Conducting Technology-mediated Research in VHA: Lessons Learned and Recommendations

Laura J. Damschroder, VA Ann Arbor Healthcare System

Joseph Holston, VA ORD Program Analyst; former Senior Research ISO

HSR&D Special Topic CyberSeminar
17 May 2018

VA CENTER FOR CLINICAL MANAGEMENT RESEARCH
Ann Arbor HSR&D Center of Innovation

U.S. Department of Veterans Affairs
Veterans Health Administration
VA Ann Arbor Healthcare System

Disclaimer

The views expressed in this presentation are our own and do not reflect the position or policy of the Department of Veterans Affairs or the United States government

Outline

- **Setting the Stage: VA Research Landscape for Technology**
- **"Stay Strong:"The project**
- **Breaking it down and Pulling it All Together**
  - Recruiting
  - Market Place v Research Pace
  - Disclosures & Privacy Protections
  - Onboarding
    - Mobile technologies
    - Survey/data collection
  - Contracting
  - IRB Process
- **Last Words**
- **Q&A**

VA Research at a Glance...

- **Our research community**
- **Our subjects/participants and the science that's helping**
- **The data and its characteristics**

Technology Woes in Research…

- **Hindered collaborations lead to missed opportunities**
- **Lack of IT support and troubles getting approval for specialized software/equipment**
- **Inadequate storage**

How Did We Get Here?

- **Both events frame the difficulties we're experiencing in attempting to implement technology in research**
  - The 2007 "Breach"
  - VA OIG Audit of Research: findings and recommendations

Stay Strong:

A physical activity program for Afghanistan and Iraq Veterans

FUNDED BY HSR&D CRE 12-305

It Takes a Village

- **Principal Investigators**
  - Dr. Caroline Richardson: Developer and PI 2012-2015
  - Laura Damschroder: PI 2015 – Present
- **Co-Investigators**
  - Dr. Gene Oddone (CREATE PI, Durham, NC)
  - Dr. Jennifer Gierisch (Site PI, Durham, NC)
  - Dr. Lori Bastian (West Haven, CT)
  - Dr. Laurie Buis (Ann Arbor, MI)
  - Dr. Hyungjin (Myra) Kim (Ann Arbor, MI)
  - Dr. Maren Olsen (Durham, NC)
  - Mona AuYoung (San Diego, CA)
- **Project Management**
  - Felicia McCant (Durham, NC)
  - Reema Kadri (Ann Arbor, MI)
  - Maria Hughes (Ann Arbor, MI)

- **Lifestyle Coaching**
  - Courtney White-Clark (Durham, NC)
- **Project Team**
  - Bradley Dokter (Durham, NC)
  - Gwendolyn Hooks (Ann Arbor, MI)
  - Jennifer Burns (Ann Arbor, MI)
  - Richard Evans (Ann Arbor, MI)
  - Rob Holleman (Ann Arbor, MI)
  - Jordan Sparks (Ann Arbor, MI)
  - Eric DeRycke (West Haven, CT)
- **Contracting/Purchasing**
  - Kimberly Beers (Ann Arbor, MI)
  - Mike Robertson (Ann Arbor, MI)
- **cIRB Support**
  - Joseph Holston, former Sr. Research ISO
  - Patricia Christensen, former cIRB Privacy Officer

Poll Question

- **Are you involved in technology-mediated research in VA?**
  - Never
  - In the past
  - I am now
  - I'd like to be

Poll Question

- **Have you had problems implementing technology in research?**
  - No problems
  - Some problems
  - Significant problems
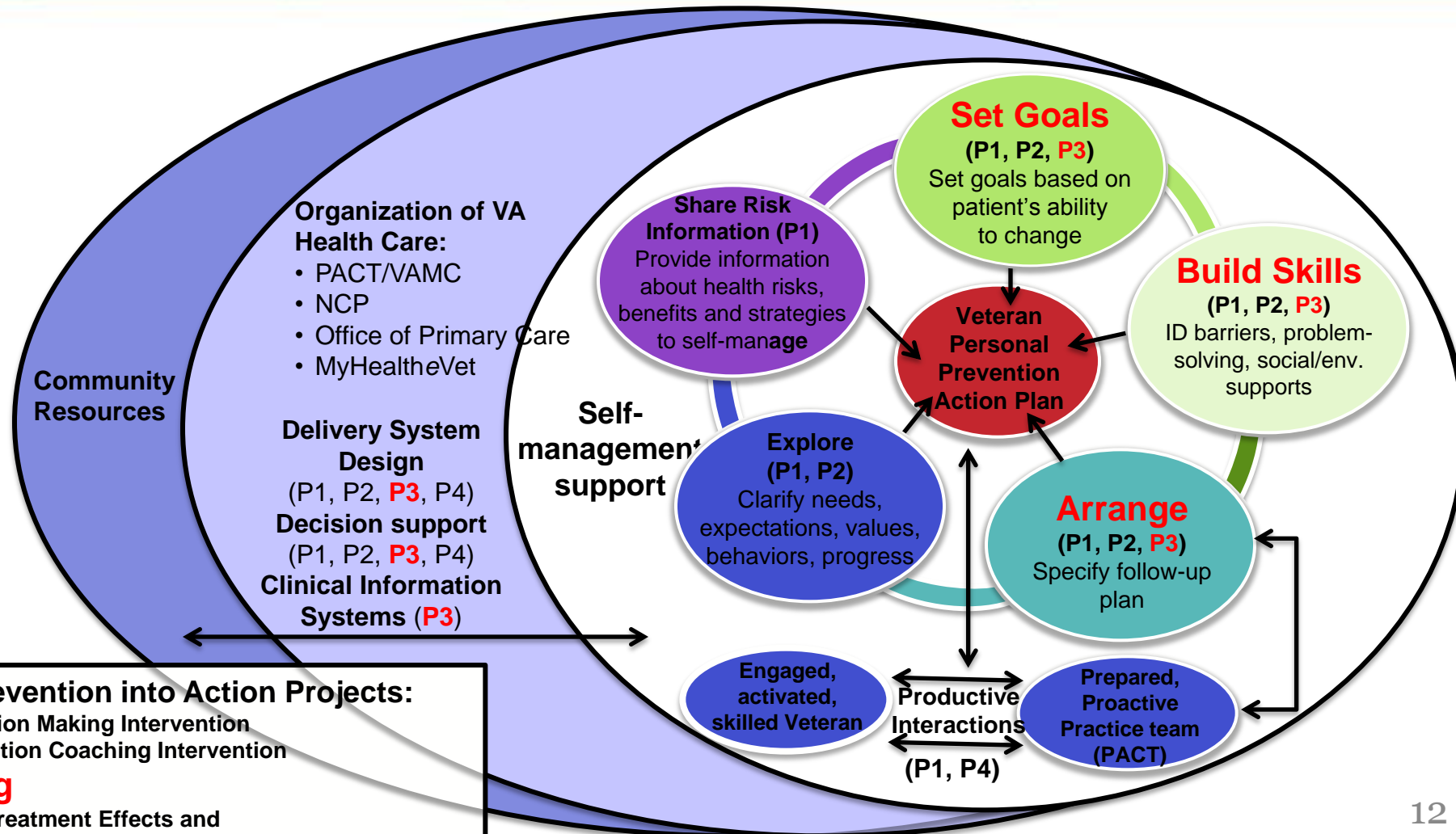 - I've never tried

Poll Question

- **What has the impact of technology challenges been on your projects?**
  - No impact
  - Minor delays
 - Major delays
  - Unable to complete
  - N/A

Stay Strong

Community Resources

Organization of VA Health Care:
- PACT/VAMC
- NCP
- Office of Primary Care
- MyHealth*e*Vet

Delivery System Design
(P1, P2, **P3**, P4)
Decision support
(P1, P2, **P3**, P4)
Clinical Information Systems (P3)

Self-management support

Share Risk Information (P1) Provide information about health risks, benefits and strategies to self-man**age**

Set Goals (P1, P2, P3) Set goals based on patient's ability to change

Build Skills (P1, P2, P3) ID barriers, problem-solving, social/env. supports

Veteran Personal Prevention Action Plan

Explore (P1, P2) Clarify needs, expectations, values, behaviors, progress

Arrange (P1, P2, P3) Specify follow-up plan

Engaged, activated, skilled Veteran

Productive Interactions (P1, P4)

Prepared, Proactive Practice team (PACT)

Transforming Prevention into Action Projects:
P1: HRA Shared Decision Making Intervention
P2: Group Visit Prevention Coaching Intervention
P3: Stay Strong
P4: Heterogeneity of Treatment Effects and
    Targeting of Prevention Programs Study

Prevention CREATE: 4 Projects

	P1: HRA Trial	P2: Group Prevention Clinics	P3: Stay Strong
Patients	Lower risk PACT patients	Higher risk, more complex PACT patients	Young, at risk Veterans who may not use VHA frequently
Mode of Intervention Delivery	Health Risk Assessment Brief Telephone Lifestyle Coaching	In-person groups & Telephone	Smartphone app & Telephone Coaching
Outcomes	• Patient Activation • Enrollment in prevention program • CVD Risk	• Patient Activation	• Patient Activation • Avg daily minutes of mod/vig activity • Weight change
P4: Heterogeneity of treatment effects			
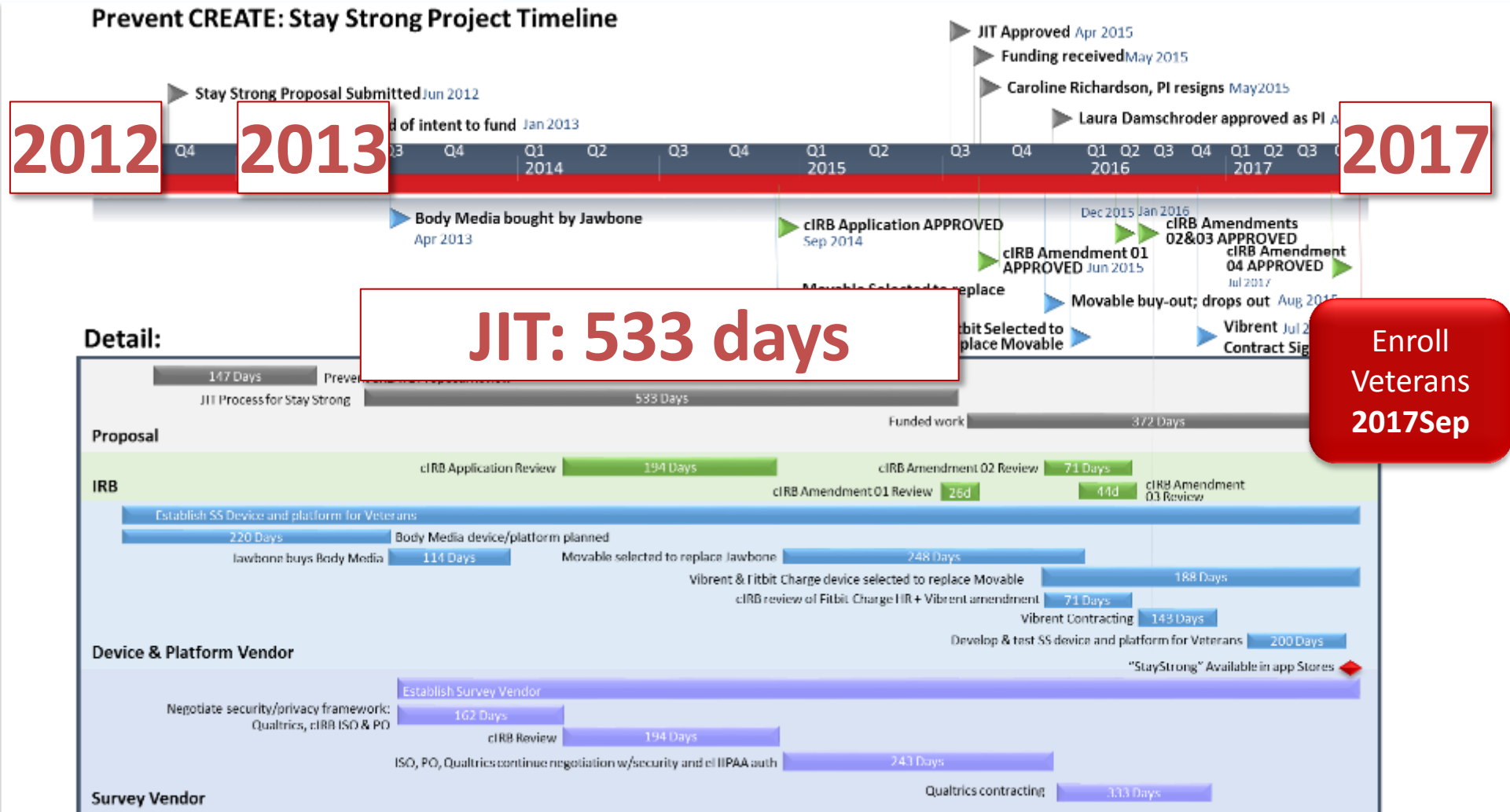
Recruiting

```
┌─────────────────────────────────────────┐
│  Electronically Screened National       │
│           Sample (CDW)                  │
│     N=30,000 OEF/OIF/OND Veterans       │
└─────────────────────────────────────────┘
                   │
                   ▼
┌─────────────────────────────────────────┐
│        Send Invitation Letter           │
│  Link to Online Survey with Personalized Code │
└─────────────────────────────────────────┘
```

Recruiting…

- **Notes on recruiting by vendor**
  - Sending subject info
  - Storage of subject info
  - Return or destruction of info

Electronically Screened National Sample (CDW)
N=30,000 OEF/OIF/OND Veterans

Send Invitation Letter
Link to Online Survey with Personalized Code

Online Consent & HIPAA Authorization

qualtrics
Q

Disclosure & Privacy Protections

- **Informed Consent**
  - Full disclosure
    - List of devices with full descriptions of each
    - Data syncing via what technologies (e.g., Fibit Connect software, Vibrent app, Fitbit servers)
    - Electronic data storage: outside the VA firewall
      - Multiple Locations: Each is described
    - Transmission of data
    - Technical issues
    - Risks
    - Protections in place

- **HIPAA Authorization**

(Copy of materials available upon request)

The Power of Informed Consent

- **Gaps in IT policy concerning consented data**
- **What does VA HB 1200.05 say about subject consent and data?**
- **Application of the subject consent clause**
- **Aligning Terms & Conditions with informed consent**

Market Place v Research Pace

BODYMEDIA® — **2012**

JAWBONE® — **2013**

movable INSPIRING MOVEMENT — **2013**

2015

fitbit + vibrent

Stay Strong

Start Work: 2016
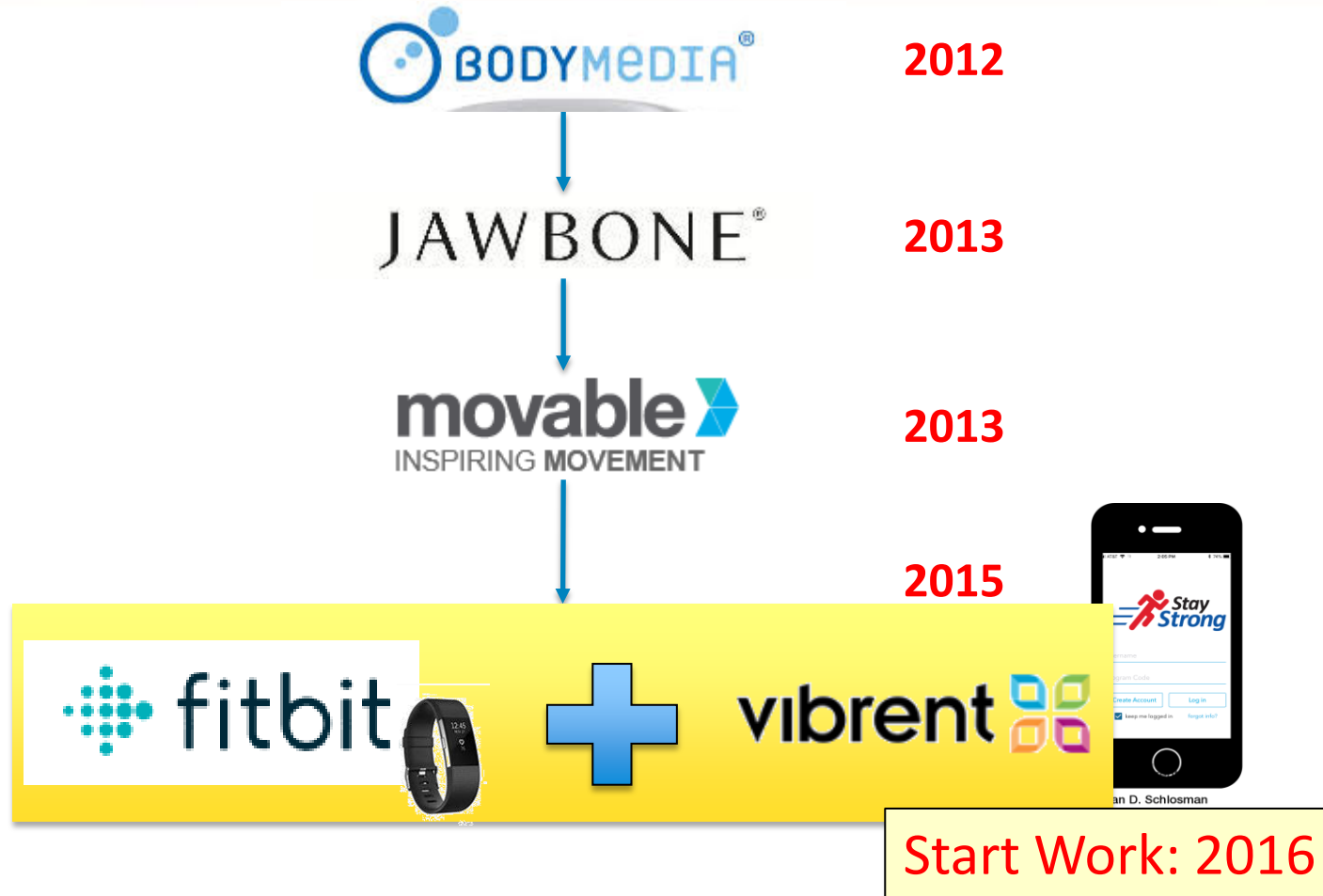
Stay Strong Configuration
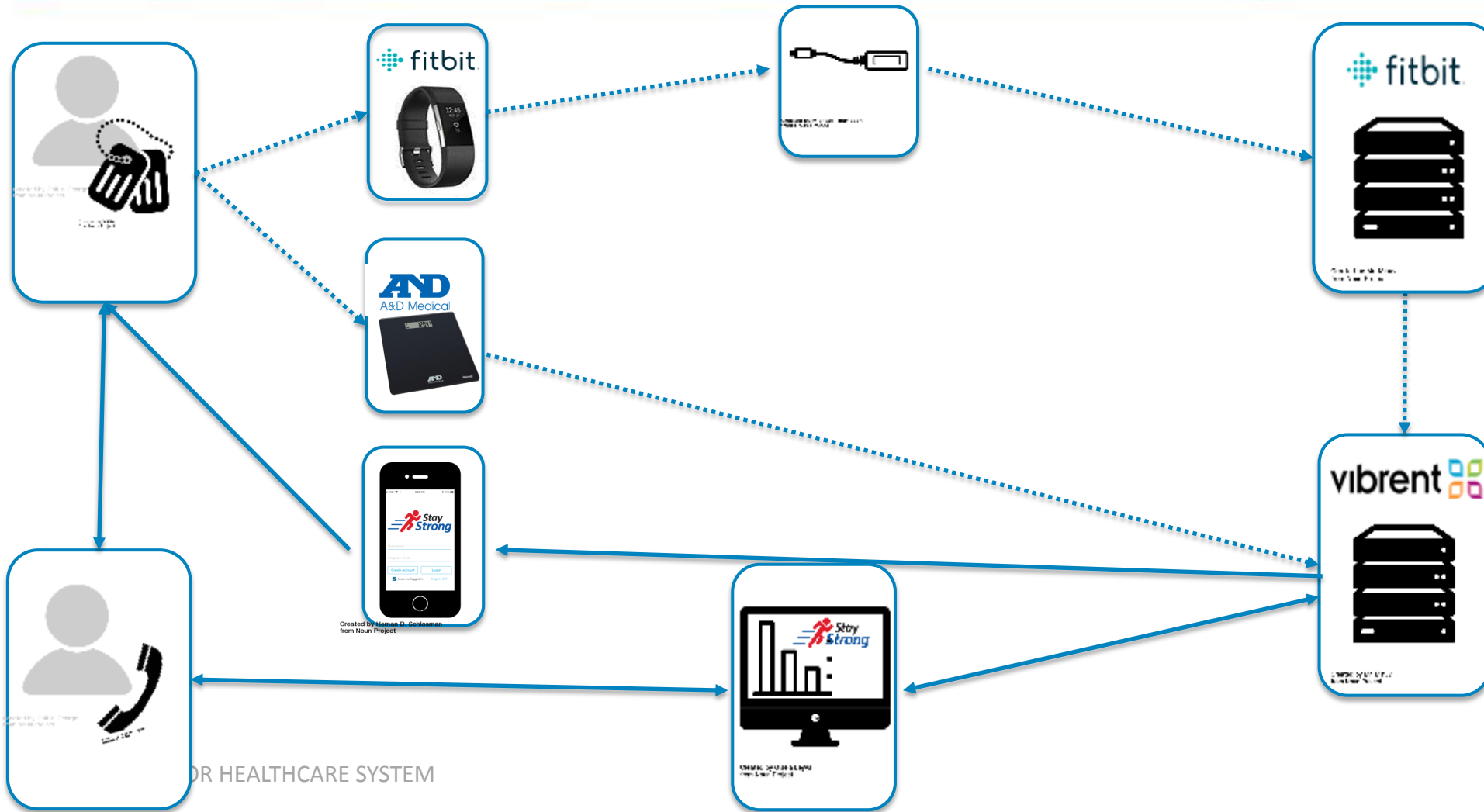
On-boarding Vendor: Mobile Technology and More

- Vibrent/Fitbit solution submitted to cIRB
- Vibrent approved by cIRB

Sep-Dec 2015

Develop Statement of Work (SOW)

6500.6 Security Checklist Completed

SOW submitted to Contracting
- Sole source justification rejected.
- Several rounds of questions from vendors

Jan 2016

Vibrent is awarded contract

Mar 2016

RV System Inventory Checklist Adventure
- We are told we must go through FedRAMP

Apr-Jun 2016

Contract Signed → Cleared to Start Work

Jul 2016

CSCA Security Checklist Completed

Jul 2016

Considerations for Mobile Device Vendor Selection...

- **What is a mobile device/how defined?**
  - Laptops, USB/flash, smartphones, tablets
- **Questions to ask yourself:**
  - Sensitivity of responses being solicited?
  - Equipment needed: VA, affiliate, subject owned?

Regulation of Mobile Devices in VA Research…

- **Policies that guide our thinking when planning for use of mobile devices:**
  - VA HB 6500
  - VHA HB 7002
- **Network Access, VA Data, Encryption**
- **Inventory, Data Storage and Destruction**

Stay Strong Configuration
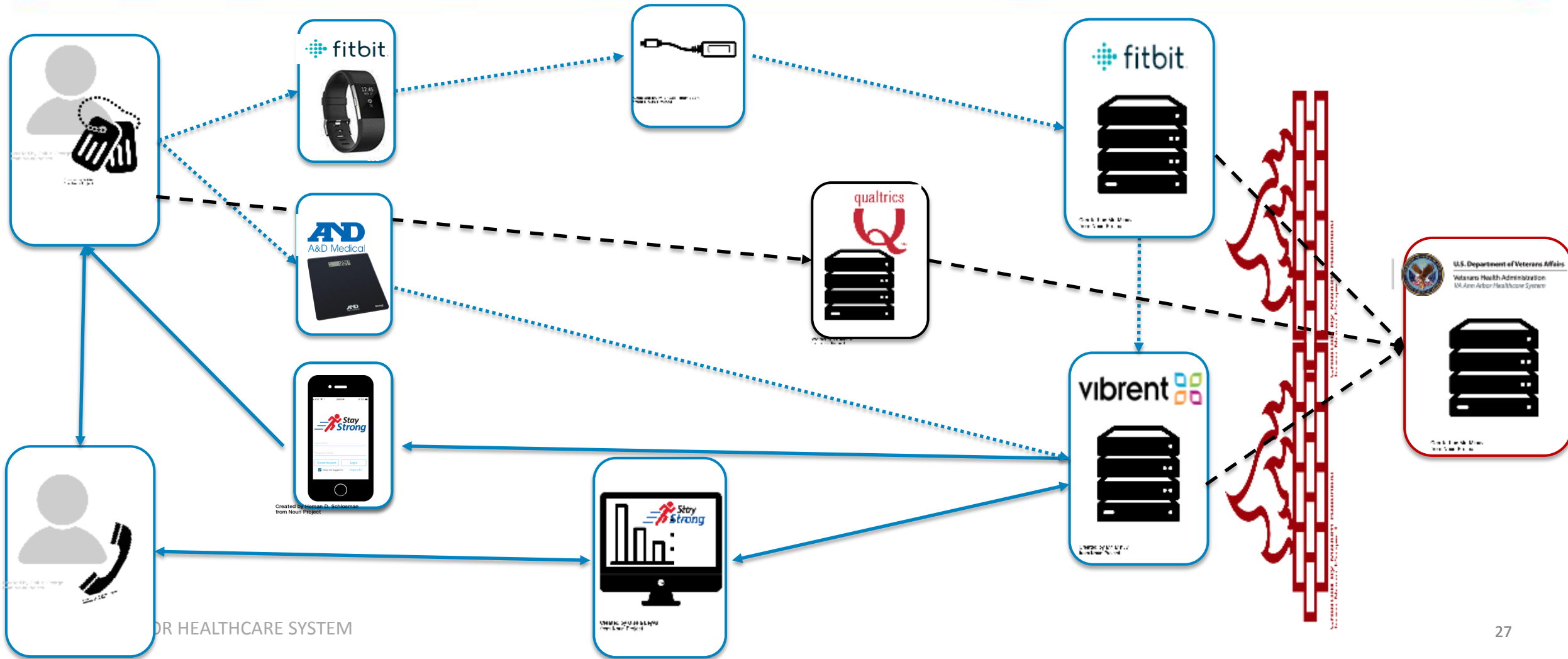
On-boarding Vendor: Survey Data Collection & Management

- Consultation with cIRB ISO (Joe Holston)

  Mar 2013

Consultations & negotiations
- cIRB ISO, cIRB PO, SS PI and co-Is

  Apr 2013

NOTE: cIRB Approval Process

Team is informed of need to meet FISMA standards
- Qualtrics commits to meet FISMA standards
- SW is FIPS 140-2 compliant
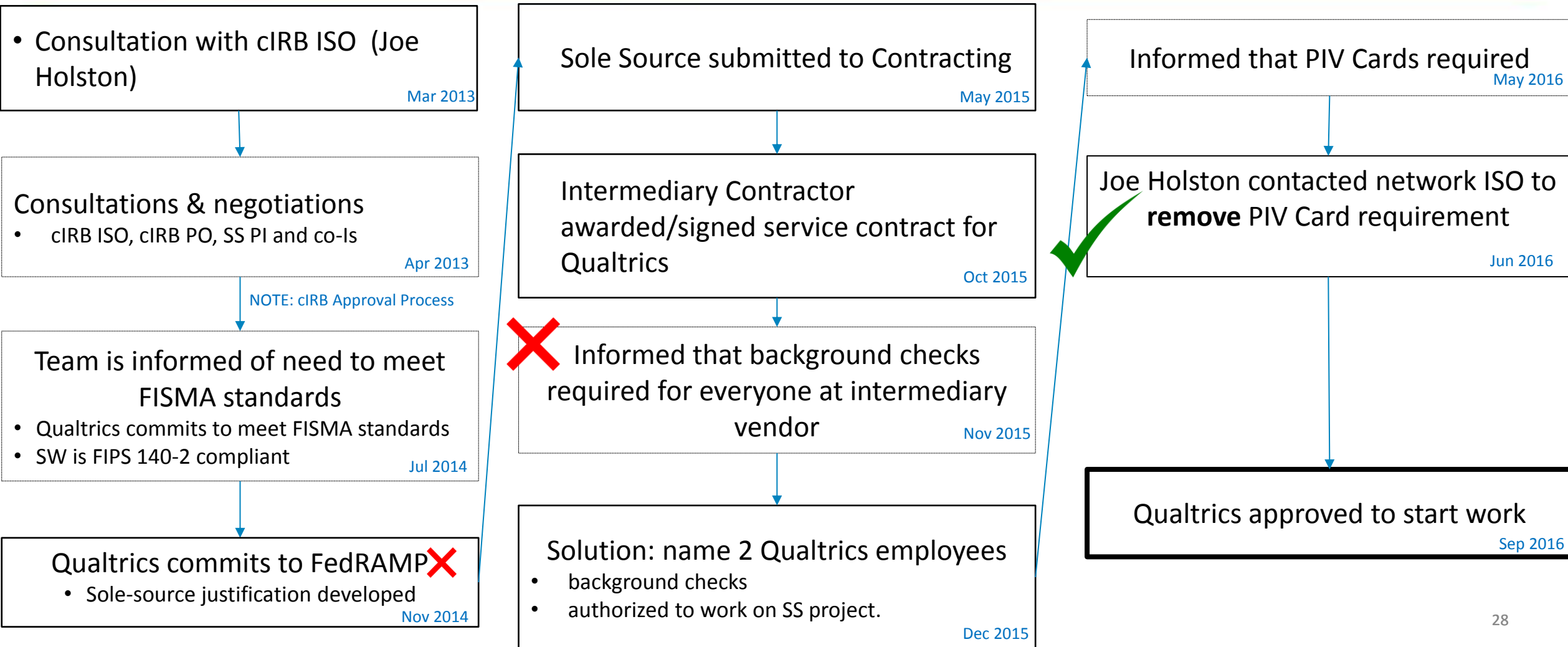
  Jul 2014

Qualtrics commits to FedRAMP ✖
- Sole-source justification developed

  Nov 2014

Sole Source submitted to Contracting

  May 2015

Intermediary Contractor awarded/signed service contract for Qualtrics

  Oct 2015

✖ Informed that background checks required for everyone at intermediary vendor

  Nov 2015

Solution: name 2 Qualtrics employees
- background checks
- authorized to work on SS project.

  Dec 2015

Informed that PIV Cards required

  May 2016

Joe Holston contacted network ISO to **remove** PIV Card requirement ✔

  Jun 2016

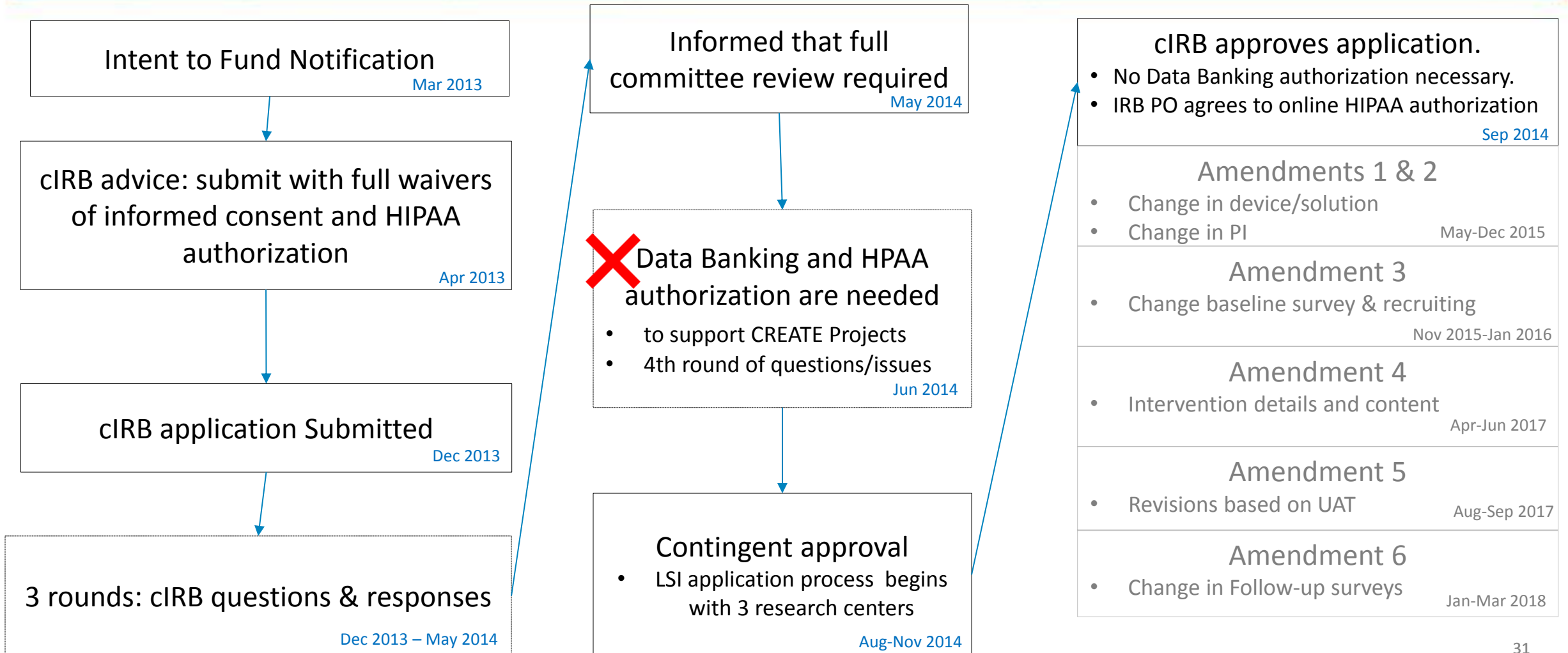Qualtrics approved to start work

  Sep 2016

Considerations When Evaluating Technologies...

- **Method of survey: how are users providing responses?**
- **Data class?**
  - de-identified
  - Coded
  - consented
- **Data Sensitivity?**
- **Privacy and data protection requirements as mandated by policy?**
- **Prior vetting?**
  - Service Catalogue
  - FedRAMP, etc

Contracting & Purchasing

- **Vendors MUST be in "SAM" system**
  - System for Award Management
  - Get "solid" representative from the Vendor before contracting

- **Service v "Goods" contracts**
  - Be careful to specify in your Budget Justification
    - TYPE of contract
  - Blanket purchase agreements

- **Work with your local contracting officer representatives**
  - And get "checklist" of process AHEAD of time
  - Research Acquisition Center: South Atlantic Office (Pittsburgh, PA)
    - Research focused

IRB Approval Process

Intent to Fund Notification
Mar 2013

↓

cIRB advice: submit with full waivers of informed consent and HIPAA authorization
Apr 2013

↓

cIRB application Submitted
Dec 2013

↓

3 rounds: cIRB questions & responses
Dec 2013 – May 2014

Informed that full committee review required
May 2014

↓

❌ **Data Banking and HPAA authorization are needed**
- to support CREATE Projects
- 4th round of questions/issues
Jun 2014

↓

Contingent approval
- LSI application process begins with 3 research centers
Aug-Nov 2014

cIRB approves application.
- No Data Banking authorization necessary.
- IRB PO agrees to online HIPAA authorization
Sep 2014

Amendments 1 & 2
- Change in device/solution
- Change in PI
May-Dec 2015

Amendment 3
- Change baseline survey & recruiting
Nov 2015-Jan 2016

Amendment 4
- Intervention details and content
Apr-Jun 2017

Amendment 5
- Revisions based on UAT
Aug-Sep 2017

Amendment 6
- Change in Follow-up surveys
Jan-Mar 2018

Will the IRB Approve My Use of Technology?

- **General policy requirements for the use of technology in research**

- **ISO role on local IRBs**

- **IRB technology review and approval**

Poll Question

- **What have been your greatest challenges?**
  - Lack of clear policies
  - Someone told us we can't use the technology
  - Trouble collaborating with others outside VA
  - Issues with data management/storage
  - Other

Last words

- **Laura**
  - Be informed
  - Role of Informed Consent
    - "Minimal risk?"
    - Balancing risk reduction with participant burden/autonomy
  - IRBs
    - Local v Central
  - Support is available
- **Joe**
  - Technology is the "future" of research. ORD is working on making this fact a reality in VA
  - New ISSO group dedicated to the management of research security issues
  - Commitment to assisting local sites push for the use of devices, software, etc. that promote research

Questions & Contact

Contact:

Joseph.Holston@va.gov

Laura.Damschroder@va.gov