2015 Annual Stakeholder Meeting Summary

On behalf of the OneFlorida Cancer Control Alliance, thank you for your valuable contributions to our first annual stakeholder meeting. Collaboration is crucial to making this alliance a success, and I am excited by the progress we made together at our first annual meeting.

While there is still much to be done, the alliance is moving forward on multiple fronts. The Minority Education program will be accepting full proposals this month, and we have begun to inform researchers in Florida about the strengths of our infrastructure and our goals for addressing health disparities and tobacco–related cancer and cardiovascular disease in our diverse state. Next month, we plan to attend the annual meeting of the American Society of Preventive Oncology (ASPO) to begin to build awareness of our efforts on a national stage.

Ultimately, our goal is to work together to improve health, health care and health policy for all Floridians. The annual stakeholder meeting proved to be an important venue for the open exchange of ideas. We appreciate the roles our varied stakeholders have played in making this alliance possible, and we look forward to our continued collaboration in the OneFlorida Cancer Control Alliance and other OneFlorida initiatives.

Thank you,

Betsy Shenkman
Principal Investigator, OneFlorida Cancer Control Alliance

MEETING INFORMATION

Our first annul stakeholder meeting was held on January 26, 2015 in Orlando, Florida. We had 35 OneFlorida partners join us at the Lake Nona campus. Below are the meeting notes. If you have additional questions regarding the discussions then please contact TaJuana Chisholm, tchishol@ufl.edu.

MEETING NOTES

Welcome and Introduction (Began at 12:15); Discussion led by Dr. Nelson

•Dr. Nelson starts the meeting with introductions of everyone in the room and provides a brief history of OneFlorida. OneFlorida began in 2009 as Health IMPACTS, a partnership between UF Clinical and Translational Science Institute, UF Health, and FSU and its clinical network. His key points include:

- Uniting Key Partners through shared research infrastructure
- OneFlorida vision developed from Health IMPACTS collaboration between the University of Florida and Florida State University. The initial goals of Health IMPACTS were to test interventions in physician practices, translate research findings into improved health care quality, and to mentor medical students and trainees. Dr. Nelson briefly reviewed the pilot projects; Concussion – Traumatic Brain Injury Management and Health Risk Assessment (HRA) in Primary Care. He then reviewed the background of the UF CTSI; the renewal was just submitted.
- OneFlorida will have a focus on improving health care quality through well designed multisite studies
- Potential future use of OneFlorida is the training/mentorship of new researchers in the field of implementation sciences
- The "Florida of today is the nation of tomorrow" and creating a learning health system is key. Dr. Nelson spoke about the governance structure of the UF CTSI and how it is a collaborative model. He ended his presentation with a review of the agenda for the Stakeholder Meeting and a breakdown of the OneFlorida CCA team.

•Former CTSI Pilot studies have illustrated potential concerns

- The lack of research knowledge at the medical practice and clinic level
    - The need to train local partners in the study protocol and rationale
- That large multisite studies place a high load on IRB
    - The need to develop and improve OneFlorida IRB capacity to support and oversee these type of studies

•Dr. Nelson discussed the CTSI grant application

- The current grant will focus on health disparities in the State of Florida, with special attention being paid to the State's minority population
- Development of Translational Science Workforce

- Learning Health System: the developing of a practice based research network that spans the whole state with a focus on testing academic knowledge in real world medical settings
- Knowledge transfer from Academic Centers to the medical population
- The need for CTSI research projects to develop mechanisms for their database to 'speak' with the databases of other national partners

·Stakeholder engagement and governance of OneFlorida
- University of Florida CTSI would serve as a hub for all of OneFlorida partners
- The OneFlorida Clinical Research Consortium would serve as an expert advisor on network development
- The network will need to allow bi–directional communication between all stakeholders

·Dr. Nelson speaks on all of the topics and goals for the day's meeting
- Governance Structure
- Access and using the research network
- Development of structure for bi–directional communication
- The Data Trust, access portal, and vision for future use
- Minority–Mentee Training Program
    - Great start
- OneFlorida IRB and Consent2Share
    - This is of a major interest to outside partners
    - Seen as a model for State level co–op IRB
    - Consent2Share: helps to engage patient for research enrollment
- OneFlorida Communication
    - Has been making use of the expertise at UF College of Journalism and Communication

·Dr. Nelson talks on the current status of the OneFlorida CCA partnership

<u>OneFlorida Cancer Control Alliance Goals</u> Discussion led by Dr. Shenkman

·Dr. Shenkman began discussion about the afternoon's breakout sessions
- That groups were assigned to be representative of the partners attending the meeting
    - Changes could be made if requested
- Background of Cancer Control Alliance (CCA)
    - CCA is working with James and Ester King Award to address heart disease and stroke risk among tobacco–related cancer
    - It was stated that the Floridians at the greatest risk for tobacco–related cancers and CVD are those of lower socioeconomic status and ethnic minorities and adolescents and young adults – these vulnerable groups are rarely included or minimally represented in clinical trials; OneFlorida includes these vulnerable populations.
- Goals of CCA
    - Transitioning research from academic centers to medical community clinics and practices
    - To better reflect the diversity of the general population

- Academic Centers study population tend to be higher social–economic–status and less ethnical diverse
- Intervention Development within the CCA
- Implementation Sciences research
- Research support within community clinic and practice settings
- Pragmatic trial design: the need to design research study that can function within the limitations of community clinic and practice settings; provide an infrastructure to support implementation science studies in a wide range of settings and pragmatic trials, interventions in real–world settings.
- Targeting future research project to address intervention in standard of care settings

- OneFlorida infrastructure
  - Dr. Shenkman reviewed some of the features of the OneFlorida infrastructure: participant recruitment, physician recruitment, integrated clinical trials network for interventional studies, the OneFlorida IRB, and the External Scientific Advisory Committee.
  - Dr. Shenkman reviewed the OneFlorida CCA partnerships and shared a map representing these partners.
  - Dr. Shenkman highlighted the diverse range of people in the OneFlorida coverage area and displayed the high risk for heart disease and stroke among underrepresented minorities and high rick for tobacco use within the coverage area.
  - Dr. Shenkman summarized the progress to date and ended her presentation with a thank you to the funders.

- Future Activities
  - Development of State–wide infrastructure
    - With a focus on technical issues in conducting studies and collecting data
    - Expansion of Consent2Share program for cohort discovery
    - Development of OneFlorida IRB
  - Identification of barriers and solutions to physician recruitment
  - The integration of clinic and patients' expertise into research study design
    - While still maintaining scientific validity
  - Expanding the External Scientific Advisory Committee

<u>Administrative Structure and Governance</u> (Began at 1:15); Discussion led by Dr. Nelson

- Stakeholder Diversity includes: Partners, Clinicians, 3rd party payers
- Current Governance Structure: Scientific Advisory Committee, OneFlorida Steering Committee, CTSI
- 3 Basic Cores: Informatics, Implementation, Administrative Core
- Major Focus – Tobacco Cessation Study, Meet with partners and address key requirements for the OneFlorida IRB and Data Trust
- Today we hope to put final plans on how to work/use the OneFlorida IRB
- Until today, current formats were webinars and teleconferences. Proposing to continue annual meeting, frequency and intensity to be determined.
- The group reviewed Figure 3 OneFlorida Governance Structure

- Discussion Question: Are these programs we should focus on?
    - Dr. Robinson – Need to make this more attractive to the community providers. May be too academic and intimidating. How to market this to the community to draw more patients.
    - Dr. Reams – Under the CTSI column, we need to add pragmatic clinical trials in that column, maybe next to Information Dissemination.
    - Dr. Nelson – Under Implementation Core, we need to be descriptive of our activity and define it better.
    - Dr. George – Where does data quality and site visits fall?
        - Dr. Shenkman – Part is embedded in the OneFlorida Data Trust, but we need to be more descriptive in our cores.
        - Dr. Hogan – We are worried about Data Quality.
        - Dr. Nelson – Taking in a lot of sites that have never had this rigorous IRB networking, we need to train them in order to get protocols pushed through.
        - Chris Barnes – This gives us an opportunity to really examine data and track quality and improve the rate of good quality data.
        - QI data checks for data coming in and out will be in the OneFlorida Data Trust. Insure data is being monitored and cleaned up and of good data quality.
    - **Member suggestion– Who is responsible for the quality of the data? Create feedback mechanism, will also help improve the quality of the data**
    - **Member suggestion– We need a mechanism where everything links to the stakeholder program. Good mechanisms for feedback and discussions when there are problems to allow those with issues to be able to discuss the problems and get positive feedback. Allow those people to be broad and transparent**
    - **Member suggestion– Have training (mentor) program as a separate core. With minority education, should mentor (training) program be a separate mission. Mentor program have its own column.**
    - Move pragmatic clinical trials next to information and dissemination program. What is learned in clinical trials will be disseminated into the group, or under implementation core.
    - **Member suggestion– Explain functions clearly under each area and have more descriptive headers**

- Discussion Question– Do we have the right programs with 3 governing structures: Scientific Advisory Committee, OneFlorida Steering and CTSI?
    - Dr. Carrasquillo – Suggest adding patient and physician stakeholder input in all those programs
    - Dr. Shenkman – One thing I'd like to see up there is the Minority Mentoring Program.
    - Dr. George – Payers represented anywhere;
        - Dr. Shenkman – Payers represented through OCHA, but we should have more representation.
        - Dr. George – Big Blue is a big one that comes to mind.

- Dr. Muszynski – A lot of focus on payers in the panhandle: Capital Health Plan

- Discussion Question – What about from an Informatics Standpoint
  - Kevin Smith – That works for me.
  - Dr. Nelson–– Key informatics people that can function independently, gather and process data would be tremendous to have.
  - Chris Barnes – Suggested ways to communicate with each other better, so that issues can be addressed and sent to the correct channel.
  - **Member suggestion–– In the past, we recruited a large number of centers who had their own informatics, we should package Oneflorida informatics and then present to other clinics and partners who have their own informatics. Start ahead of time to prospectively recruit and spread the word and knowledge that this system is available and for people to use.**

- Discussion Question – Are we missing stakeholders?
  - **Member suggestion–– We had to recruit a lot sooner. In the future we should talk to potential partners a head of time.**
  - **Member suggestion–– Have liaison groups with facilitators who need to be in the know. For those that cannot always make the meetings, have off shoots of smaller groups to interact and build upon that.**
  - **Member suggestion–– Make more attractive to community providers, to help bring those practicing in the community more interested in coming.**

<u>Using the Network</u> Discussion led by Dr. Muszynski and Michelle Vinson

- FSU has research network that was established even before HealthIMPACTS and is integrated into six regional campuses.
- FSU has a community–based resident model, when students graduate they are sent to one of the six regional campuses.
- Suggest letting the studies drive the enrollment of networks, not just recruit practices into the network.
- When writing grants make sure to put in budget requests for grants. Coordinators meeting with PIs to determine budget, making sure the protocol is feasible and what is allowable within the protocol and if there is enough money for what they want.
- Getting into the Network – Submitting a Protocol
  - Meet with Program Manager who tells you how to collect data and go through assessments, Talk ahead of time, and try to plan out as much as possible. Define study and recruit clinics based on that, Define how it will benefit the patients of each clinic, Define how it will benefit the PBRN
  - Protocol gets submitted for feasibility – Are there appropriate patients in the network? Are there appropriate clinics in the network? We also look at scientific impact and merit

- Protocol is reviewed.
- Goes to scientific advisory committee
- Goes to OneFlorida Executive Committee for final approval.
- Project gets approved and then you will work with the OneFlorida Project Manager
    - Katie Eddleton – It's helpful if we are involved before grant is submitted.
    - Dr. Muszynski – The sooner the better, because if we need to recruit 10 practices, we want to do that, not say we cannot supply that.
- Dr. Shenkman—We are putting data use agreements in place
- Dr. Iafrate – I have found it better in the long run if the IRB is involved sooner. Avoid obstacles.
- Dr. Nelson – People applying for grants and wanting to access OneFlorida Network? What does that process look like? We need to facilitate and have a process for that situation.
- Dr. Muszynski – Suggest a Research Advisory Committee to review the protocols before IRB. We look at them and determine one of 3 things. Saves time by fixing mistakes before IRB review. Maybe a practice that we should implement.
    - Doesn't need more then material sign–off
    - Needs a few committee members for review
    - Needs a Full review
- Dr. Shenkman – Since this is larger, we need something more stable and systematic
- Dr. Muszynski – At FSU we were able to let people know if we could get where they wanted such as 80 patients among 8 clinics.
- Michelle Vinson – The more we work with investigators and communicate upfront, the better we can accommodate. Let us know budget upfront as well.
- Katie Eddleton – It doesn't matter about knowing how much things cost, but how well everything fits together.
- Discussion Question – Other part of the budget, what do practices need? How does it impact their workday?
- Discussion Question – How do you get your medical directors engaged in research?
    - Dr. Muszynski – When they decide to do a study, it is key to answer every one of their questions with an expectation with what your study entails. Keep them involved with studies that provided value to the practice. After study completion, get back with them and ask for feedback. Are there other studies you want to be involved in? Keep the practices involved, stay engaged and hopefully consent2share becomes big.
- Dr. Robinson – Our center is unique since it's a Community Health Center. We have to be careful to not make patients feel used or like a guinea pig. We made any research we did invisible to patients, clinics and workers. We had people assist patients with routine work and maybe slip in the iPad and asked about some participation. For those that don't want to be involved, you need to leave them alone for now.

    - Michelle Vinson – Practice Facilitators need to listen to what the clinics are saying. Ask them what they want.
    - Dr. Muszynski – Know you population. We can't help get you study participants if you don't know your population. Site visits are also helpful, puts a face to the whole thing.
- Member suggestion–– Streamline use for the investigators.
- Member suggestion– Get IRB involved early in the process
- Member suggestion– More systematic communication to determine study feasibility instead of informal communication.
- Member suggestion– Providers need to know exactly what is needed of their practice before they will buy in. PI can meet with providers at the site, puts face of the study to the providers. Be open and responsive; be sure to communicate with the clinic. Each clinic is its own unique challenge. How much is too much when it comes to the study? Provide answers immediately when clinics ask them.
    - One–sheet executive summary from the prospective of the practitioner.
    - Add value to the practice; give the clinics something they can use.
    - Any research questions that you have, submit to design studio to design new studies.
    - Engage practices and create involvement to get them to buy–in and then become advocates for other practices to become involved.
    - Make sure practices do not feel used and abused by the study.
    - Never make patients feel like guinea pigs, draw them in for their primary care and then ask for studies when they feel comfortable.
    - Make studies invisible and seamless to patients; tell patients that we need their help. Facilitators and research coordinators should meet with providers to ensure a good relationship, and facilitate discussion between the coordinators and the providers.

<u>Bi–Directional Engagement;</u> Discussion led by Drs. Carrasquillo and Cottler

- If you want to improve community health, you have to engage in research. Engage stakeholders in all phases of the research project – more of an art than a science. UM has one central group that meets once a year. We found it easier to have a lot of little groups that meets once every 2 months.
- Community Planning Council – create an open group in which people could come and discuss their ideas.
    - Grass–roots ideas. Get scientists to talk in a simplistic way to engage community.
    - Researchers who want to do a project within a particular group or community should find ways to integrate themselves and the research project into the group or communities regular routine. Become familiar with the participants and use community partners to help develop a good relationship.
- Health Street: Community Health Worker Model.
    - Go out and meet people in the streets, find out concerns, and then direct them to people to address those concerns. Meet again in a few months to get their satisfaction with their referrals and research. They also have town meetings where the findings of the research are provided for the community.

    - Town hall meeting for dissemination of findings "Our Community, Our Health". To discuss with community members what the findings in research studies mean to the community members that were a part of the study.
    - Goal is to bring this to a multi–site community and incorporate into OneFlorida and around the state in order to use.
- Recruit the community; go to churches, join community advisory boards, local places where people gather (locally–owned markets)
- Dr. Shenkman – Scientist present protocols, people present ideas for studies for design studios. Next step is to implement Design Studios on the road.
- Dr. Carrasquillo – Get local feedback by utilizing people and "ins" that you are aware of. What works for people, what are the best ways to engage us [researchers]? We can send out updates via email or teleconference.
- Discussion Question – How do you get providers on board? Difficult part?
    - Dr. Muszynski – We were lucky, we could tell providers that they would be getting free iPads and have access to a central data portal. Sometimes that was enough.
    - Dr. Robinson – Someone has to facilitate the study other than the provider.
    - Dr. Nelson – We use a model, anyone who enrolls a patient can be a co–author and we are curious to see how well it will work.
    - Dr. Muszynski – You have to be aware of connections. It does get people's names out there and sometimes gives them legs.
    - Dr. Carek – The big barrier is the knowing–doing gap. Asking them to be co–investigators. Getting them more engaged. It's about setting the relationship and going and getting those names out there.
    - Dr. Shenkman – Important part is to have that information out there and having online tools.

- Discussion Question– Did you have a way for your community groups to find out what each other were doing?
    - Dr. Carrasquillo – Communication could have been better – maybe a newsletter. They did have meetings.
- **Member suggestion–Ensure providers do not feel used**
- **Member suggestion– Giving people items to make things work easier within their practices.**
    - **Make items seamless within their practice.**
    - **What resources are available in your area to impact them? Bring the final product to the physicians. Someone needs to be able to help within the clinic to do the grunt work.**
    - **Add value within design study and push it to clinics.**
- **Member suggestion– Ask physicians to be clinical investigators, not researchers**
- **Member suggestion–Add physicians to papers and giving them authorships.**

Data Visualizations Discussion led by Chris Barnes and Katie Eddleton

- Private portal – a location for customizable clinic information and reports. This web portal provides MOC credit using online training modules and the participating practices will be provided with insight into the needs of their local communities
- Public website is live: OneFloridaconsortium.org
- Hope to use the private portal to place all the data instead of faxing. People will be able to see all the data relative to their site.
- Both the public and private portals are live now and in development: Adapted from previous projects
- We want your feedback on the portals – What do you want to see? What is helpful?
- Data Visualizations make data that would be hard to view as tables or numbers easier to understand.
- Portal will be useful to see data in a non–raw data form.
    - Easy to read graphs and charts
    - Tracking study enrollment and patient participation
- Give providers a goal, and give them updates on their goals
- Discussion Question – What are your thoughts about looking at the data for your site?
    - Dr. Robinson – When we start gathering data, we need a mechanism to pull data from the consortium to review data.
    - Dr. Iafrate – An issue for the patient or subject will be clarifying how secure their data is going to be. How much information will they know about me? Is another country going to hack it?
    - Katie Eddleton – We have asked practices to keep PHI out of the portals. PHI will be housed in the OneFlorida Data Trust and linked data will only be viewed by an honest broker.
    - Dr. George – The MOC opportunity is a great addition to get practices involved. Many practitioners go through insurances and claims to get their data back.
- **Member suggestion––Explain in consent forms what the data will be used for, in case of use for other areas.**

OneFlorida IRB Discussion led by Dr. Iafrate

- Goals is to have a multicenter IRB
    - Members participating from all sites
        - Virtual meeting
    - Each location represented in protocol review
        - Each institution would send one member current in their IRB
        - Need a few names of citizen scientist to join this initiative
- Goal is to seek agreement on protocol submission standards
    - Basic Introductory Questionnaire sections
        - The core consent and local consent sections
    - Local sites would include institution logos
- Discussion Question – What's the difference if a PI wanted to use a commercial IRB? WIRB?

    - Dr. Iafrate – A little complicated. WIRB changes for everything you do. Would they be ok with a big group with one submission? I don't know, probably not.
- Dr. Nelson – We need a short term fix and a long–term vision.
    - Dr. Iafrate – Short–term is to use UF IRB, FSU can dial in but not vote.
- Discussion Question – How does this affect the MEP trainees? Does this apply to them as well?
    - Dr. Iafrate – Depends on what your institution is ok with implementing OneFlorida IRB. As long as you include UF IRB on a FWA, it will be ok.
- Dr. Mandal – Is this limited to UF and FSU projects? Or any OneFlorida projects? How often do you meet?
    - Discussion Question – UF IRB, the serving IRB, meets once biweekly for 6 hours. This will be for all OneFlorida projects.
- Dr. Iafrate discussed the Integrated Data Repository (IDR)
    - Data goes into the IDR and once a month a query goes in that de–identifies the data. Will not let you query rare diseases.
    - The IDR has the potential to share de–identified data across the state.

<u>Minority Education Program</u> Discussion led by Dr. Folakemi Odedina. Table participants included Dr. David Nelson, Dr. Bryan Weiner, Dr. Torhonda Lee, Brian Sevier and Deborah Morrison.

- General questions and comments
    - Dr. Nelson asked if there are Institutional disparities at the HBSCs that need to be addressed.
    - Dr. Weiner asked if these awards provide opportunities to buy out time form teaching load for research.
    - Dr. Odedina said that prior to writing the grants they got letters of support from FAMU administration to be released from some teaching.
    - Dr. Odedina –EWC requires administrative engagement and a movement from teaching to research to encourage release from historically heavy teaching loads. They would also require institutional and faculty change to be included in the program.
- Comments by Dr. Lee on becoming a PTIS–MEP awardee:
    - Dr. Lee stated that it was perfect that Dr. Odedina brought the JEK Award information to FAMU, where she is well known and knows the institution, and so had built–in trust prior to this meeting. She expressed the perception that the meeting attendees were in a state of disbelief that UF was bringing this opportunity there, and that people asked why this was happening and wondered how it would work. Dr. Lee stated that the grant process for her has been "full of trepidation" and that she feels this is a confidence–building exercise.
- Comments from Dr. Weiner (OneFlorida CCA Scientific Advisory Board member had the following comments and questions:
    - How will we know that this program (PTIS–MEP) was successful? Is there a career path expectation for Awardees, including an R–series extramural grant? What types of presentations or submissions do we expect?
- Dr. Odedina answered these questions in general, and added that other successful overall outcomes would include the following:
    - An increase in health disparities research by Jr. Faculty at Florida's HBSCs;
    - An increase in mentoring in cancer health disparities;
    - An increase in the number of minority scientists;

    - The creation of synergy in cancer disparities research due to the multi–institutional structure of this research program
- Lessons learned:
    - When making program presentations at Edward Waters College, it became clear that there would be challenges due to the faculty make–up of the school (Master's degree vs. PhD).
    - **Member suggestion– Provide a different type of development (PhD Dissertation assistance) or create triads for JEK MEP with FAMU PI, coupled with EWC CO–PI together with a mentor.**
    - **Member suggestion–– Define all resources that are available to MEP Awardees. (Consent to share, ISIS studios, website portal, etc., and post these to the website).**
    -

<u>Tobacco Cessation Protocol</u> Discussion led by Drs.Shenkman and Carek. Table participants included Dr. Thom George, TaJuana Chisholm, Heather Williams, and Lori Drum.

- Drs. Shenkman and Carek led discussions about the Tobacco Cessation Study Protocol, using the PowerPoint presentation as reference
- Dr. Shenkman stated that the samples collected during this study will lay the groundwork for a bio repository.
- The pilot data will open the door for Research Funding Announcement (RFAs) in the future which include implementing research in rural populations. In the future, there could be focus on e–cigarettes, smokeless tobacco, hookah, nicotine in general and executive functioning test
- Incentives should be given at each visit (including NicAlert follow–up), the group agreed on a $25 Visa card.
- Why not use the under 18 population for this study? It's a diverse population but a parent must be present and the patient must be reconsented at 18. Study team will check the guidelines for medication strategies for the under 18 population.
- The security of the iPads in the physicians' offices was brought up but it was stated that there hadn't been a problem in previous studies with theft. Wi–Fi may be an issue for some providers; Dr. Shenkman said that the OneFlorida would pay for Wi–Fi for the duration of the study.
- The study team will work to register the tobacco cessation project with clinicaltrials.gov
- **Member suggestion– It was mentioned that in primary care nurses are the ones conducting the assessments and doing the interventions; there should be a way to track who is offering the advice.**
- **Member suggestion– Information should also be taken to see what the patients recalled from the experience. Did providers change behavior? Did patients change? The general population will want to know how the patient changed. Patients' saliva will be collected but how can we encourage compliance?**
- Should they come back to the physician's office to complete the NicAlert, maybe in a large group, or should the kit be mailed directly to each patient?
    - **Member suggestion– There would have to be a strong incentive to get the kit back from each person. If collected at the physician's office, make sure to schedule it around routine visits so it's not a burden. Rural practices may have trouble getting the patients to come back for a follow–up.**
    - **Member suggestion– Collect bio specimen during a follow–up visit and remind patients with a phone call prior to return visit**
    - **Member suggestion– It was suggested that the test results be reported back to the physicians and to try to offer CEUs to nurses.**

- **Member suggestion– Patients who screen negatively could be offered lifestyle educational tools to give to caregivers, community members, etc.**

<u>Data Trust Protocol</u> Discussion led by Dr. Hogan and Chris Barnes. Table participants included Mahmoud Enani, Dr. Michael Muszynski, Liz Manini, Theresa Shannon, and Dr. Renee Reams.

- Discussion––Private practices are concerned that they will lose their patients; they are worried patients will be contacted without the practices knowledge.
  - Response (Dr. Hogan and Chris Barnes): Although data will be housed at UF, UF will not have access to identified information. Only limited data sets will be available to query for cohort identification and to determine study feasibility. The only way to get access to PHI is through a local honest broker. Patients will not be contacted without the knowledge of the practice.
- Discussion––Certain Institutions want their own Data Trust
  - Response (Dr. Hogan): A federated model is feasible, but would be cost prohibitive – especially for smaller entities.
- Discussion––If a patient is seen at multiple practices, which practice is contacted when a patient is identified as eligible for a new study
  - Response (Dr. Hogan): Good question! More thought will need to be given to this matter.
- Discussion––Will the grand vision of the Data Trust be in place at its inception or will there be a piecemeal approach?
  - Response (Chris Barnes): The Data Trust will be built in stages. The full vision will take between 5–10 years to accomplish.
- **Member suggestion– Group as a whole stressed the importance of crafting a compelling story that would both highlight benefits of participating in the Data Trust and elevate concerns potential partners would have.**
- **Member suggestion– Dr. Muszynski suggested inviting skeptical entities that have yet to commit to collaborating (Orlando Health was an example) to events like this one.**

<u>OneFlorida IRB Consent 2Share</u> Discussion led by Dr.Iafrate. Table participants included Robert Albury, Dr. Al Deeb, Katie Eddleton, Josh Hanna, Dr. Prabir Mandal, and Michelle Vinson.

- Discussions addressed during the breakout sessions
  - How will external unaffiliated partners interact with the OneFlorida IRB
    - External unaffiliated partners are physicians in private practice that work with a OneFlorida partner
    - These agreements are made with the physician and not their practice but require their OneFlorida affiliated partner to sponsor them
  - External unaffiliated partner would be able to access the OneFlorida IRB if their affiliated partners files a letter of support with the IRB
    - The letter would state that the external unaffiliated partners meets all of the training requirements for IRB access
    - If an external unaffiliated private practice is incorporated by another affiliated partner, the new controlling affiliated partner would have send a new letter of support before the physician could access the OneFlorida IRB
  - How can affiliated partner interact with the OneFlorida IRB if the OneFlorida IRB is not listed as a possible IRB for their use

        - An IRB Authorization Agreement (IAA) can be signed between the OneFlorida IRB and another external IRB
        - This agreement states that one defined project that the OneFlorida IRB can be the IRB of record for that affiliated partner
        - The IAA will require negations at level Dean/Vise President of Research between the affiliated partners
    - The Development of an OneFlorida IRB audit system
        - **Member suggestion–A system will be needed that can ensure physician and practice training and data collection quality assurance**
        - Physician and Practice Training: a means to educate study participates about their involvement in the study and to insure that the participates are taking the correct actions
        - Data Collection: a system to insure that data is being collected accurately by the practices and that the data is being transferred to the OneFlorida Data Trust accurately
    - Questions from larger group
        - Will there be a contact person for the OneFlorida IRB at the University of Florida IRB
        - For the short–term this contact would be Peter Iafrate
        - Administrative and staff support would be developed as the OneFlorida IRB grows
        - How to cover the cost of operating the OneFlorida IRB
        - The need to develop a cost recovery mechanism, potentially worked into future OneFlorida related research project's grants
    - How to access the OneFlorida IRB
        - Current OneFlorida projects will have to contact the UF IRB01, Peter Iafrate will review
        - IAAs will have to be made with partners that do not list OneFlorida IRB as IRB of Record
            - How external IRBs interact with OneFlorida will be determined at this time until the formal network is established

<u>Communications</u> Elizabeth Hillaker Downs. Table participants included Damian Alderman, Claire Baralt, Dr. Olveen Carrasquillo, Donna O' Neal, Dr. Temple Robinson and Kevin Smith.

- Discussion Points
    - Familiarize all stakeholders with key message points, Start by reaching out to researchers to recruit more studies
    - Need to build awareness that we exist
    - We want to show that we are competent, professional and performing rigorous science
    - How can we show unity between the alliances, yet highlight their individuality
    - Going to print documents in small batches, with "date updated" dates inside each document in order to keep up to date with the changing partners
- Key Messages
    - We are a statewide organization
    - We are bringing together many stakeholders

- We are bringing together a large number and vast diversity of patients
- We are conducting a variety of research in the real world

- Materials: Folders
  - Make the large circle in the middle of the folder the circle representing patients but make sure it is gender neutral
  - Move the connection lines to link mostly to the OneFlorida logo but a secondary focus should be the patients' circle because we are patient–centered
  - Change the circle representing hospitals/sites to something less "ivory tower". Use a picture that also represents the smaller clinics and family practices. It should be a small clinic, perhaps with a caduceus.
  - The circle representing doctor–patient relationship needs be more generic. Current bubble looks like it is more family oriented, which excludes certain stakeholder populations
  - Don't have the iPad cut off.

- Materials: Brochures
  - Bond Clinic no longer exists, it should be changed to Bond Community Health
  - Above the 'About' section, we should include a OneFlorida "quote" like a mission statement that stands out and indicates what we are all about
  - On the darker OneFlorida Clinical Research Consortium brochure, it is tough to see the scope of the clinics at the bottom. You could bold it or make it white.
  - Change the content in each brochure to fit each alliance
  - The circle re Perhaps we should reintroduce the #s on the cover in the map or at the bottom of the brochure to emphasize our scope; it could be an interesting infographic
  - The group did not have time to review the content

- Materials: Business Cards
  - Addressed issue of having multiple cards or just a single card. Both opinions were shared. One researcher said he wasn't interested in balancing any more individual cards because he has a role that would span over several alliances whereas another stakeholder wanted individual business cards for each alliance to make them more relevant for a particular situation, such as a lung cancer conference.
  - As a compromise, they suggested we list the alliances on the back and add more as they come so people can check or circle the relevant alliance.
  - We discussed having the lines spread out from the logo on the business cards but decided it would be too busy on such a small space.

- Materials: Letterhead
  - We discussed having a single letterhead for all alliances/the CRC or having individual alliance letterheads.

- As a compromise, the stakeholders thought that you should be able to type the relevant alliance out at the top if necessary and have a single basic letterhead.
- Another suggestion was to have all the alliances listed all the time, along with all the partners.

- Questions and Comments
  - Is there any way to put the documentation or the brochure on the portal? This way we can have the most current version of the documentation available.
    - It is certainly possible to place all the documentation in a centralized area on the OneFlorida website, which would link to a pdf file of the documentation, and contain printing instructions
  - Color says a lot. So far the color makes it difficult to distinguish between any of the different alliances within the OneFlorida umbrella. It's challenging trying to explain which alliance you belong to, when the individual alliances do not stand out.
    - The plan is to print the alliance title beneath the OneFlorida logo, in a blue title bar that will allow it to stand out on the documentation. This way it is easier to identify which alliance the document relates to while still keeping a unified look. Individual colors for each alliance, as we grow, will become increasingly untenable if we desire a unified look. In addition, it is difficult to keep track of individual alliance identity standards and to find enough complementary colors as the number of alliances grow.
  - Is there any way that we can get OneFlorida pins to place on collars and lapels, to act as a conversation starter and provide additional exposure?
    - This is an idea that we will hopefully be going to implement in the near future

EVALUATION SUMMARY

35	In–person meeting attendees
5	Joined via conference call
17	Evaluation sheets returned

1. What was most valuable to you today?
   - ✓ Peer interaction
   - ✓ Learning about the goals and existing infrastructure of the consortium
   - ✓ Round table discussion
   - ✓ Face to face meeting with stakeholders and leaders, seeing/meeting members
   - ✓ The discussion sessions and having back and forth with stakeholders
   - ✓ Meeting everyone and hearing direct provider feedback
   - ✓ All of it
   - ✓ Breakout sessions
   - ✓ Meeting the other stakeholders in person
   - ✓ Meeting face to face
   - ✓ Everything
   - ✓ Meeting project partners
   - ✓ The communications meeting
   - ✓ Networking, meeting other members
   - ✓ Meeting presented a clearer picture of the project and the association between the consortium and the alliance, it also showed participants their position in the project
   - ✓ Face–to–face interaction with people from other institutions
   - ✓ Real–time answers to questions, networking

2. What was least valuable to you today?
   - ✓ All interactions were positive and constructive, so no comment here
   - ✓ Nothing
   - ✓ N/A
   - ✓ Everything was valuable. Enjoyed the process
   - ✓ All the information was important
   - ✓ None of it
   - ✓ None—all was valuable
   - ✓ I wish we had more time
   - ✓ Nothing
   - ✓ N/A
   - ✓ N/A

3. Please offer your feedback regarding the breakout table session you were in.
   - ✓ I was unaware of the issues with HBCU and ideas for modifying that [PTIS–MEP] program were good.
   - ✓ It was great. Maybe have participants pre–assign themselves
   - ✓ I so enjoyed hearing about the creation of big data, using electronic health records across Florida!

- ✓ Very productive, everyone gave some great comments and feedback
- ✓ Extremely helpful to discuss major details of the protocol. Especially the inclusion of adolescents
- ✓ Informative
- ✓ Engaging conversation and ideas leading to other concerns
- ✓ IRB discussion was very illuminating for me. I didn't have much to add though
- ✓ Great discussion. Wish we had more physicians and more time to talk
- ✓ It was excellent
- ✓ Excellent way to open up discussion
- ✓ Effective, efficient
- ✓ Communications was well run
- ✓ Excellent, productive, good facilitation
- ✓ It was great that people felt free to express their major concerns
- ✓ Very interactive and valuable perspectives

4. <u>What would you change about that format of the meeting, if anything?</u>
   - ✓ More strict timing mechanism
   - ✓ Nothing
   - ✓ Nothing
   - ✓ A bit rushed, we were hit with time constraints
   - ✓ Well done—wouldn't change it
   - ✓ Self–selecting on the breakouts
   - ✓ Less presenting, more breakouts and reporting back. More info on what other partners are doing. Great to hear from Miami.
   - ✓ Nothing
   - ✓ More time tracking so discussions don't go too long
   - ✓ Liked the interaction and the size, keep the same
   - ✓ Move participants so they can see each other, horsehoe, etc…
   - ✓ Less moving from room to room, more coffee

5. <u>What would you suggest we do differently for the next annual meeting? (Try to be as specific as possible.)</u>
   - ✓ Generally need a little more time
   - ✓ Nothing. I think now that we know each other—conversations will flow. I like the idea of OneFlorida pins so we know each other at other meetings.
   - ✓ A lot more time for the meeting. We had to rush a bit at the end
   - ✓ No changes—it was enlightening and informative…oh, can you add a cheese tray to the delicious food
   - ✓ All day meeting. Keep sessions to strict time. Publish time limits (i.e. 30 min breakout, 10 min report back to team)
   - ✓ No change in program except the cocktail reception should be the evening of the previous day
   - ✓ Extend invites to providers earlier
   - ✓ More time tracking so discussions don't go too long
   - ✓ Decrease use of acronyms
   - ✓ Many of the presentations were quite informative, suggest a round of program update reports
   - ✓ Less moving from room to room, more coffee

6. In what ways, could we best engage and keep you informed over the coming year?
   - ✓ TaJuana's listserv works great for me, but do more "This week in OneFlorida" instead of just announce the next meeting
   - ✓ This is a big challenge. I suggest a OneFlorida point person at each location that could disseminate information.
   - ✓ Website; newsflash or newsletters
   - ✓ Email and website
   - ✓ Teleconferences and email
   - ✓ Email, WebEx, more conferences like this
   - ✓ At least monthly newsletter (events, updates, success stories, etc.)
   - ✓ Via email and well in advance (not 30 min before a meeting)
   - ✓ Hate to say but monthly emails
   - ✓ Continue email and "invites"
   - ✓ Email portal
   - ✓ Communications via email including "updates"

7. Other comments
   - ✓ Thank you very much. This was a great meeting
   - ✓ The breakout sessions seemed to be the most popular activity of the day
   - ✓ A method for holding presenters to their time limit would be beneficial, some participants appeared annoyed to me but it wasn't a major problem
   - ✓ The location at Lake Nora was great, I do have some concerns about the logistics of the site if the meeting grows beyond 60–80 participants because of the room sizes
   - ✓ Arthur's was a great choice for the food
   - ✓ The format for the meetings seemed to work well, maybe more time in breakout sessions for future meetings

8. Overall event experience:

Excellent	Above Average	Average	Below Average	Poor
14	3			

9. Discussion sessions:

Very Important	Important	Limited Importance	Not Important
13	4		

10. Breakout sessions:

Very Important	Important	Limited Importance	Not Important
17			

11. Online communications:

Very Important	Important	Limited Importance	Not Important
14	2		1

12. Registration process:

Excellent	Above Average	Average	Below Average	Poor
17				

13. Helpfulness of event staff on site:

Excellent	Above Average	Average	Below Average	Poor
17				

14. Meals and refreshments:

Excellent	Above Average	Average	Below Average	Poor
16	1			