SCORE Monthly Seminar Series
Wednesday, May 15th, 2019
3:00pm – 4:30pm ET
1W-501 Fiaretti Classroom
EMBARK
Accelerating to a new era of clinical research together.
More research, faster.

- Integrated systems
- Participant tracking
- Financial management
- Support billing compliance

- Accurate and timely reports
- Enterprise revenue recovery
- Shared best practices and enterprise standards
Now we need the right tools for the work.
OnCore Implementation: First Year

- **Planning**
  - August 2018
  - Creating our solution and rollout plan with the research community
  - Consistent communication

- **System Configuration**
  - April 2019
  - Training & support
  - Enter ~350 billing risk studies

- **Data Entry Begins**
  - October 2019
  - Limited reports for PIs, Chairs, URMC leaders
  - Minimize strain on research teams

- **Limited Reports**
  - April 2020
  - Enter ~150 other cancer studies to support NCI-designation

- **Major Milestones**
  - Completed
  - Targeted
OnCore Phase I: Scope

Billing risk studies in any department
- Studies with billable clinical services (eRecord billing risk)

Active Status
- IRB initial approval
- Open to accrual
- Closed to accrual

Total = 1048

Active, Billing Risk 43%, 452
Other 57%, 596

URMC data, as of 4/15/2019
URMC data, as of 4/1/2019
Join the Kickoff

Wednesday, June 5, 2019
2:00 pm to 3:00 pm
Class of '62 Auditorium

Join us for a panel discussion and Q&A session to get the inside scoop on Embark, a transformative project that will streamline clinical trial management and allow research teams to reach their full potential.

Panelists:

• **Mark Taubman, MD** - CEO, University of Rochester Medical Center
• **Stephen Dewhurst, PhD** - Vice Dean for Research, School of Medicine and Dentistry
• **Martin Zand, MD. PhD** - Co-Director, Clinical & Translational Science Institute
• **Patricia Ames, Phd, CCRC** - Director, Office of Clinical Research

[https://www.urmc.rochester.edu/events/event-detail/30263007331943](https://www.urmc.rochester.edu/events/event-detail/30263007331943)
The Revised Common Rule:
A 2nd Look at Changes Concerning Consent

SCORE, May 15, 2019
Just a Reminder...

Compliance Date = January 21, 2019

Pre-2018 Requirements ('Old' Common Rule)

Research approved prior to January 21, 2019 will follow 'old', pre-2018 requirements

(No changes!)

2018 Requirements (Revised Common Rule)

Research approved on or after January 21, 2019 will follow 'revised', 2018 requirements
In Click® IRB...

**Regulatory Authority Field in Click® IRB:**

Pre-2018 Requirements = ‘Old’ Common Rule  
2018 Requirements = Revised Common rule
For Today’s Purposes...

Pre-2018 Requirements
(‘Old’ Common Rule)

2018 Requirements
(Revised Common Rule)

1/21/2019
Key Information
Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject...in understanding the reasons why one might or might not want to participate in the research.”

So... what’s ‘key’?

- Consent being sought for research;
- Voluntary participation;
- Purposes of the research;
- Study procedures and duration of participation;
- Reasonably foreseeable risks and benefits; and
- Alternatives to participation.
CONSENT FORM

[Insert Title of Study]

Principal Investigator: [Insert]

This consent form describes a research study. What you may expect if you decide to take part and important information to help you make your decision. Please read this form carefully and ask questions about anything that is not clear before you agree to participate. You may take this consent form home to think about and discuss with family or friends.

Key Information

The 2018 changes to the Common Rule (45CFR46) require that consent forms must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. Below is guidance for key elements that should be addressed as appropriate to the study—modify accordingly.

- Being in this research study is voluntary— it is your choice.
- You are being asked to take part in this study because [Specify condition, situation, circumstances or other reason for recruitment].
Keys for ‘Key Information’

• Template ‘key information’ bullet points are guidance only
  ➢ Add/remove bullet points as necessary based on the nature of the research
  ➢ Consider: What does the subject need-to-know up front? What will facilitate decision-making?

• Remember...
  ➢ Requirement does not apply to studies approved prior to 1/21/2019!
  ➢ Requirement does not apply to exempt research
  ➢ Consent is a process!

• Strive for a ‘happy’ balance
  ➢ Meet key information requirements without making the consent form unnecessarily long or more complex
‘Happy’ Balance

• Higher risk/complex studies: short focused summary of critical elements that are explained further later in the consent form

• Lower risk/simple studies:
  ➢ ‘Key information’ may be minimal; highlighting multiple benign points in an already brief document will not likely aid much in the decision-making process
  ➢ Preamble to the revised Common Rule: “if the information included at the beginning of the consent form satisfies both [key information requirements and the elements of consent]... more generally, the information in the beginning need not be repeated later in the body of the informed consent.”
    - E.g., information letter or verbal consent
Key Information [Template]

• Being in this research study is voluntary – it is your choice.
• You are being asked to take part in this study because...
• The purpose of this study is...
• Your participation in this study will last for about..
• Procedures will include... Some of these procedures may be optional.
• There are risks from participating.
  ➢ The most common risk is...
  ➢ One of the most serious risks is... See the “Risks of Participation” section in this consent form for more information. You should discuss these risks in detail with the study team.
• You will not benefit from being in this study. -OR- You might not benefit from being in this research study. The potential benefit to you might be...
• If you do not want to take part in this study...
Provisions for Subject Screening
Subject Screening:

*Pre-2018* Common Rule (OLD)

### Scenario A
- **Consent** → **Screening** → **Study Procedures** → **Withdraw Subject**

### Scenario B
- **Waive Consent** → **Screening** → **Consent** → **Study Procedures**
  - **Screen Fail** → **Study Procedures**

### Scenario C
- **Screening Consent** → **Screening** → **Study Consent** → **Study Procedures**
  - **Screen Fail** → **Study Procedures**
Subject Screening: 2018 Common Rule (NEW)

Scenario A
- Consent
- Screening
- Study Procedures
- Withdraw Subject

Scenario B
- Consent Exception
- Screening
- Consent
- Screen Fail
- Study Procedures

Scenario C
- Screening Consent
- Screening
- Study Consent
- Screen Fail
- Study Procedures
Provisions for Subject Screening

• New provision allows for a consent *exception* (not a waiver) for obtaining information/biospecimen for the purposes of screening, recruiting, or determining the eligibility of prospective subjects, *if*:
  - Info obtained by oral or written communication
  - Info obtained by accessing records or stored samples

• **BEWARE**: Not all screening procedures will meet the criteria!
### Provisions for Subject Screening

Is the screening procedure permissible under consent exception provisions?

<table>
<thead>
<tr>
<th>Case</th>
<th>Screening Procedure</th>
<th>Permissible?</th>
</tr>
</thead>
<tbody>
<tr>
<td>CASE 1</td>
<td>Verbal Medical History &amp; Medical Record Review</td>
<td>Yes</td>
</tr>
<tr>
<td>CASE 2</td>
<td>Verbal Medical History &amp; Physical Exam</td>
<td>No</td>
</tr>
<tr>
<td>CASE 3</td>
<td>Brief Interview &amp; Saliva Sample</td>
<td>No</td>
</tr>
<tr>
<td>CASE 4</td>
<td>Mini-Mental State Exam &amp; Sleep Questionnaire</td>
<td>Yes</td>
</tr>
</tbody>
</table>
Provisions for Subject Screening

• Want to include the provision?
  ➢ Request/document exception in study protocol
    - *Potential* ramifications for:
      ▪ Recruitment Methods
      ▪ Consent Process (**HIPAA??**)
      ▪ Study Procedures
      ▪ **Privacy & Confidentiality**
      ▪ Maybe more...

• Remember...
  ➢ Information included within the protocol should be clearly stated and consistent across all sections (avoid repeats!)
6. INCLUSION AND EXCLUSION CRITERIA

Note: enrollment will not be restricted based on gender, race or ethnic origin.

Inclusion Criteria:
- Superhero
- Fluent in English
- Willing and able to provide informed consent
- In possession of a smartphone and willing to: a) receive study-related text messages; and b) complete study tasks via smartphone

Exclusion Criteria:
- Decisional-impairment
- Non-English speaking

7. RECRUITMENT METHODS

Potential subjects will be identified via the Justice League of America, Avengers and X-Men organizations. Recruitment emails will be sent to members of each organization through their respective email distribution lists. Recruitment flyers will also be posted in each organization’s communal areas (e.g., break room and locker room). Those interested in participating will be directed to contact the study team.

8. CONSENT PROCESS

Individuals who contact the study team will be provided a verbal description of the research. If uninterested, subjects will be queried for why, no identifiable information will be recorded with this information. If willing to participate, eligibility will be confirmed via brief verbal interview over the telephone. The interview will include the Mini-Mental State Examination (MMSE) and Superhero-7 assessment. No identifiable information will be collected until eligibility is confirmed. All screening procedures are detailed in the attached Screening & Eligibility Script. For screening purposes, per 45 CFR 46.116(g), a consent exception is requested. Written consent for study participation will be obtained at the baseline visit.

9. STUDY PROCEDURES

Following consent, basic demographic information will be collected and subjects will undergo a comprehensive battery of assessments at a baseline visit that will include the following:
- Big 5 Personality Test
- COPE Inventory
- MAAS (Mindful Attention Awareness Scale)
- PANAS-SF (Positive and Negative Affect Schedule)
- Perceived Stress Scale
- State-Trait Anxiety Inventory
- Dispositional Resilience Scale

10. PAYMENT FOR PARTICIPATION

None

11. SUBJECT WITHDRAWALS

Subjects may choose to withdraw from the research at any time. The study team may also choose to withdraw subjects if they determine subjects are ineligible or non-compliant, or if the study team feels that participating is no longer in the best interest of the subject. Any data collected up to the point of subject withdrawal will still be used for analysis.

12. PRIVACY AND CONFIDENTIALITY OF SUBJECTS AND RESEARCH DATA

All screening data will be de-identified. Identifiable information will not be collected until confirmation of eligibility, at which point identifiers will only be collected for the purposes of scheduling the baseline visit. In the event a subject passes screening but does not consent to participate in the research at the baseline visit, any previously collected identifiers (e.g., name, phone number) will be removed from study documentation.

In-person study visits will occur in a private research space or, if necessary, the office of the Principal Investigator.

All data will be stored in a secure, coded manner. Only study team members will have access to the data. Data collected during in-person study visits, will be collected primary via paper/pen and stored in a locked file in the Principal Investigator’s office. All electronic data, including the information captured via the text message and the mindful breathing application, will be encrypted. Following analysis, the data set will be de-identified.

Data will be maintained for at least 3 years following publication. Only aggregate data will be shared in presentations, publications, etc.

15. DATA / SAMPLE STORAGE FOR FUTURE USE

Not applicable.

16. DATA AND SAFETY MONITORING PLAN

As risks are minimal, data and subject safety will not be monitored formally monitored. As applicable, programming will be used within the database to identify data fields that are missing, out of specific range, and inconsistent with other recorded data.

In the event an incident indicates that the subject’s health or wellbeing may be at risk as a result of participating in the study, the event will be directed to the Principal Investigator and discussed with the subject. When necessary, subjects will be advised to seek treatment from their primary care provider. All events that require IRB reporting per ONSP Policy 801 (events that are serious, related to participation, and unanticipated) will be documented and reported accordingly.
Additional Common Rule Revisions
Additional Revisions

Elements of Consent

• Required: whether or not data/biospecimens may be used for future research

• Additional (i.e., required when applicable):
  ➢ For research involving biospecimens:
    - Whether the subject will/will not share in commercial profit
    - Whether the research will (if known) or might include whole genome sequencing
  ➢ Return of clinically relevant research results

Waiver of Consent for Use of Identifiable Private Data/Biospecimens

• Existing waiver of consent criteria PLUS (new) justification for why collection of identifiers is necessary
  ➢ E.g., collecting a MRN to link data between two separate databases vs. collecting a DOB to determine age
Clinical Trial Consent Form Posting

- **Scope (per HHS):**
  - Clinical Trial = one or more human subjects are prospectively assigned to one or more intervention... to evaluate the effects of the intervention on biomedical or behavioral health-related outcomes
  - Trial is conducted or supported by a Federal department or agency

- **What to post?**
  - ‘...one IRB-approved version of the... consent form that has been used to enroll subjects...’

- **When to post?**
  - After trial is closed to enrollment & no later than 60 days after the last study visit

- **Where to post?**
  - ClinicalTrials.gov or Regulations.gov (Docket folder)
SCORE Needs Assessment

Overview

SURVEY RESULTS AND COMMENTS
## SCORE Needs Assessment

### Demographics

<table>
<thead>
<tr>
<th>Years worked as a Coordinator</th>
<th>N</th>
<th>Total N</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt; 6 years</td>
<td>52</td>
<td><strong>68</strong> Participants with ≥3 years experience as a coordinator</td>
</tr>
<tr>
<td>3 – 5 years</td>
<td>16</td>
<td></td>
</tr>
<tr>
<td>1 – 2 years</td>
<td>14</td>
<td><strong>24</strong> Participants with &lt;3 years experience as a coordinator</td>
</tr>
<tr>
<td>&lt; 1 year</td>
<td>10</td>
<td></td>
</tr>
</tbody>
</table>
## SCORE Assessment

### Biggest Positive and Negative Points Discussed

<table>
<thead>
<tr>
<th>+/-</th>
<th>Theme</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>Sharing updates, information, resources &amp; best practices</td>
<td>34</td>
</tr>
<tr>
<td></td>
<td>Networking</td>
<td>19</td>
</tr>
<tr>
<td>Negative</td>
<td>Too much focus on clinical and FDA trials</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Not enough focus on networking and/or mentorship</td>
<td>2</td>
</tr>
</tbody>
</table>
SCORÉ Assessment

Comments on Most Beneficial Aspects of SCORÉ

<table>
<thead>
<tr>
<th>Theme</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Networking</td>
<td>16</td>
</tr>
<tr>
<td>Educational content/training opportunity</td>
<td>15</td>
</tr>
<tr>
<td>Sharing updates</td>
<td>5</td>
</tr>
<tr>
<td>Sharing best practices</td>
<td>3</td>
</tr>
</tbody>
</table>

Suggestions for Making SCORÉ More Useful

<table>
<thead>
<tr>
<th>Theme</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ask Coordinators for topics/</td>
<td>4</td>
</tr>
<tr>
<td>Let coordinators pick topics</td>
<td></td>
</tr>
</tbody>
</table>
Considerations

• More networking opportunities

• More flexibility and access to attending meetings
  ➢ We have started to record the meetings and are posting the slides and presentations on the SCORE website

• More mix of topics for SCORE meetings

• Topics that relate job duties include budget development, adverse reporting, audits/monitoring, case report forms, data management, database creation, electronic data capture, informed consent, IRBs, protocol deviations, regulatory science, subject management, operations
SCORE Monthly Seminars

Recent Seminar Topics Include

• The Revised Common Rule: Changes Concerning Consent
• What I wish I would have known my first year as a coordinator
• Recent Regulatory Guidance on Data Integrity
• Keys to Successful Mentoring
• Leveraging DIAMOND to Identify and Improve Your Career Trajectory
• Self Determination Theory
• Streamline Your Clinical Trial Workload with Effective Project Management

Requests for 2019 SCORE Seminar topics

• Acronym Bingo
• How to manage a difficult monitor
What we are providing so far

• Presentations
  ➢ Coordinator presenters
  ➢ Topics relevant to job
• Group Discussions/Panel
• Half-Day Seminar
• Skills Lab/Workshop
Bridging the Gap Between the Two/Future Directives

Updates
• Asking for updates at every SCORE meeting

Networking
• Socialize outside of work
• Lunch/coffee break
• Other Ideas?

Mentorship Program
• Those who have been a coordinator ≥3 years should match up with those who been a coordinator for less than 3 years
## SCORE: Satisfaction Ratings per Event Type

<table>
<thead>
<tr>
<th>Event Type</th>
<th>Good (Extremely or Very Satisfied)</th>
<th>Middle of the Road (Moderately Satisfied)</th>
<th>Not So Good (Slightly or Not at All Satisfied)</th>
<th>Have Not Attended</th>
</tr>
</thead>
<tbody>
<tr>
<td>Presentations</td>
<td>73.4%</td>
<td>18.3%</td>
<td>5.0%</td>
<td>3.3%</td>
</tr>
<tr>
<td>Open Discussion</td>
<td>36.7%</td>
<td>21.7%</td>
<td>20.0%</td>
<td>21.7%</td>
</tr>
<tr>
<td>Half-Day Seminar</td>
<td>68.3%</td>
<td>21.7%</td>
<td>3.4%</td>
<td>6.7%</td>
</tr>
<tr>
<td>Skills Lab / Workshop</td>
<td>50.0%</td>
<td>8.3%</td>
<td>5.0%</td>
<td>36.7%</td>
</tr>
</tbody>
</table>
SCORE: Satisfaction Ratings per Event Type

- Presentations: 73.4% Good, 18.3% Middle, 5.0% Not So Good, 3.3% Have Not Attended
- Open Discussions: 36.7% Good, 21.7% Middle, 20.0% Not So Good, 1.7% Have Not Attended
- Half-Day Seminar: 68.3% Good, 21.7% Middle, 3.4% Not So Good, 6.7% Have Not Attended
- Skills Lab/Workshop: 50.0% Good, 8.3% Middle, 5.0% Not So Good, 36.7% Have Not Attended
<table>
<thead>
<tr>
<th>Event Type</th>
<th>Rating</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Good (Extremely or Very Satisfied)</td>
<td>Middle of the Road (Moderately Satisfied)</td>
<td>Not So Good (Slightly or Not at All Satisfied)</td>
<td>Have Not Attended</td>
</tr>
<tr>
<td>Presentations</td>
<td>62.1%</td>
<td>21.4%</td>
<td>10.3%</td>
<td>3.4%</td>
</tr>
<tr>
<td>Open Discussion</td>
<td>32.8%</td>
<td>22.4%</td>
<td>24.1%</td>
<td>20.7%</td>
</tr>
<tr>
<td>Half-Day Seminar</td>
<td>56.1%</td>
<td>29.8%</td>
<td>7.0%</td>
<td>7.0%</td>
</tr>
<tr>
<td>Skills Lab / Workshop</td>
<td>37.9%</td>
<td>19.0%</td>
<td>8.6%</td>
<td>34.5%</td>
</tr>
</tbody>
</table>
SCORE: Helpfulness Ratings per Event Type

- **Presentations**: Good (62.1%), Middle of the Road (24.1%), Not So Good (3.4%), Have Not Attended (10.3%).
- **Open Discussions**: Good (32.8%), Middle of the Road (22.4%), Not So Good (24.1%), Have Not Attended (20.7%).
- **Half-Day Seminar**: Good (56.1%), Middle of the Road (29.8%), Not So Good (7.0%), Have Not Attended (7.0%).
- **Skills Lab/Workshop**: Good (37.9%), Middle of the Road (19.0%), Not So Good (8.6%), Have Not Attended (34.5%).

*Legend: Good (Extremely or Very Satisfied), Middle of the Road (Moderately Satisfied), Not So Good (Slightly or Not at All Satisfied), Have Not Attended.*
Factors preventing SCORE Attendance

- Topics have not been relevant to my role (31 people, 36%)
- My schedule conflicts with attendance (63 people, 73.3%)
- I have too many other things to do (39 people, 45.3%)
- I wasn’t aware of SCORE opportunities (9 people, 10.5%)
Major Points from SCORE Assessment of Event Types

Presentations
- High Satisfaction Ratings – 73% Extremely or Very Satisfied 😊
- High Helpfulness Ratings – 62% Extremely or Very Satisfied 😊

Half-Day Seminar
- High Satisfaction Ratings – 68% Extremely or Very Satisfied 😊
- High Helpfulness Ratings – 56% Extremely or Very Satisfied 😊

Skills Lab / Workshop
- Have Not Attended – 34.5%
  ➢ In the future: Kelly Unsworth’s revised flowsheets for August 2019 summer workshop
Upcoming SCORE Events

- Monday, May 20th, Clinical Trails Day
  • Coordinators – pick up your buttons please! (tables 11am – 1pm)
  • We will be providing citrus fruits in honor of CT.day, pens and goodies, and we will be showcasing coordinators favorite experiences as a coordinator

- Tuesday, June 4th, Half Day SCORE Seminar
  • Topics include (registration begins at 8am until 8:45am)
    ➢ Recruitment and Retention
    ➢ Professional Development for Research Personnel Coordinators
    ➢ Emergency Department Research Associate Program (EDRA)
    ➢ Panel: Respectful Way to Conduct Clinical Research
Thank you!!

Questions?