

**Arizona Cancer Control Program
Research Committee Meeting Minutes
July 9, 2009, 10:00-12:00**
City of Hope Bone Marrow Transplant Office
926 E. McDowell Street, Suite 123, Phoenix, AZ

Attendees: Michele, Tim, Sherryl, Gayle , Karen , Jesse , Shaun, Barbara F. , Kendra & Raoul

Excused: Joan, Victor, Sharon

Call-In: Barbara

TOPIC	DISCUSSION	OUTCOME(S)
1. Welcome and introductions.	1. Everyone introduced themselves and signed in on the meeting roster.	1. Invited guests included Raoul Tibes, MD, PhD, Gayle Jameson, ACNP-BC, AOCN, and Michele Avery, Translational Genomics, Scottsdale Clinical Research Services (TCRS).
2. Review and approval of prior meeting minutes.		2. Minutes were approved as written.
3. Background to the Research Committee	3a. Jesse gave a brief introduction to the background of the Research Committee and its goals.	3a1. Copies of the "Logic" Model were distributed that contain the 4 goals of the Committee: <ol style="list-style-type: none"> 1. Promote cancer research collaboration. 2. Promote tissue banking and accessibility. 3. Promote clinical trials especially among the underserved. 4. Improve the accessibility, analysis and evaluation of cancer data 3a2. The Committee has decided to prioritize goal #3 as our #1 priority with the other goals (1,2,4) being subsumed within the context of promoting clinical trials.
4. Promote clinical trials especially among the underserved.	4a. Jesse described from his perspective that there are basically two broad categories of clinical trials: <ol style="list-style-type: none"> 1. Therapeutic drug trials that usually involve cancer patients. These drug trials usually have restrictive eligibility criteria. 2. Health promotion, screening, and prevention trials that usually involve healthy people such as social 	

	<p>–behavioral studies that address smoking cessation, colorectal screening, exercise and the prevention of obesity and diabetes.</p> <p>3. These “health promotion” trials also can include cancer survivors and can address symptom management and life style changes as well (e.g., fatigue, sleep, exercise, and psychological intervention research studies).</p> <p>4b. Federal funding for clinical trials usually requires formal oversight that recruitment of diverse and underserved populations are included in these studies whereas non-federally funded or commercially-funded trials do not have this automatic requirement to promote accrual diversity, although in this era of targeted drug therapy development, this will become more of a need in the future.</p>	
<p>5. National resources available to help our committee focus and succeed in its efforts.</p> <p>5a. EDICT</p>	<p>5. Jesse briefly summarized the following national programs: EDICT, ICC, and ENACCT.</p> <p>5a1. EDICT (Eliminate Disparities in Clinical Trials) is housed at Baylor College of Medicine and is a national 4-year project funded by Genentech (2005-2009) that was co-developed with the Intercultural Cancer Council (ICC) to design practical & reliable <u>policy</u> solutions to enhance diversity participation in clinical trials. Dr. Armin D. Weinberg is the PI of this project (www.bcm.edu/edict.)</p> <p>5a2. EDICT “launched” its national policy recommendations at the ICC’s 11th Biennial Symposium on Minorities, the Medically Underserved, and Cancer in Washington, DC April 2008.</p>	<p>5a1. We need to contact Dr. Weinberg to obtain a copy of the final report and summary from the activities of the 8 participatory cities that was presented to Genentech in San Francisco June 2009. Obtaining this report should be able to give us additional ideas from other cities about activities/programs that have worked/not worked to increase trial accruals and determine whether Genentech and others will have future funding available for the continuation of these policy efforts particularly for the 8 cities/communities that participated in the “rollout.”</p> <p>5a2a. It is suggested that everyone on the Research Committee reads “The EDICT Project: Policy Recommendations to Eliminate Disparities in Clinical Trials” (10/2008, Version 2) and see if its stakeholders model and recommendations offer any ideas/implications for organizing our committee efforts.</p>

<p>5b. Intercultural Cancer Council (ICC)</p>	<p>5a3. Eight cities or regions were selected to host roundtables and meetings as part of the EDICT “Rollout Plan.” Focus groups were held in Tucson June 3, 2009 and meetings (AM + PM) were held June 4, 2009 in Phoenix.</p> <p>5a4. The focus for the meeting in Tucson was on Hispanic/Latinos. The focus for the Phoenix meetings was on reimbursement issues for clinical trial participation and on American Indians.</p> <p>5b1. The ICC promotes policies, programs, partnerships and research to eliminate the unequal burden of cancer in racial and ethnic minorities and medically underserved populations in the US and its associated territories.</p> <p>5b2. It was founded in 1991 by Dr. Armin Weinberg and is housed at Baylor College of Medicine.</p> <p>5b3. It was a collaborating organization on the EDICT Project. Individuals and organizations can join the ICC.</p> <p>5b4. One current ICC Board member lives in Arizona:</p> <p>Jody Pelusi, FNP, AOCN, PhD Northern Arizona Hematology/Oncology Oncology Nurse Practitioner US Oncology PO Box 6330 6601 W. Cortez Glendale, AZ 85312</p> <p>Sharon Jaycox is also a member. Sharon Jaycox, BS, MHA Liaison to Special Populations</p>	<p>5a2b. EDICT identifies the following groups as being underrepresented in clinical trials: the elderly, racial/ethnic groups (African-Americans, Asian-Pacific Islanders, Hispanic/Latino & American Indians/Alaska Natives), women, children, adolescents, low income, rural & others (disabled, chronic illness, co-morbidities) and the uninsured.</p> <p>5a4. We need to obtain the minutes of these three meetings and determine if the EDICT “Backpack” and “Class act” projects have any resources/implications to help us achieve our outcomes as a committee.</p> <p>5b3. We need to consider if we as individuals or as an organization want to join ICC (icc@bcm.edu, iccnetwork.org.)</p> <p>5b4. Perhaps we need to consider inviting Dr. Pelusi to join our Research Committee.</p> <p>5b5. We need to consider targeting the leadership/resources in the Southwest Region Network for Arizona to begin to prioritize and achieve our goals</p>
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<p>5c. ENACCT</p>	<p>Comprehensive Cancer Control Program Outreach Coordinator Asthma Liaison Arizona Department of Health Services</p> <p>5b5. Arizona is in the Southwest Region of the ICC which includes AZ, CO, NM, OK, TX, and UT.</p> <p>5b6. Jay Silver attended the EDICT “Rollout” meetings held in Arizona June 3-4, 2009. He is the current ICC Executive Director and is an EDICT collaborator.</p> <p>5c1. ENACCT (Education Network to Advance Cancer Clinical Trials) is the national organization involved solely to implementing and evaluating clinical trial <u>evidence-based educational</u> efforts.</p> <p>5c2. ENACCT was founded in 2004 1010 Wayne Ave, Ste 770 Silver Springs, MD 20910 Ph: 301-562-2774 info@enact.org</p> <p>5c3. Between 9/07-3/08, ENACCT developed a strategic plan for improving accruals and decreasing disparities in multi-site phase III cancer clinical trials.</p> <p>5c4. In February 2009, 4 sites out of 43 submissions were selected to receive funding to improve cancer clinical trial participation. These 4 sites are called “implementation partners.”</p>	<p>as a Research Committee.</p> <p>5c3. We need to review the ENACCT plan and its 50 recommendations to see what resources/implications it has for achieving our Committee outcomes.</p> <p>5c4a. We need to see if future funding might be available for us to receive funding by designing a demonstration project that shows “community engagement” to enhance clinical trial accruals.</p> <p>5c4b. Sources of funding for these 4 demonstration projects included the Agency for Healthcare Research and Quality (AHRQ), NCI, ASCO, Genentech, GSK, the ICC, the Lance Armstrong Foundation, the California Breast Cancer Research Program, the Wellness Community and the University of Michigan Comprehensive Cancer Center.</p> <p>5c4c. We need to develop a listing of funding agencies/groups to help in our own efforts as a committee.</p> <p>5c5. We need to obtain minutes/program handouts of these meetings to see if they have any resources/implications for our activities.</p>
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	<p>5c5. In February 2009, Jesse and others attended two ENACCT meetings.</p>	
<p>6. Outcomes of Arizona EDICT and ENAACT meetings</p>	<p>6. No one in attendance at these meetings seemed to have a good handle on where clinical trials are being conducted, who the contact people are, who are doing the trials and what resources are within the underserved communities to get the word out about these trials to these underserved people.</p>	<p>6a1. Everyone at these meetings indicated a need to be better informed about what trials were being conducted, who to contact for further information etc etc.</p> <p>6a2. Making a state-wide website to include all clinical trials is expensive and trials change too much for this to be a realistic endeavor our part.</p> <p>6a3. So what should be our committee's role; how do we establish our strategic plan, set priorities for the next 5 years, always focusing on our desired outcome: increasing accruals to clinical trials.</p> <p>6a4. We need to identify what works in other settings and communities and attempt to replicate and extend them in our state (e.g. The Sisters Program.)</p>
<p>7. Dr. Tibes and TCRS: Phase I and II Cancer Clinical Trials.</p>	<p>7a1. Dr. Tibes described the evolution historically of TGEN (Translational Genomics) and the establishment of Phase 1 and 2 cancer clinical trials at Scottsdale Health Care, Shea Medical Center (TGen /Scottsdale Clinical Research Services) (TCRS).</p> <p>7a2. The primary purpose of studies at TCRS, the clinical research arm of TGen, is to expedite information being developed from bench or laboratory science/research to practice settings. This is termed "translational" research.</p> <p>7a3. Phase I trials are the first time a drug is tested in humans. These patients must come to TCRS where they can be monitored closely by physician drug development trained investigators and others. In these trials, patients are required to stay at TCRS for at least one full day of each drug cycle to have blood draws and other tests performed to determine how the drug is being metabolized and how</p>	

	<p>the patient is tolerating the medications. Patients also must return periodically several times during the same week and during each cycle for additional lab tests and monitoring over time.</p> <p>7a4. Phase II studies are usually conducted in patients once the “safe” dose of the medication is identified in the Phase I study to see what specific malignancies the agent may be effective against.</p> <p>7a5. In this era of “personalized” or “targeted therapy” it is important to recruit as diverse a population as possible who may respond to and metabolize these drugs in different ways and/or who may have unique signaling pathways or gene variants that need to be identified that affect drug development and targeting studies.</p>	<p>7a4. Unfortunately, despite extensive marketing and outreach efforts to medical oncologists, newspapers, and community support/advocacy groups, TCRS is not getting the number of referrals that they would like to see for their trials.</p>
<p>8. How do we get trials to the patients who might be offered opportunities to participate in these clinical trials.</p>	<p>8a1. Much discussion then ensued about the challenges and barriers that exist to recruiting patients to these trials not the least of which is the “competitive medical landscape.”</p> <p>8a2. Dr. Tibes and others mentioned several approaches to “take clinical trials to patients and agencies” where they are currently being seen and treated, particularly the Phase III</p>	<p>8a1. First of all we need to identify the “stakeholders” who are involved in conducting clinical trials.</p> <p>8a1a. Phase I trials are currently being conducted at the Arizona Cancer Center, Mayo Clinic Scottsdale, and TCRS.</p> <p>8a1b. It’s not clear if Cancer Treatment Centers of America are doing these trials and if MD Anderson/Banner Healthcare may be doing Phase II but not Phase I studies.</p> <p>8a1c. We need to consider contacting the institutions who are doing Phase I and/or Phase II trials, determine who the institutional contact person is at these institutions who can determine possible eligibility criteria and which trials they may want to prioritize for accruals.</p> <p>8a1d. For TCRS these prioritized trials might include the SU2CA (Stand-up-2–Cancer) Pancreatic trial and leukemia studies.</p> <p>8a2a. We need to consider identifying agencies/MD offices doing Phase III clinical trials; identify the contact person at these institutions to determine if a patient</p>

	<p>trials that are more “moveable than are the earlier Phase I & II trials.</p>	<p>might be eligible to participate on these trials, and if they have websites that are constantly being kept updated and whether these websites are internal and/or externally available for access.</p> <p>8a2b. We need to consider asking these agencies/institutions which Phase III trials they want to prioritize for accruals.</p> <p>8a2c. We need to consider whether some of these institutions/agencies and prioritized phase III studies can be taken to community health care centers, for example Maricopa Integrative Health Service or Mountain Park, that currently may not have trials/oncologists on site to provide care.</p> <p>8a2d. We may want to consider seeing if we can obtain a copy of the state’s CTSA (Clinical Translational Science Award Application) that lists research sites including community health care centers and other agencies from perhaps Dr. Peter Lance and/or Keith Joiner at UA, and “match” these identified research potential resources/agencies with what already has been compiled by the Arizona State Cancer Control and Prevention Program and its “Statewide Coalition.”</p> <p>8a2e. We need to consider designing both an “educational intervention and a systems” type of intervention like the “patient navigator” system that may be helpful to promote clinical trials at the site or “point of contact for patient care” who would serve as the clinical trial contact person for each site.</p> <p>8a2f. We need to consider obtaining from Dr Weinberg, if not already in the final EDICT Report, the results of the patient navigator meetings with Paula Rieger (CEO Oncology Nursing Society) and others held June 2009 immediately after the EDICT meetings were held in Tucson.</p> <p>8a2g. We need to consider replicating and extending models that have worked in the past in other areas of</p>
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		<p>the country to accrue patients to clinical trials such as the African-American Sisters program for Breast Cancer to see if these models might work here in Arizona.</p> <p>8a2h. We need to consider using the “snowball technique” commonly used in qualitative research studies where one patient identifies and accrues another person to a trial (for example one Native American women goes on a clinical trial and then she educates others about her experiences.</p> <p>8a2i. One other suggestion was to make clinical trial information/educational materials available at sites where everyone has to come into contact (i.e., obtaining a driver’s license)</p> <p>8a2j. We need to consider finding out more about the September 9, 2009 Healthcare Disparities Committee Program/Projects planned and whether there would be any benefit on collaborating on a programs/projects to increase clinical trial recruitment efforts</p> <p>8a2k. We need to consider exploring whether developing a flyer to put into each of the 6000 “BAG IT!’s” is cost, time, and accrual effective.</p> <p>8a2l. We need to always consider “ Where do we get the most bang for our buck and efforts”?</p> <p>8a2m. Promotoras have been found to provide excellent care and navigation roles following training within the Hispanic/Latino communities. The committee may want to consider designing a clinical trials training program for this group of health care workers/navigators and then track the program’s impact on accrual rates for Hispanic/Latinos for specific trials.</p> <p>8a2n. The challenge for the research committee and its desired outcome, will be how to reach out to individual patients particularly if they have poor healthcare</p>
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		<p>access, no health insurance and/or no reimbursement for travel, food or hotel lodging.</p> <p>8a2o. It was agreed that this committee would not address the clinical trials accrual barriers/issues associated with the uninsured.</p> <p>8a2p. AHCCCS, the state's Medicaid program doesn't pay for Phase I or II trials but supposedly the state is one of only 20 nationally that legislatively requires costs associated with clinical trials to be covered by insurance plans.</p> <p>8a2q. We as a research committee need to consider finding out more information about what are the state's laws on clinical trial reimbursements; how effective and enforceable are they; and perhaps consider contacting Tony Rogers to obtain more information about how to "lobby" the legislature on this area of need.</p> <p>8a2r. We need to consider how to reach out to patient advocacy agencies/groups (leukemia, lymphoma and myeloma societies) to refer patients to clinical trials.</p> <p>8s2s. Another area that we need to consider exploring is how to target patients early in their illness such as targeting programs to surgeons, diagnostic/treatment centers and patients earlier in their illness trajectory to inform them of clinical trials and their availability.</p> <p>8a2t. We need to decide as a committee if we want to target our efforts initially in Maricopa and/or Pima counties; to which underserved group we want to prioritize our efforts; and what our 5-year strategic plan and annual priorities and projects might look like....</p> <p>8a2u. Do we want to consider establishing working groups to begin to address each of these potential areas that are open for our consideration and action?</p> <p>8a2v. Do we want to consider asking/recruiting representatives from each of these "Stakeholder"</p>
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		<p>agencies who know the clinical trial network at their own institution to become a part of our research committee and its working groups? Dr. Tibes, Gayle Jameson and Michelle Avery agreed to be added to our roster's mailing list.</p> <p>8a2w. We need to consider how we might track both screenings and accruals in a centralized location to tell us if we are effective in recruiting patients to clinical trials as a result of our efforts as a research committee.</p> <p>8a2x. We need to consider how best to build/collaborate with others to build the clinical trial research and referral structure and network throughout the state to better connect the patient with the researcher and patients with appropriate trials</p>
9. What can be accomplished between now and our next meeting.	<p>9a. Minutes</p> <p>9b. Listing of active research committee members.</p> <p>9c. Beginning to identify key clinical trial stakeholders.</p>	<p>9a. Barbara Piper will take an initial stab at doing the minutes.</p> <p>9b. Kendra Sabol will put together a listing of people at the meeting today and give it to Barbara.</p> <p>9c. Barbara will see if she can identify/assign tasks to various members to accomplish before the next meeting. Kendra will get a copy of the Arizona Cancer Control Program Book and CD that lists resources/agencies within the state.</p>
10. Meeting adjournment	10. Meeting adjourned at 12:00	