Putting real-time participant feedback into the hands of investigators

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Associate Professor, Center for Clinical Translational Science
The Rockefeller University
First, the landscape........
What we do now.....

Facilitate Translational Science to Improve Human Health

INPUTS ➔ ACTIVITIES ➔ OUTPUTS ➔ EFFECTS ➔ Functionalized Knowledge

- Recruitment expertise
- Community engagement expertise
- Cultural competence
- Studios
- CABs
- Patient panels
- Research team expertise

- Patient engagement
- Community engagement
- CEnR
- Recruitment outreach
- Align incentives
- Patient-centered design
- Culturally-appropriate advertising
- Population-customized advertising

- Better recruitment
- Better retention
- Representative cohorts
- Papers Accepted
- Methods Advanced

- Faster study completion
  
  Results applicable to affected populations
  
  Best practices

- Improve Human Health
- Reduce Health Disparities
#1 – Do you/investigators at your institution collect participants’ feedback about their research experiences?

Select all that apply:

- Yes --Generally investigators DO collect feedback
- No – Generally investigators DO NOT collect feedback
- Yes --We have an institutional program to collect participant feedback
- No - No institutional program to collect participant feedback
- I don’t know whether participant feedback is collected
Evaluation - Causal Pathway

**Inputs**
- Patient engagement
- Community engagement
- CEnR
- Recruitment outreach
- Aligning incentives
- Assess participant experiences during research

**Activities**
- Participant experience data
- Data-driven Patient-centered design
- Pragmatic /adaptive design
- Responsive design

**Outputs**
- More.......
  - Trust
  - Sense of partnership
  - Patient & Community-centeredness
  - Communication
  - Respect
  - Felt listened to
  - Better participant experiences

**Effects**
- Faster study completion
- Results applicable to affected populations
- Best practices

**Functionalized Knowledge**
- Facilitate Translational Science to Improve Human Health
- Improve Human Health
- Reduce Health Disparity
• #2 – Would it be valuable to investigators to have real-time feedback from participants (and when)?

Select all that apply:

- Around/after recruitment
- Around/after Informed consent
- During conduct/at specific milestones (e.g. crossover, withdrawal)
- At the end of the study
- No, I don’t think this information would be valuable
#3 – Do you have standard tools to collect feedback

Select all that apply:

- Email / mail survey
- Mobile app survey
- Survey through patient portal
- Research Participant Perception Survey, or derivative
- Other
Development of the Research Participant Perception Survey

Vision

To develop validated measure(s) of the human subjects protections such as the informed consent process, and obtain actionable data about participant’s experiences in order to improve the experience and enhance research recruitment, retention, and integrity.
Research Participant Survey Acknowledgements

The Clinical Center at NIH
  David Henderson
  Laure Lee
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  Joel Correa da Rosa
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  Jennifer Yessis
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  Jean Larson
  Sandra Alfano

Feinstein Medical Institute, LIJH
  Cynthia Hahn

*CTSA institution
Research Participant Perception Survey Project - Methods

Part I

- NIH Clinical Center
- Public/private partnership – NRC-Picker
- 34 CTSA/GCRCs provided early design input
- 8 CTSA/GCRC collaborated for the first study
- Rockefeller CTSA grant: UL1RR024143
- NIH/NCRR SO7 Award: S07 RR018141
Research Participant Perception Survey Project - I

- Participants
  - 45% male
  - 50 yrs old (19-86)
  - 58% white
  - 28% African American
  - 2% Asian
  - 2% Native American
  - 9% Not reported

- Education
  - 13% < high school
  - 28% some college
  - 31% college graduate
  - 26% graduate education

- Experience
  - 1-20 protocols experience
Research Participant Perception Survey Project - Methods

Part I

Focus Groups

• Participants & stakeholders identify themes that move forward

Part II

Survey Draft

• “Actionable” question design
• Face/Content Validation – by participants and other stakeholders

Fielding

• Broad Sampling – representative of research population

Analysis

• Psychometric Analyses
• Instrument Reliability, validation
• Local & Aggregate Outcomes

• NIH/CTSA Administrative Supplement UL1RR024143-03S1- supported expansion to 15-sites
Design of the survey - scope

- Demographics – usual, plus research characteristics
- Recruitment experience
- Motivation to join
- Informed Consent
- Experience during study – actual vs. expectations, unanticipated pain, side effects, burdens, pressures, benefits, feeling of partnership, being listened to, courtesy, respect, trust
- Motivation to leave/stay
- Sharing of research results, test results
- Likelihood to participate again
- Overall Rating & Would recommend to family and friends
- Top Box Scores
Survey Validation - Cohort characteristics

- 15 NIH-supported research centers
- Mailed to over 18,890 research participants
- Received 4,961 responses (29%)
  - 57% female
  - 63% “disease-affected”
  - 37% healthy volunteer
  - 50% in studies with test drug/device/procedure
  - 7% Hispanic / 85% White / 9% Black / 3% Asian
Overall Rating of the research experience

Would recommend research participation to a friend or family member

Creation of Research-Specific Dimensions

<table>
<thead>
<tr>
<th>Dimensions and individual items within each dimension</th>
<th>Cronbach’s Alpha Coefficient</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Item Numbers</td>
</tr>
<tr>
<td>All Items</td>
<td>1–44</td>
</tr>
<tr>
<td>Informed consent</td>
<td>1–13</td>
</tr>
<tr>
<td></td>
<td>1–12</td>
</tr>
<tr>
<td>1. Overall study explained understandably</td>
<td></td>
</tr>
<tr>
<td>2. Someone took the time to answer questions about the study</td>
<td></td>
</tr>
<tr>
<td>3. Study details explained understandably</td>
<td></td>
</tr>
<tr>
<td>4. Risks/benefits of joining study explained</td>
<td></td>
</tr>
<tr>
<td>5. Study details included in informed consent docs</td>
<td></td>
</tr>
<tr>
<td>6. Informed consent document understandable</td>
<td></td>
</tr>
<tr>
<td>7. Prepared for what to expect by informed consent document</td>
<td></td>
</tr>
<tr>
<td>8. Something happened that you were not prepared for</td>
<td></td>
</tr>
<tr>
<td>9. Prepared by info/discussions before participation</td>
<td></td>
</tr>
<tr>
<td>10. Felt pressure from research staff to join study</td>
<td></td>
</tr>
<tr>
<td>11. Had enough time before signing informed consent</td>
<td></td>
</tr>
<tr>
<td>12. Felt pressure from research team to stay in study</td>
<td></td>
</tr>
<tr>
<td>13. Understood which tests/visits were for research*</td>
<td></td>
</tr>
</tbody>
</table>

Adapted from Table 5, Internal Consistency and Inter-item Correlation, from Yessis, Kost, Lee et. al. Clin Trans Sci 2012
# Motivations to Join a Research Study

<table>
<thead>
<tr>
<th>Factors influencing decision</th>
<th>Relative importance in decision to join a study</th>
<th>Subgroups</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Healthy volunteer</td>
<td>Disease-affected volunteer</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>To help others</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Concern about the topic</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Because of center’s reputation</td>
<td>3</td>
<td>6</td>
</tr>
<tr>
<td>To obtain education/learning</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>To find out more about my disease</td>
<td>7</td>
<td>3</td>
</tr>
<tr>
<td>To gain access to new treatment</td>
<td>8</td>
<td>4</td>
</tr>
<tr>
<td>Because no other options available</td>
<td>11</td>
<td>7</td>
</tr>
<tr>
<td>To obtain free healthcare</td>
<td>9</td>
<td>10</td>
</tr>
<tr>
<td>Because of prior positive experience</td>
<td>5</td>
<td>8</td>
</tr>
<tr>
<td>To earn money/payment</td>
<td>6</td>
<td>12</td>
</tr>
<tr>
<td>Because of family influence</td>
<td>10</td>
<td>11</td>
</tr>
<tr>
<td>Because of caregiver encouragement</td>
<td>12</td>
<td>9</td>
</tr>
<tr>
<td>Because of relationship with the team</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Because of improved health</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Because of feeling valued</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

# Motivations to Remain in a Research Study

<table>
<thead>
<tr>
<th>Factors influencing decision</th>
<th>Relative importance in decision to remain in a study</th>
<th>Subgroups</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Healthy volunteer</td>
</tr>
<tr>
<td></td>
<td></td>
<td>No</td>
</tr>
<tr>
<td>To help others</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Concern about the topic</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Because of center's reputation</td>
<td>4</td>
<td>7</td>
</tr>
<tr>
<td>To obtain education/learning</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>To find out more about my disease</td>
<td>8</td>
<td>1</td>
</tr>
<tr>
<td>To gain access to new treatment</td>
<td>10</td>
<td>6</td>
</tr>
<tr>
<td>Because no other options available</td>
<td>13</td>
<td>10</td>
</tr>
<tr>
<td>To obtain free healthcare</td>
<td>12</td>
<td>12</td>
</tr>
<tr>
<td>Because of prior positive experience</td>
<td>7</td>
<td>11</td>
</tr>
<tr>
<td>To earn money/payment</td>
<td>9</td>
<td>15</td>
</tr>
<tr>
<td>Because of family influence</td>
<td>14</td>
<td>14</td>
</tr>
<tr>
<td>Because of caregiver encouragement</td>
<td>15</td>
<td>13</td>
</tr>
<tr>
<td>Because of relationship with the team</td>
<td>11</td>
<td>9</td>
</tr>
<tr>
<td>Because of improved health</td>
<td>6</td>
<td>4</td>
</tr>
<tr>
<td>Because of feeling valued</td>
<td>3</td>
<td>8</td>
</tr>
</tbody>
</table>
Top Actionable Lessons from Survey Results

- 85% said they would have liked to receive results of the study
  - Only 23% reported receiving aggregate research results

- 72% said receiving results would be a factor in deciding about future participation

- Participants who trusted the research team completely (86%) felt they were treated with courtesy and respect (99%) and listened to (93%) (p<0.001)

- Participants stayed when they felt valued and perceive benefit.
Research Participant Perception Survey Project I & II

Assessing Research Participants’ Perceptions of their Clinical Research Experiences
Rhonda G. Kost, M.D.1, Laura M. Lee, R.N., B.S.N.1, Jennifer Yessis, Ph.D.1, Barry S. Coller, M.D.1, and David K. Henderson, M.D.1, and The Research Participant Perception Survey Focus Group Subcommittee.

Clin Transl Sci 2011

Development of a Research Participants’ Perception Survey to Improve Clinical Research
Jennifer L. Yessis, Ph.D.

Clin Transl Sci 2012

Research Participant-Centered Outcomes at NIH-Supported Clinical Research Centers

Clin Transl Sci 2014

Assessing Participant-Centered Outcomes to Improve Clinical Research
Rhonda G. Kost, M.D., Laura M. Lee, M.S., R.N., Jennifer Yessis, Ph.D., Robert A. Wesley, Ph.D., David K. Henderson, M.D., and Barry S. Coller, M.D.

NEJM 2013
Research Participant Perception Survey Project - Methods

**Part I**
- **Focus Groups**
  - Participants & stakeholders identify themes that move forward

**Part II**
- **Survey Draft**
  - Face/Content Validation – by participants and stakeholders
- **Fielding**
  - Broad Sampling – representative of research population
- **Analysis**
  - Psychometric Analyses
  - Local & Aggregate Outcomes

**Part III**
- **Performance Improvement**
  - Benchmarking, improvement cycle

*CTSA grants: UL1TR000043; UL1 TR001866*
Internal Benchmarks - Unit

RPS: Reasons for delays were explained *

*60-70% report no delays
Internal Benchmarks - Unit

**RPS: Able to reach member of research team when needed**

- **2010:** 59.3
- **2017:** 65.9
- **2018:** 73.1

- **Outpatient - Score**
- **Total (65.5)**
Internal Benchmarks – Across Teams

RPS: Prepared by info/discussions before participation

February, 2015 to February, 2016 - Outpatient

μ - Warning: n-size is under 30!
Internal Benchmarks – Performance Improvement

RPS: Prepared for what to expect by informed consent

Outpatient

Proficiency

0 20 40 60 80 100

Sem 1 2017  Sem 2 2017  Sem 1 2018  Sem 2 2018

Lab
L1, L10, L121, L1454, L1454, L1504, L1584, L1745, L1845, L201, L22, L23, L34, L4, L40, L41, L42, L43...
Internal Benchmarks – Individual Research Team

RPS: Rate research study experience

Outpatient

- Sem 1 2017
- Sem 2 2017
- Sem 1 2018
- Sem 2 2018

Lab
- L43
What are the barriers to collecting timely feedback from participants? Select all that apply:

- No barriers
- Finding the right survey (questions, length, language)
- Level of effort/cost to collect/analyze the data
- Response too low/slow to be relevant
- Something else
What would facilitate collecting timely feedback from participants?
Select all that apply:
- Short validated surveys
- Making my own survey
- Integrated survey/collection/analysis tools
- Mobile friendly platform
- Low cost/free
Making the survey shorter.......  

Multiple Regression: Rating score captured in 6 questions

<table>
<thead>
<tr>
<th>Items included in model*</th>
<th>$R^2$</th>
<th>Adjusted $R^2$ for each additional question in the model**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treated with courtesy and respect by the investigator or research doctor</td>
<td>0.816</td>
<td>0.809</td>
</tr>
<tr>
<td>Prepared for what happened by information and discussions provided before participation</td>
<td>0.896</td>
<td>0.888</td>
</tr>
<tr>
<td>Research doctor or investigator listened carefully</td>
<td>0.939</td>
<td>0.932</td>
</tr>
<tr>
<td>Prepared for what to expect by informed consent documents</td>
<td>0.950</td>
<td>0.942</td>
</tr>
<tr>
<td>Knew how to reach research team</td>
<td>0.961</td>
<td>0.953</td>
</tr>
<tr>
<td>Able to reach member of research team when needed</td>
<td>0.968</td>
<td>0.959</td>
</tr>
</tbody>
</table>

Validated Suite of tools

<table>
<thead>
<tr>
<th>Survey</th>
<th>Cronbach's alpha (95% C.I.)</th>
<th>Cohen's Kappa (95% C.I.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>RPPS-Ultrashort</td>
<td>0.81</td>
<td>0.84</td>
</tr>
<tr>
<td>RPPS-Short</td>
<td>0.83</td>
<td>0.85</td>
</tr>
<tr>
<td>RPPS-Long</td>
<td>0.87</td>
<td>0.81</td>
</tr>
</tbody>
</table>

ResearchMatch® registry
4,000 responses
2,500 interested
1,875 eligible/sent
997 completed
Overall: 53% response

Rockefeller CSTA award 2015: UL1TR0001866
### Impact of length and compensation

<table>
<thead>
<tr>
<th>Survey version</th>
<th>RPPS-U</th>
<th>RPPS-S</th>
<th>RPPS-L</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sent</td>
<td>481</td>
<td>494</td>
<td>617</td>
</tr>
<tr>
<td>Started survey</td>
<td>312</td>
<td>314</td>
<td>316</td>
</tr>
<tr>
<td>Completed</td>
<td>301</td>
<td>267</td>
<td>227</td>
</tr>
<tr>
<td><strong>Response Rate</strong></td>
<td><strong>65%</strong>*</td>
<td><strong>64%</strong>*</td>
<td><strong>51%</strong>*</td>
</tr>
<tr>
<td><strong>Completion Rate</strong></td>
<td><strong>63%</strong>*</td>
<td><strong>54%</strong>*</td>
<td><strong>37%</strong>*</td>
</tr>
</tbody>
</table>

P=0.001

- Compensated respondents were younger (p<0.001) and more often persons of color (p=0.03) than were uncompensated respondents.
Uptake...

• RPPS
  • Johns Hopkins University: fielding RPPS-S, post results every 6 months since 2016
  • Wake Forest University: 1) RPPS-U in NHLBI cohort; 2) via patient portal (JCTS 2018)
  • University of Rochester: RPPS-S at large & adapting for Deaf Community
  • NIH Clinical Center: RPPS derivative
  • ? Duke, UCSF, University of Florida, Children’s Hospital Connecticut
#6

When you collect participant feedback, how do you/investigators use it?

- We don’t collect participant feedback
- We collect data, but have not yet been able to use it
- We use data to revise current practices (recruitment, consent)
- We use data to design the next study
- We share participant feedback with leadership/teams
Time for a paradigm shift.....

• Previously, top down, institutional use with dissemination to teams
• Survey free, but fielding and analysis required resources

• Flip, to put surveys and results into the hands of teams
• Contribute results “up” to the institution, if they want to
• Design to overcome barriers to use and to facilitate benchmarking
Evaluation - Causal Pathway

**INPUTS**
- Survey infrastructure, (REDCap, MyCAP)
- Validated tools
- Flexibility to ask new questions
- Survey analysis tools (dashboard)

**ACTIVITIES**
- Patient engagement
- Community engagement
- CEnR
- Recruitment outreach
- Aligning incentives
- Assess participant experiences during research

**OUTPUTS**
- Participant experience data
- Data-driven Patient-centered design
- Pragmatic/adaptive design
- Responsive design

**EFFECTS**
- More........
  - Trust
  - Sense of partnership
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  - Communication
  - Respect
  - Felt listened to
  - Better participant experiences

**FUNCTIONALIZED KNOWLEDGE**
- Facilitate Translational Science to Improve Human Health

**FUNCTIONALIZED KNOWLEDGE**
- Faster study completion
  - Results applicable to affected populations
  - Best practices

**IMPROVE HUMAN HEALTH**
- Reduce Health Disparity
REDCap platform for new RPPS infrastructure

- Free, Easy, Robust - REDCap, MyCap
- Core survey – RPPS-Ultrashort – benchmark
- Research team ‘brand’ likely to boost response rate
- Team determines best timing

- Build specific dashboard features
- Provide the ability to pair with team’s own questions, scales
- Create infrastructure to contribute team-level data to institution
Blue sky......

• If you could easily push out short validated surveys to participants, what would you want to see on your dashboard?

• What would you want to see?
• How would you use it?
• What would you be worried about?
Contact

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