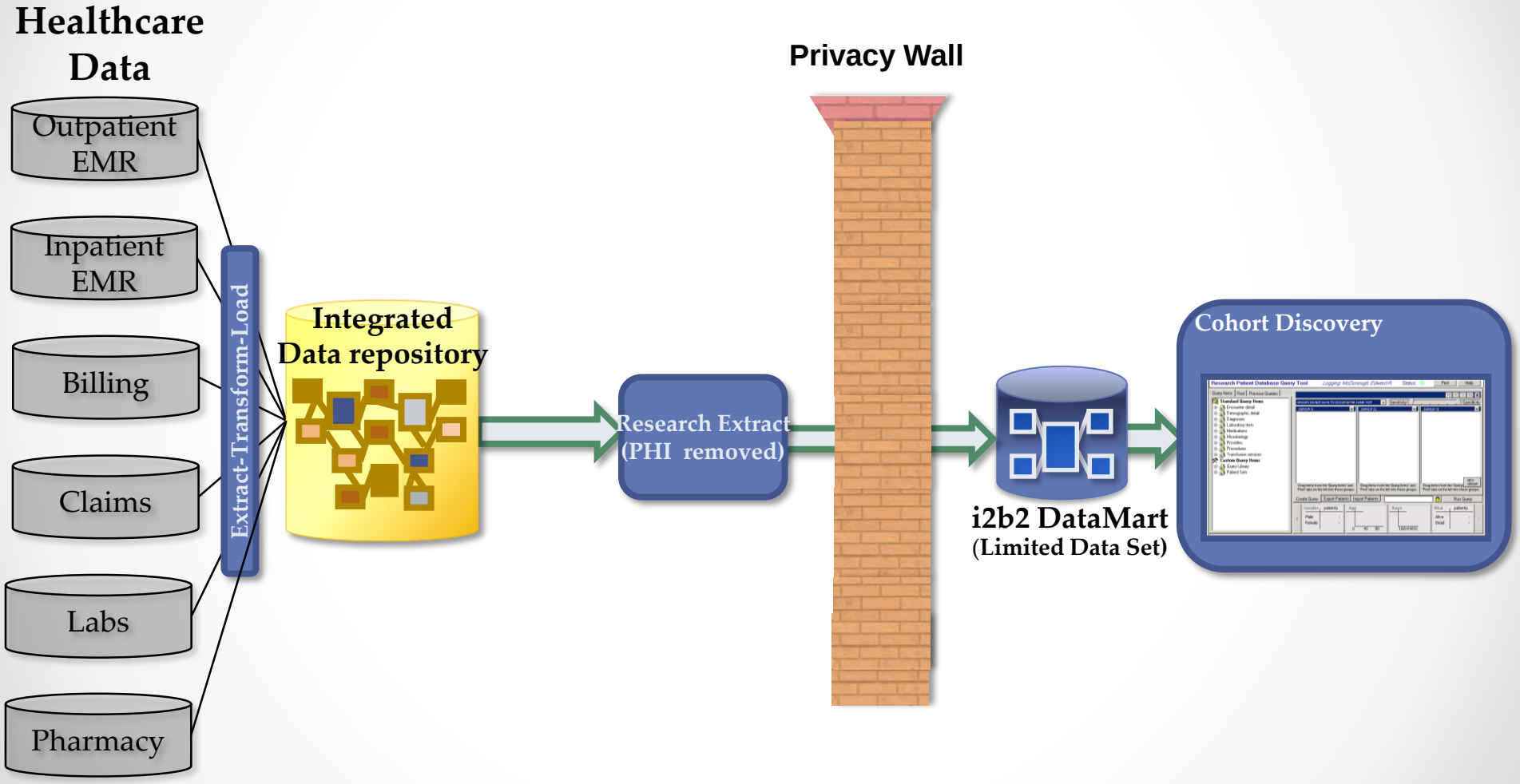
R. Peter Iafrate, Pharm.D.

IRB Chairman, Health Center IRB
College of Research
University of Florida
iafrate@ufl.edu

"Integrated Data Repository (IDR)"

A Research Protocol approved by the University of Florida IRB in 2011

Integrated Data Repository (IDR)

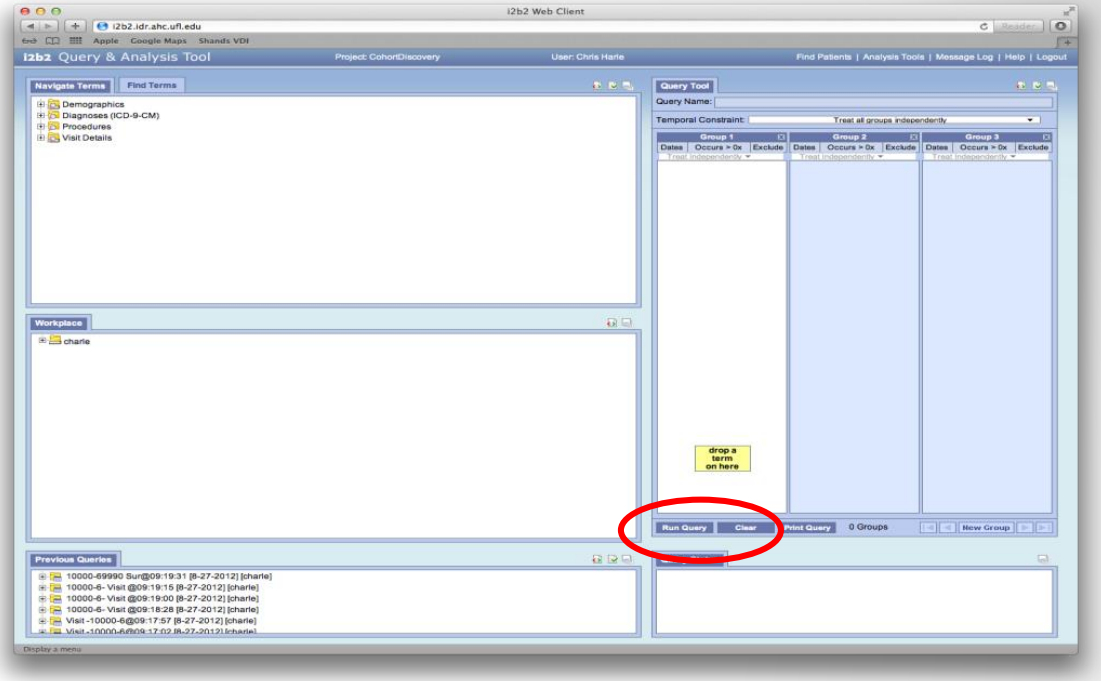


Courtesy: Manini 2013

How many people ages 45+ with a low back pain diagnosis were in the ED in 2013?

i2b2

Informatics for Integrating Biology and the Bedside



N = 3,468 patients

Female: 2,055
Male: 1,413

Black/African American 1,006
White: 2,335
Other: 127

UF UNIVERSITY of FLORIDA

"Consent2Share"

- A process by which patients in the UFHealth System can agree to be contacted by a researcher in the future to ask the patient if they might be interested in a research study.
- Built into the EMR (EPIC)

What Type of Patients Can Agree?

- Any Adult (older than18 years old)
  - Only those that can consent for themselves
  - A wife or husband cannot consent for their spouse

- Any Child (younger than 18 years old)
  - Parent or legal guardian must agree for child
  - If child is >7, child should also agree by signing consent form.
  - When the child turns 18, they have to then consent for themselves

What are patient's consenting to??

- Periodic review of their medical information to see if they might qualify for a future research study, and if so,

- Be contacted sometime in the future about being part of new research studies at UF Health.

Identifying potential research subjects is a key part to a successful research enterprise.

Consent2Share - Process

1. Consent form (eConsent) is included in the group of consent forms provided on the iPad at admission to the clinic
2. This research consent is always the last consent that will appear.
3. Any straight forward questions are addressed by trained admissions staff, other questions can be referred to either their doctor or the Consent2Share Hotline listed on the consent form
4. Patients are given time to review
5. Offer to print out a copy of the research consent if patient wants one.

Pediatric Consent

Protocol #349-2011

VOLUNTARY RESEARCH CONSENT

Unlike the other documents you have just signed, the next document is a request to you to be placed on a list to hear about future research. This is an easy way you can help advance health research today: Consider joining our "Consent2Share" research contact list. By joining the list, you are allowing UF Health to share your contact information with UF researchers when the information in your medical records shows you might qualify for a future research study.

It is your choice to answer yes or no on the following consent form. Answering yes or no will have no impact on the care you will receive from UF Health.

Read the following consent form to learn more, including how your information will be protected and potential benefits and risks of saying yes to participating. If you have questions, talk to the person who gave you this iPad. When you are ready, answer "yes" or "no" on the consent form and complete the electronic signature.

UF Institutional Review Board
UNIVERSITY of FLORIDA

MRN: 02303932 Patient: TEST,ESIGONE Visit Date: 04/24/2015

INFORMED CONSENT FORM
to Participate in research, and
AUTHORIZATION
to Collect, Use, and Disclose
Protected Health Information (PHI)

What they are agreeing to.

Under the name "Consent2Share", the University of Florida and Shands Teaching Hospital & Clinics Inc. (UF Health) are asking for your permission to include you in this Research Contact Registry. If you sign this document, you will agree to:

a. Periodic review of your medical information to see if you might qualify for a future research study, and if so,
b. Be contacted sometime in the future about being part of new research studies at UF Health.

Please read the information below before you decide if you want to participate in this Research Contact Registry. If after you read this, you still have questions, do not sign this form until you talk to your physician or call the Consent2Share Helpline at (352) 265-3282.

The choice to let UF Health review your medical information and contact you later to see if you are interested in joining a future research study is entirely up to you. If you chose not to participate in the registry you will not be penalized or lose any benefits that you would otherwise be entitled to.

If you decide to participate in this research contact registry:

- Your medical record will be flagged as someone who is interested in hearing about research opportunities
- Your name and contact information will be shared with researchers once the researcher has an approved study and your records show that you potentially qualify for the study. Studies are approved by the Institutional Review Board (IRB), which is a committee of scientists, ethicists and community members.
- If you are contacted, you will be told about a specific research study at that time. At that time, you can choose whether or not to be involved in that research project.

Other things you should know:

- Your medical information will be kept in a very safe location (on a password-protected and encrypted computer server).
- If you do not agree, you will not be denied or refused any treatment, payment or enrollment in a health plan, or lose any benefits that you would otherwise be entitled.
- There will be no cost to you for your involvement in this registry.
- Your involvement in this registry might not result in any benefit to you.
- There may be other research studies that involve the review of your medical information, any of which you can choose to participate in.
- You may choose to stop your involvement at any time. You will not be penalized or lose any benefits to which you are otherwise entitled. You can call the Consent2Share Helpline at (352) 265-3282 to have your name removed from the "re-contact" list.
- By signing this document, UF Health will be allowed to collect, use and/or give out your contact and medical information, but only to other researchers whose research is approved by an IRB.

Help line

What are the Risks to Agreeing to be in this Research Contact Registry?

- That your medical data being reviewed by a researcher is given to people that should not have it. Every effort will be made to keep your information secure and confidential. However, there is a small risk that an unauthorized person may see your information. Depending on the information this could affect you and/or your family (for example: embarrass you, cause you anxiety or distress).
- You may be contacted several times for different research studies. If at any time you wish to be taken off the "re-contact registry", you may contact the Consent2Share Helpline at (352) 265-3282.

Signature of Subject providing Informed Consent & HIPAA Authorization
You have been informed about the possible review of your medical information and possible re-contact if you are a potential candidate for a research study. You have also been told of possible benefits and risks, and that you are free not to agree to be in this Research Contact Registry. You have received a copy of this informed consent or have been told where a copy this informed consent is located on a web site. You have been given the opportunity to contact your physician or the Helpline to ask questions before you sign, and you are aware that you can ask other questions at any time.

Please Choose:
If you potentially qualify for a future research study, you agree **to be contacted** about your potential involvement in a research study. These studies will be described to you and you can choose whether or not to participate at that time.

(Please **check** Yes or No, then **sign** below)

Choose "Yes" or "No"

○ Yes ○ No

Parent/Adult Legally Representing the Subject. By signing this form, you voluntarily give your permission for the person named above to participate in this study. You hereby authorize the collection, use and sharing of protected health information for the person named below as described above. You are not waiving any legal rights for yourself or the person you are legally representing. After your signature, please print your name and your relationship to the subject.

Consent & Authorization Signature of Parent/Legal Representative:

Name of Legal Representative:

Relationship to Patient: (•) Parent ( ) Court Appointed Guardian

Participants Who Cannot Consent but Can Read and/or Understand about the Study registry. Although legally you cannot "consent" to be in this study registry, we need to know if you want to take part. If you decide to take part in this study registry, and your parent or the person legally responsible for you gives permission, you both need to sign. Your signing below means that you agree to take part (assent). The signature of your parent/legal representative above means he or she gives permission (consent) for you to take part.

Assent Signature of Participant:

☐ **I verify that I am the legal representative for this child, and that my signature is above.**

If you would like a copy of this form, please ask the staff member to print one out for you.

Clear Form | Ask Me Next Time | Continue

Patient's Decisions

- Potential Subject's Outcomes
  - Clear Form -will print again at next clinic visit
  - They choose yes or no
    - "Yes"– indicated in EPIC, consent will not print again
    - "No"- indicated in EPIC, consent will not print again
  - "Ask Me Next Time" – indicated in EPIC, will print again at next clinic visit
- Enrollment decision lasts unless patient changes their mind
- If a minor, will print again after their 18th birthday
- They can still consent to other research studies

View from the Researcher

- Use i2b2 to query IDR to determine if there are sufficient potential study subjects
- If they need to contact potential subjects, can factor in Consent2Share
- Submit to the IRB, if approved,
- Submit their query to the Consent2Share data hotline – UF Data Management
- List of potential subjects with contact information is provided.

Metrics to Date

34,468 have Consented to Share (147 peds)

Total Patients asked to Participate (N = 42,476)				
	Yes		No	
4/30/2017	n	%	n	%
Adult	34,321	81%	8,155	19%
Peds	147	56%	114	44%
Total (n)%	34,468	81%	8,269	19%

- 43 studies have used Consent2Share to identify patient cohorts (nearly all funded by industry)
- 17,351 potential study subject's names provided to investigators
- 8 patients have withdrawn from Consent2Share

UF UNIVERSITY of FLORIDA

Lesson's Learned

- Started out in a large medical subspecialty clinic with a paper consent printed from the EMR, asked for re-contact and left over tissue
- After signed, would be scanned into the EMR
  - Self audit discovered 75 consents we couldn't find
  - Stopped study, did a complete audit of 10,000 consent forms
- Simplified the consent form and eliminated tissue collections, reviewed each consent
- Moved to an EMR generated eConsent
  - Allowed expansion of program
  - Lower costs

Journal of Clinical and Translational Research 2016; 2(4): 113-122

Journal of Clinical and Translational Research

Journal homepage: http://www.jctres.com/en/home

ORIGINAL ARTICLE

Consent2Share: an integrated broad consenting process for re-contacting potential study subjects

R Peter Iafrate[1*], Gloria P Lipori[2], Christopher A Harle[3], David R Nelson[4], Timothy J Barnash[5], Patricia T Leebove[6], Kathleen A Adams[6], Debbi Montgomery[7]

1 Institutional Review Board, University of Florida, Gainesville, Florida, United States
2 Operational Planning & Analysis, University of Florida Health and University of Florida Health Sciences Center, Gainesville, Florida, United States
3 Department of Health Policy and Management, Indiana University, Indianapolis, Indiana, United States
4 Department of Medicine, University of Florida, Gainesville, Florida, United States
5 Practice Management Applications, UF Health Physicians, University of Florida, Gainesville, Florida, United States
6 Medical Specialties and Transplant Clinic, UF Health Physicians, University of Florida, Gainesville, Florida, United States
7 Information Technology, UF Health, Gainesville, Florida, United States


Questions at the end
St. Augustine, Florida

#3 Kate Wilkinson
University of Texas Southwestern

UT Southwestern
Medical Center

Recruiting Patients for Clinical Research: UTSW Volunteer Research Participant Registry

Registry Objectives

- Link UT Southwestern patients with clinical research opportunities.
- Focus on a consumer-friendly marketing initiative.
  - *Identified lack of marketing/education as a barrier to success for other institution's registries.*
- Improve the efficiency of research recruitment.

Registry Planning

- Reviewed multiple other institutional registries

UCSF Medical Center

Washington University in St. Louis School of Medicine

VANDERBILT HEALTH

University of Pittsburgh

UNIVERSITY OF MICHIGAN

BOSTON UNIVERSITY

UNC MEDICAL CENTER
UNC HEALTH CARE

UFHealth
UNIVERSITY OF FLORIDA HEALTH

MUSC Health
Medical University of South Carolina

Registry Planning- Team Effort

Developed concept and planned execution with a wide variety of experts:

Marketing

Health Systems/ Ambulatory Services

Dallas Heart Study

Legal Affairs

Academic Information Services

EHR Team

Center for Translational Medicine

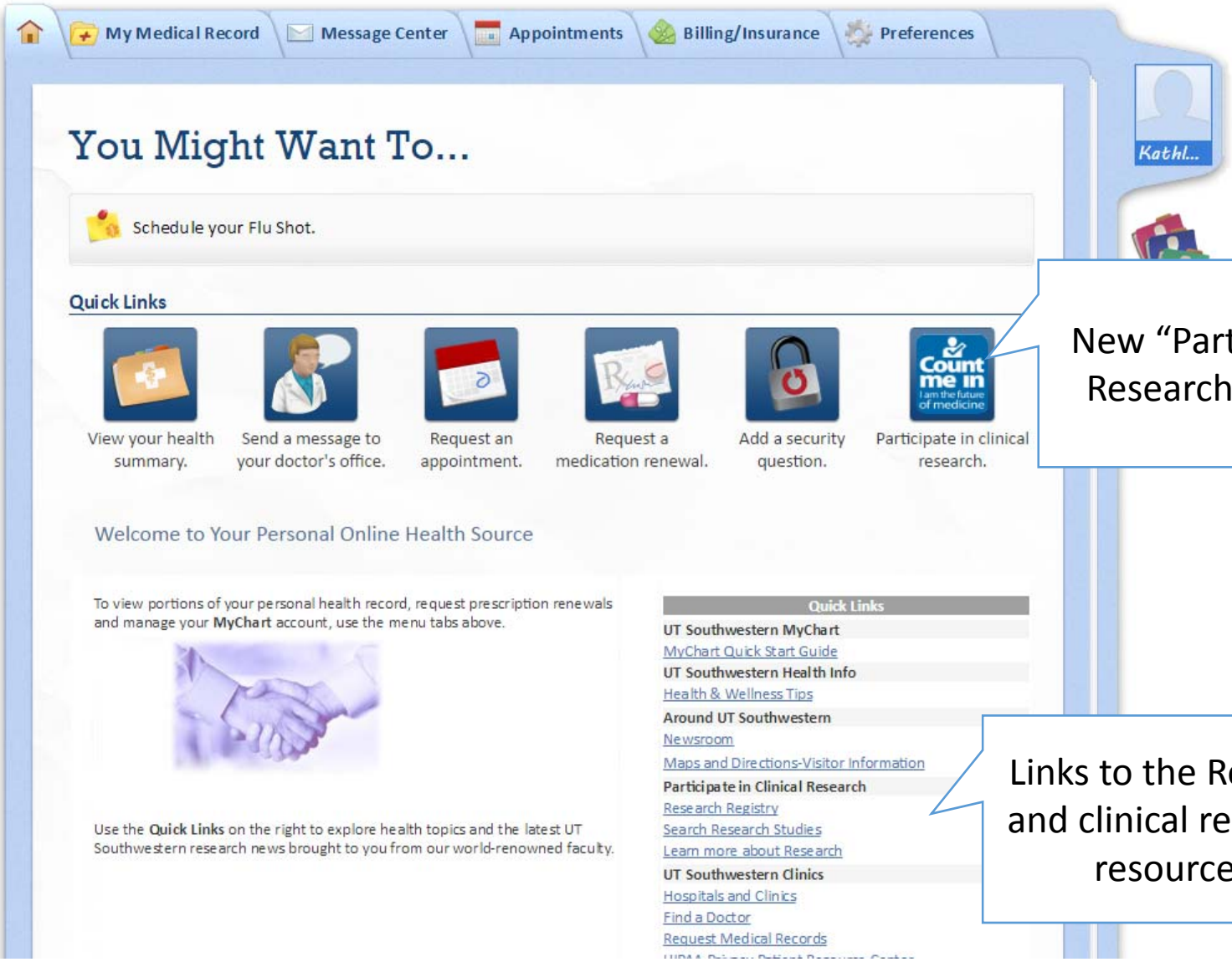
Research Administration

UT Southwestern Medical Center

Registry Planning

- Sought input from a **focus group (12)** of experienced research coordinators.
  - *Why do people participate in research?*
  - *What is important to participants?*
- Created a **5 minute video** (marketing + consent information)

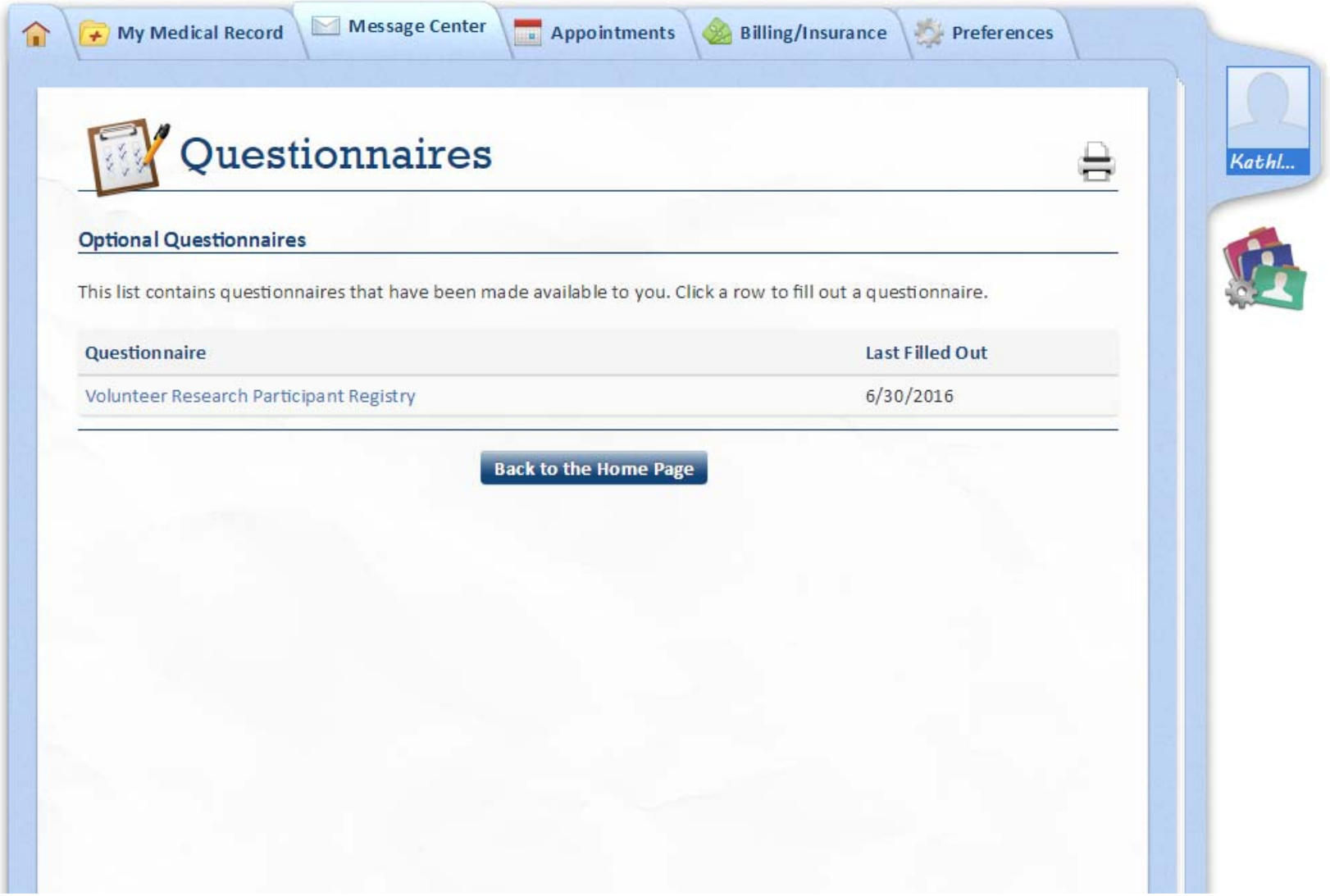
MyChart Homepage



New “Participate in Research” Button

Links to the Registry and clinical research resources

Questionnaires



MyChart Registry Questionnaire

Volunteer Research Participant Registry

The University of Texas Southwestern Medical Center,
Zale Lipshy University Hospital, William P. Clements Jr. University Hospital

VOLUNTEER RESEARCH PARTICIPANT REGISTRY

The University of Texas Southwestern Medical Center (UTSW) is committed to providing the best healthcare possible to our patients. As part of this commitment we offer the opportunity for future participation in medical research aimed at improving detection, prevention, diagnosis and treatment of disease. We have created a Research Recruitment Registry that is made up of people like you who are interested in learning about future medical research opportunities.

If you agree to be added to this Research Recruitment Registry, you are agreeing to be contacted in the future to see if you are interested in volunteering for a research study at UTSW or to give you general information about research and the Registry. We will only use the contact information you have provided to UTSW. Eligibility for a research study is usually based on information in your medical record. Any future study will be described to you and you can choose whether or not to participate at that time.

Your care will not be affected in any way based upon your decision to participate in the Research Recruitment Registry or in any future research study. The choice to participate is entirely up to you. You may choose to withdraw from the Registry at any time by contacting the Research Participant Advocate at 214-648-5005. If you have any questions or would like any additional information regarding the Research Recruitment Registry, please contact 214-648-5005 or researchregistry@utsouthwestern.edu.

UT Southwestern respects the privacy of your health care records. Information about you in the Registry is protected just like your healthcare record and is stored and transmitted in a secure system. As with all electronic health records, there is a risk of loss of confidentiality; therefore, every effort will be made to keep your information secure and confidential. Comprehensive information about the Registry is contained in the accompanying FAQ sheet and at www.utswmedicine.org/researchregistry .

* Indicates a required field.

* **Do you agree to be added to the Research Recruitment Registry?**

By clicking on the "I agree" button below, you agree to (1) **be added** to the Research Recruitment Registry and (2) potentially **be contacted** about volunteering for a research study.

✓I AGREE

NOT AT THIS TIME

I DECLINE

Continue > Finish Later Cancel

Questionnaire is always available to view in MyChart with status. Participant can change status at anytime.

Confirmation Emails

Confirmation of Enrollment

NoReply-ResearchRegistry to me 12/6/16

We Can Count You In!

Thank you for enrolling in The UT Southwestern Research Participant Registry. Without volunteers like you, clinical research simply is not possible.

What Happens Next?

We may contact you about a study soon, at some point in the future, or not at all. If we have a study you may qualify for, a researcher will contact you. At that time, you can choose to learn more about the study and begin the informed consent process, or you can decline to participate in the study.

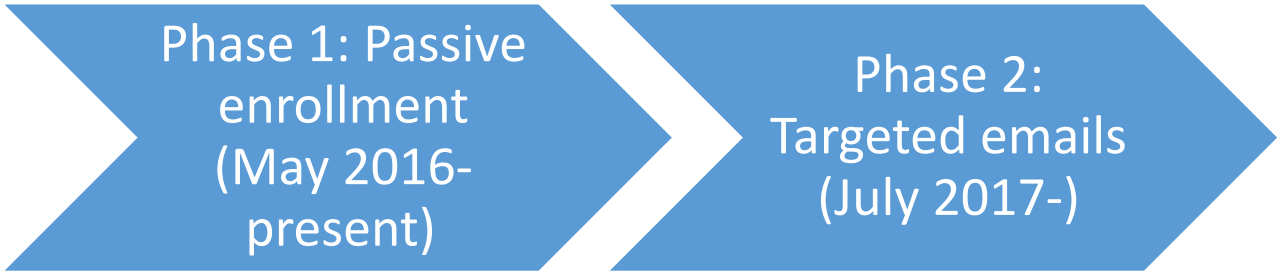
You are a valuable part of our research community at UT Southwestern whether or not we contact you or if you participate in a study. We sincerely appreciate your willingness to be a research volunteer.

Everyone who enrolls in the Research Participant Registry will receive an email newsletter to keep you informed of research progress and news at UT Southwestern.

More Information

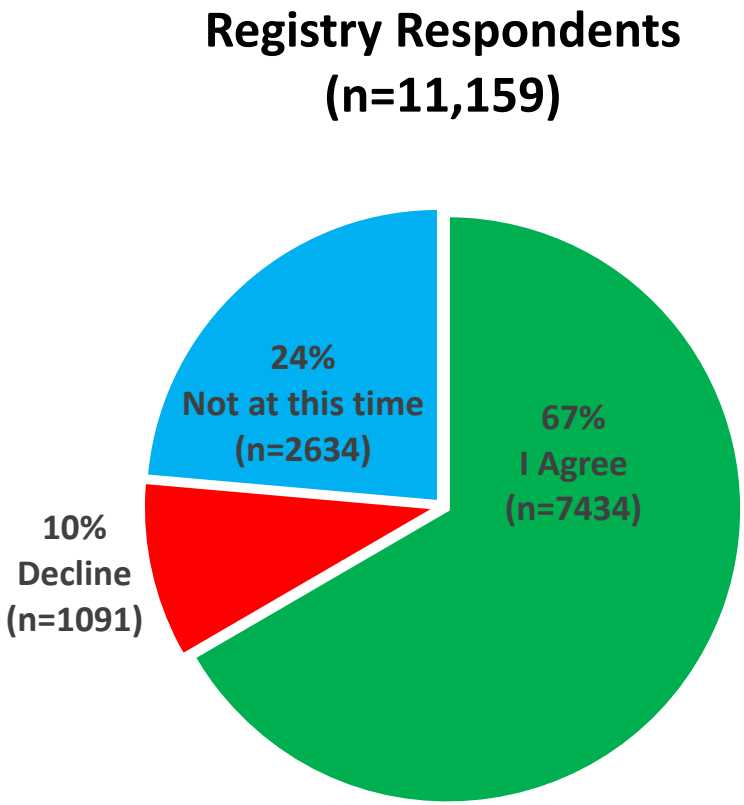
Please visit our website to learn more about being a research volunteer and watch a video about the Research Participant Registry. The video shows patients just like you who have chosen to participate in research at UT Southwestern.

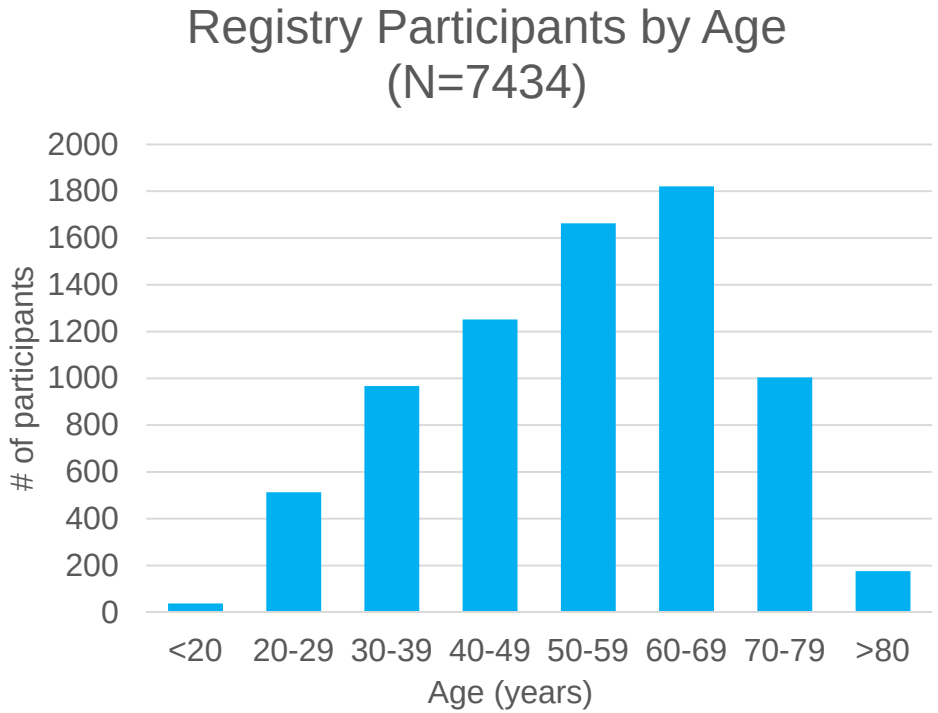
Enrollment in the Registry



- Central Recruitment office (1.8 FTEs) available via phone and email to answer any questions about participation.

Phase 1: Passive Recruitment

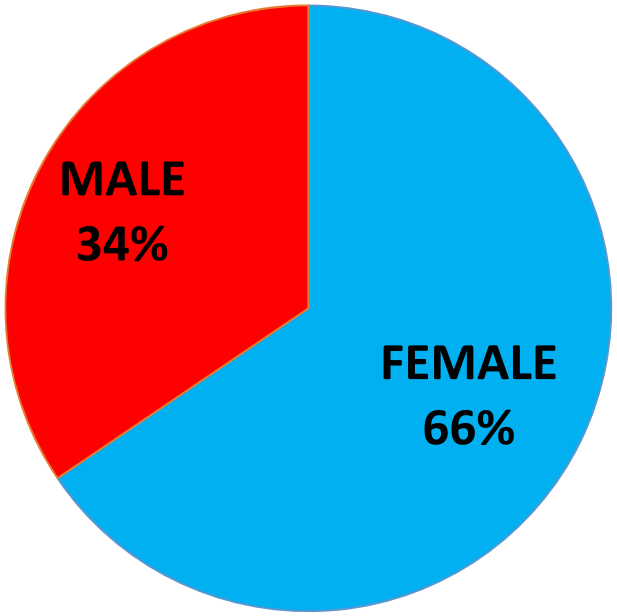




UT Southwestern Medical Center

Phase 1: Passive Recruitment

Registry Participants by Sex



Other Demographics:

- 7% Hispanic
- 9% African American
- 77% White

How to use the Registry to Recruit Participants

Select “UTSW Volunteer Research Participant Registry” as recruitment method in eIRB smartform.

Investigators can identify Registry participants through i2b2 (Clinical Research Data Warehouse) query.

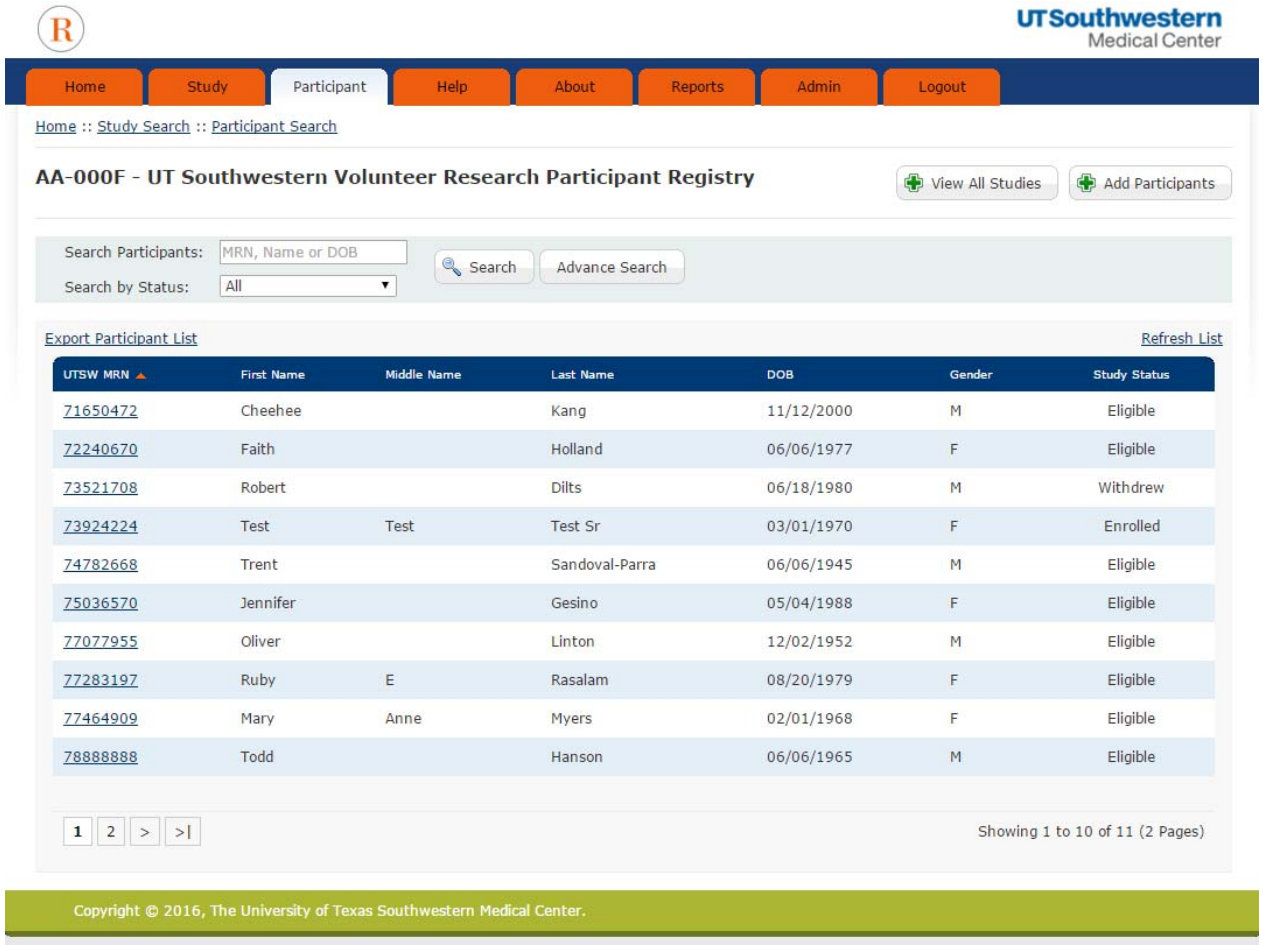
Research staff will be able to access participant list and contact information through tracking system.

Registry Logistics

- Release 25 registry participants at a time
  - Require outcomes (enrolled, refused, not able to contact) before new participants are released.
- Participants only released to one study at a time.
- Participants released every 3-6 months.

Tracking System

- Open-source (PHP) tracking system built based on successful tracking system used by a longitudinal study (10+ years)



Pilot Recruitment Results

- 3 studies piloted use of Registry for recruitment
  - Facial Aging: 14 enrolled
  - Depression: 3 enrolled
  - Anxiety: 2 enrolled

- 3 other studies just received initial Registry participant lists
  - Cluster Headache
  - Alzheimer's Disease
  - Depression & Asthma

Questions?

Kate Wilkinson
Kathleen.Wilkinson@utsw.edu

Sarah Lynch
Sarah.lynch@utsw.edu

Blair Holbein, PhD
Blair.Holbein@utsw.edu

http://www.utswmedicine.org/patients-visitors/research/