

resulted in informed consents with a mean readability of 7th grade (range 6–9th grade), compared to a mean of 10th grade (range 7–11th grade) for the comparator (“no adoption” group,  $n=24$ ). Data collection will continue through May 2017. The focus group is forthcoming and results will be included in the poster. **DISCUSSION/SIGNIFICANCE OF IMPACT:** Low health literacy is common in individuals with healthcare disparities and can limit their participation in clinical research. Few studies have examined interventions to address this barrier to research. Preliminary results of this study support the utilization of a plain language informed consent template in investigator-initiated research. Moreover, this study demonstrates the importance of stakeholder engagement among CTSA leadership, health literacy experts, the institutional review board, investigators, and research subjects in the development and testing of this intervention to make informed consents “understandable to the subject” while containing all required elements.

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### Empirical assessment of a theatrical performance on attitudes and behavior intentions toward research: The informed consent play

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**OBJECTIVES/SPECIFIC AIMS:** Exposure to theatrical performances holds promise for addressing bioethical issues, but there has been little empirical examination of the impact of dramatic presentation on audiences' attitudes. This study assessed the short-term impact of the play, *Informed Consent*, on perceptions of trust, willingness to donate biospecimens, attitudes toward harm and privacy among the general public and in faculty, medical and undergraduate students within an academic medical center in the intermountain west. **METHODS/STUDY POPULATION:** Surveys were administered before and after a staged reading of the play by professional actors. Pre and post survey responses were linked for each participant. Survey items included the short form Trust in Medical Researchers, and single item questions about group identity, of genetic testing in children, and willingness to donate biospecimens. In total, 3 additional questions about harm, consent, and ethical investigator behavior as represented in the play were asked in the post survey. In addition, respondents were given the option to answer open-ended questions through email. **RESULTS/ANTICIPATED RESULTS:** Out of the 481 who attended the play, 421 completed both the pre and post surveys, and 166 participants completed open-ended questions online ~1 week after the play. Across all participants, there were significant declines for Trust in Medical Researchers and for the survey item “is it ethical for genetic testing in children for adult onset conditions,” ( $p < 0.001$  for both) following the play. There was a significant increase in agreement to improve group identity protections ( $p < 0.001$ ) and no differences on willingness to donate biospecimens to research ( $p = 0.777$ ). When differences were analyzed by race of the participant, non-White participants ( $n=68$ ) compared with White participants ( $n=344$ ) were less willing to donate biospecimens in general ( $p < 0.001$ ). Further, non-White participants' willingness to donate biospecimens decreased ( $p = 0.049$ ) after viewing the play while the white participants' willingness to donate was unchanged. Qualitative data provided extensive contextual data supporting these perspectives. **DISCUSSION/SIGNIFICANCE OF IMPACT:** This is one of the first studies to empirically examine the impact of a theatrical performance on both attitudes and behavioral intentions toward research and clinical research participation. Some attitudes changed following the play performance, but there were no significant differences on intention to donate biospecimens for research overall. Future research can further address the value and impact of theatrical performances and other creative arts as tools to engage the public and investigators in dialogue about the ethical issues and complexities in clinical research and further evaluation of the impact of performances on attitudes about research and ethics. Creative arts may be used to motivate investigators and study participants to confront fundamental questions about research participation and trust.

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### Knowledge, attitudes, and experiences towards genetic research among persons of African descent

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**OBJECTIVES/SPECIFIC AIMS:** The purpose of this descriptive study is to explore knowledge, attitudes, and behaviors related to genetics and genetic research in a sample of persons of African descent. **METHODS/STUDY**

**POPULATION:** Data were generated using a cross-sectional survey design. A nonprobability sample of 272 persons of African descent, ages 18 and older, were recruited from the Washington, DC metropolitan area through public advertisement and word-of-mouth. Participants had diverse backgrounds with most born in the United States (93%), female (71%), some college or above education (57%), household income under \$40,000 (54%), and some with a reported disability (38%). Before survey recruitment and administration, this study was reviewed and approved by the Howard University Institutional Review Board. **RESULTS/ANTICIPATED RESULTS:** The majority (79.8%) of the participants considered themselves as having a “fair” to “good” knowledge of genetics. The sample had a 2.24 ( $SD = 77$ ) mean score on the 5-item genetics knowledge questionnaire with total possible mean scores ranging from 0 (no correct responses) to 5 (all correct responses). Most (53.3%) participants believe it is important for persons of African descent to participate in genetic research. However, almost one-half (46.7%) felt that information from genetic research can be used to discriminate against minorities. In terms of behaviors, 83.4% of the participants never had genetic testing conducted. However, an overwhelming majority reported that they would be willing to participate in a genetic research project specifically for detection of risk factors such as cancer (87%), diabetes (89.3%), Alzheimer disease (88.6%), and alcohol use disorder (75%). **DISCUSSION/SIGNIFICANCE OF IMPACT:** This investigation suggests that persons of African descent generally view participation in genetic research as important and are willing to have their genetic profile analyzed to detect susceptibility to certain diseases. However, ethical issues, such as misuse of genetic research to discriminate against minorities, remain a prominent concern. Further studies are needed to illuminate KABEs and to help identify the role these factors may play in this population's willingness to participate in testing and research. Such information could provide invaluable insight to the development and implementation of more ethical and culturally competence strategies for recruiting minority participants into genetic research.

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### Satisfaction and perceptions of research participants in Clinical and Translational Studies

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**OBJECTIVES/SPECIFIC AIMS:** The objectives of this study were (1) to examine research participant levels of satisfaction, experiences, and perceptions; and (2) to determine best practices for researchers for engaging research volunteers in clinical trials, and thereby reducing barriers to participation. **METHODS/STUDY POPULATION:** A self-administered IRB approved survey on satisfaction and perceptions of research participants in clinical and translational studies was developed. The study questions were validated by 5 key informants from each of the 3 research centers who were asked to provide constructive feedback on the clarity and relevance of the questions. The final survey was a 25-item questionnaire that used a Likert scale and focused on 5 domains to reflect satisfaction with “Staff delivery of care,” “Environment,” “Center Operations,” “Study specific questions,” and “overall experiences.” Questions to reflect participant perceptions were open ended. A convenience sample of all participants currently enrolled in research studies at CTSA institutions (GU, HU, and MHRI) was obtained. In total, 131 participants completed the survey. Of these, 15 were “surrogate” partners. **RESULTS/ANTICIPATED RESULTS:** Eighty-two (60%) of the participants were African Americans, 40 (29%) were Whites; 94 (67%) were first time study participants. Over 90% of those surveyed strongly agreed that they were “treated well,” that their “privacy was respected,” and that they “felt comfortable asking questions of the staff.” Eighty-four percent indicated they would participate in future studies while over 91% indicated they would recommend a family member or a friend. Only 46% of participants coming for their first research visit strongly agreed that the “compensation received was satisfactory.” However, 74% of participants returning for follow-up or who had been enrolled in a previous study felt the compensation was appropriate. Seventy-four percent of those enrolled for the first time indicated “knowing the duration of this study” as compared with only 38% of repeat visitors. When asked what they liked most about participating in a research study their primary responses were “contribution to science” and “knowledge about their diseases.” Conversely, when asked what they liked least about the study they responded that the blood draws were uncomfortable and there were often barriers to transportation and parking. **DISCUSSION/SIGNIFICANCE OF IMPACT:** The results of this survey demonstrated that the majority of research participants rate their experience as highly favorable even among those who had never participated in clinical research previously. In some existing literature, it has been reported that financial compensation was a major

motivation to participation in studies involving healthy volunteers. In this current study, however, financial compensation did not appear to be the primary motivation for participation. The participants' at all 3 sites stated that the main reason for their participation was the increased knowledge about their disease and the contribution to science. Negative experiences cited were primarily discomfort with blood draw, transportation, and parking logistics. Most importantly, a majority of the participants stated they would participate in future studies and would recommend a family member or a friend for a clinical study. In our sample, there was no difference in the favorable ratings as determined by race/ethnicity. In conclusion, the findings of this study inform the community with regard to how the research participants rate their experiences, and thus motivate others to participate in clinical research. Reasons for participants to withdraw from trials may be associated to their dissatisfaction with a trial or with the study staff. Thus, the degree of satisfaction with the research staff and the trial itself is crucial to reducing drop-out rates and increasing compliance with study procedures. Hence participant satisfaction is key to increasing participation in clinical trials, particularly among African Americans and other racial and ethnic minorities.

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### Should all clinical research subjects pay the same?

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**OBJECTIVES/SPECIFIC AIMS:** Discuss ethical and policy issues that will impact clinical research. Raise awareness of the need to understand internal policies at home institutions. Encourage further examination of ways to facilitate clinical research participation. **METHODS/STUDY POPULATION:** Ethical and policy analysis. **RESULTS/ANTICIPATED RESULTS:** Ideally, clinical research participants should not be required to pay to participate in research. However, if we go with an equity model, as opposed to an equality model, policies should be changed to allow equal access to research participation. This is a matter of justice and also will enhance the quality of the science. **DISCUSSION/SIGNIFICANCE OF IMPACT:** Unless steps are taken to make participation in clinical research less burdensome financially for participants, research may slow or results may be biased, because only those who can pay will be able to participate.

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### Beyond "REACH": The Research, Education, And Community Health (REACH) coalition as an exemplar for broad-based stakeholder engagement

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**OBJECTIVES/SPECIFIC AIMS:** The Institute for Transnational Sciences (ITS) has developed novel methods to ethically engage stakeholders across the transnational research spectrum, up to and including public health practice and policy. **METHODS/STUDY POPULATION:** In 2014, the ITS co-founded The Research, Education, And Community Health (REACH), the mission of which was to facilitate communication, collaborative research, and service activities between faculty and scientists and area community leaders. The intent was to identify and meet the needs of our communities without gaps and/or redundancies, thus better leveraging time, funding, and efforts. **RESULTS/ANTICIPATED RESULTS:** REACH now boasts 23 Centers, Departments, and Institutes, as well as 39 community organizations, including public and mental health agencies, clinicians, policy makers, family service centers, cultural and faith-based organizations, business, and local schools/colleges. We offer 3 methods for consideration as best practices: (1) a comprehensive community health needs assessment, (2) an "Offer and Ask" community/campus partnership mechanism, and (3) Community Science Workshops, based on the European Union's Science Shops. **DISCUSSION/SIGNIFICANCE OF IMPACT:** Results of REACH's work have been used to provide guidance for enhanced, data-driven programs and allocation of resources for local and statewide initiatives. The organization has evolved into an independent coalition seeking 501(c)3 status and is planning to expand its scope to 5 counties. REACH thus serves as model for successful replication across applicable CTSA hubs.

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### Participatory development of a CTSA-wide Community Advisory Board: Enhancing community engagement at the Michigan Institute for Clinical & Health Research

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**OBJECTIVES/SPECIFIC AIMS:** To describe how Michigan Institute for Clinical & Health Research (MICHR) has engaged communities in its leadership and governance structure. This presentation will describe these practices, how they are being evaluated, and future plans for institute-wide engagement of communities in translational research. **METHODS/STUDY POPULATION:** Engaged partners from various communities across Michigan in various ways within MICHR's Community Engagement Program. **RESULTS/ANTICIPATED RESULTS:** MICHR has utilized participatory practices in the development of the CAB to strengthen existing relationships and build new ones with potential partners. **DISCUSSION/SIGNIFICANCE OF IMPACT:** MICHR-wide Community Advisory Board (CAB) will ensure community voices are heard and utilized in leadership and strategic decisions for CTSA activities.

### MECHANISTIC BASIC TO CLINICAL

2014

#### Identification of novel shared tumor antigens for the development of T-cell-based immunotherapies

Sherille Bradley and Greg Lizee

**OBJECTIVES/SPECIFIC AIMS:** The specific objective of this proposal is to identify and validate targetable tumor-associated antigens (TAAs) in ovarian and pancreatic cancer. It is our central hypothesis that the accurate identification and selection of appropriate TAAs will provide a foundation on which to develop of novel and effective cancer immunotherapies. We have formulated this hypothesis on the basis of preliminary results in which we have used high-throughput tandem mass spectrometry (MS) to successfully identify TAAs from melanoma patient tumors. We have subsequently generated TAA-specific T-cells that showed specific recognition and killing of tumor cells, and will form the basis of an upcoming clinical trial for our melanoma patients. We now have extended this antigen identification pipeline into ovarian cancer to accomplish our objective of developing effective T-cell-based immunotherapies for ovarian cancer and pancreatic patients. **METHODS/STUDY POPULATION:** We have collected patient tumor specimens, and we performed HLA immunoprecipitation, peptide elution, and completed high-throughput tandem MS on these eluted samples to identify TAAs. In addition, we have validated the safety of potential targets through the use of the publicly available RNA sequence data sources GTEx and TCGA. **RESULTS/ANTICIPATED RESULTS:** To date, we have successfully completed over 60 peptide elutions from ovarian and pancreatic patients samples. In total, we have found several potential novel tumor-associated targets. VGLL1, is one of these identified antigens, and in conjunction with our collaborators, we have successfully generated T-cells against it. Additionally, we have found that VGLL1 is a potential novel TAA for 3 other cancer types, including bladder, gastric, and triple negative breast cancers. We are now focusing our efforts on testing these T-cells against additional ovarian cancer cell lines and these cancer types to determine their specificity. We plan to continue the generation and testing other identified potential TAAs as well. We plan to use these T-cells directly in clinical trials in the future. **DISCUSSION/SIGNIFICANCE OF IMPACT:** The rationale for this proposal is that through the identification and validation of TAAs, we can open the door to a new world of therapies that can potentially increase the survival rate in a disease with a historically grim prognosis.

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#### Deconstructing the peptide specificity of TCR recognition

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**OBJECTIVES/SPECIFIC AIMS:** The off-target and organ-specific toxicities observed in cancer immunotherapy present an obstacle to T-cell-based therapeutics. A recent clinical trial underscored the need for improved