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An Empirical Assessment of the Short Term Impacts of a Reading of Deborah Zoe Laufer's Drama *Informed Consent* on Attitudes and Intentions to Participate in Genetic Research

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Abstract

Objective: This study assessed the short-term impact of the play “Informed Consent” by Deborah Zoe Laufer (a fictionalized look at the controversy over specimens collected from the Havasupai Tribe for diabetes research in 1989) on perceptions of trust, willingness to donate biospecimens, attitudes toward harm and privacy among the medical and undergraduate students, faculty and the public in the intermountain west.

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Methods: Surveys were administered before and after a staged reading of the play by professional actors. Survey items included the short form Trust in Medical Researchers, and single item questions about group identity, ethics of genetic testing in children, and willingness to donate biospecimens. In addition, respondents were given the option to answer open-ended questions through email.

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 approximately one 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 investigators to test children for adult onset diseases,” ($p < 0.001$ 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 ($p = 0.777$). Qualitative data provided extensive contextual data supporting these perspectives.

Discussion: This is one of the first studies to document short-term impacts of a theatrical performance on both attitudes and behavioral intentions toward research ethics and clinical research participation. Future research should continue to explore the impact of theatrical performances among public and investigators on the ethical issues and complexities in clinical research.

Keywords

theater; medical education; play; arts; bioethics; biospecimens

INTRODUCTION

Theatrical texts have addressed ethical issues in medicine for well over a hundred years,ⁱ and exposure to theatrical performances is a powerful way to engage a wider public in discussion of bioethical issues. However, there has been limited published empirical research on the impact of dramatic presentation on audience attitudes toward research with biospecimens (Perry et al. 2011). Theatrical performances have long been seen as a useful modality for educating and exposing individuals to complex, ethical issues (Arvekle et al. 2015). With roots in the ancient Greek theatrical tradition of the *agon*—a debate between two characters—much Western drama reuses or a conflict between two or more opposing forces. This conflict is developed and later resolved (with varying degrees of success) through the play’s action. In other words, a play might show us how specific characters try to resolve a conflict—often ethical in nature—over a controversial problem in a particular context. There are many differences between theater and a traditional case study, but two pertinent to our research: (1) the conflict is performed live rather than described and (2) the audience experiences the emotional impact of the conflict as it is portrayed by other human beings.

One setting that has utilized theater to encourage both self-reflection and increased empathy is medical education (Acuna 2000; Eisenberg et al. 2015). An argument for the broader inclusion of the humanities in medical education is that accessing patients’ individual and

ⁱAmong the earliest of these is Georg Büchner’s unfinished play *Woyzeck* (1837), which features a doctor who limits his patient to a diet of only peas and then measures his physical decline by testing his urine.

subjective experiences of illness through literature, including dramatic literature, allows medical students to reflect on their future roles in creating more positive and healing clinical environments (Kirklin 2001). Most commonly within medical education, two types of theatrical tools are used today: Reader's Theatre and simulated, or "standardized" patient encounters (Yaffe 1989; Tetel-Hanks 1993). These approaches are often used in the context of difficult subjects such as grief (Stokes 1980; Kim and Baek 2017), death and dying (Holleman 2000; Arveklev et al. 2017), and breaking bad news (Rosenbaum and Kreitei 2002; Skye et al. 2014). Yet these modalities generally do not allow for shared learning, as can happen in a group like a theatrical audience, or the witnessing of dramatized metaphors for real-life situations (Matharu 2009). Watching a performance by professionally trained actors, rather than taking on one role as a learner, allows for exploration of different roles, including differing perspectives and experiences of various stakeholders portrayed in the performance (Shapiro and Hunt 2003).

One theatrical play, *Informed Consent* (2015) by Deborah Zoe Laufer, is a powerful artistic examination of social and ethical issues relevant to research with biospecimens. The play is a fictionalized version of the controversy that arose over specimens collected from the Havasupai Tribe for diabetes research in 1989. These specimens were subsequently used for other purposes (Mello and Wolf 2010). The play features a central character, Jillian, who is a highly motivated genetic researcher approached by a social anthropologist to help address the alarming levels of obesity-related diabetes in the Havasupai tribe. Jillian, her anthropologist counterpart and all the other named characters are fictional, created by the playwright to represent aspects of the controversy and its possible outcomes. However, like the real Havasupai, the Native American tribe portrayed in *Informed Consent* is small, generally isolated, and carries a long history of difficult interactions with people outside their group. The fictional tribe in the play has 670 living members and their isolation makes them an ideal gene pool for Jillian's proposed research. The audience learns of Jillian's career ambitions and her intent to use the blood for studies beyond diabetes, driven, in part, by her personal concerns about inherited early-onset Alzheimer's and that she suspects she and her daughter might have inherited the same genetic variant. Jillian's desire to test daughter for the Alzheimer's variant is opposed by her daughter's father, her husband. Questions raised through exploration of Jillian's personal and professional genetic research include whether DNA can ever be decoded in such detail as to track the ancestral migration of the world's people. The fictional tribe's traditions, like many real human communities, have an established and sacred explanation for their arrival in their homeland, and it directly conflicts with any explanation Jillian might offer. With her talk of "inbreeding coefficients," and her single-minded attention to her own family's struggles with genetic inheritance and identity, Jillian provides further fodder for discussion of a persistent stereotype: the researcher as an outsider who is oblivious to the needs or desires of her research subjects. The play presents Jillian as complex, motivated not only by career ambition and cultural ignorance—although both are present—but also by fear of death and loss of her own agency.

While the facts of the legal case between Arizona State University and the Havasupai Tribe are used accurately to provide a skeleton for *Informed Consent*, the motivations of the characters and the layered ethical dilemmas presented in the play are fictitious, but carefully framed for the audience's understanding of a number of possible contemporary

controversies in human genetics and genetic research. The aim of our evaluation was to discern attitudes about these issues and toward participation in research after watching the performance. The researchers did not have a hypothesis about how the audience would respond, but were more interested in how the impacts attitudes related to the topics presented. As such, this study assessed the short-term impact of the play *Informed Consent* on perceptions of trust, willingness to do: attitudes toward harm and privacy among the general public and in faculty, medical, and undergraduate students within an academic medical center.

METHODS

Informed Consent was performed as a staged reading by professional actors on two consecutive evenings in Fall 2016. Pre-and post-test surveys were administered immediately before and after the performances. This play was part of an ongoing partnership between the on-campus performing arts organization and the academic medical center at a university in the Intermountain West. Faculty, medical, and health science graduate students, undergraduate students, and the public were targeted for advertisement. A significant portion of the sample (46.5%) was comprised of students, many of whom attended as part of a required course. Also, the demographic data collected did not distinguish between public and faculty and the play was performed on campus and as such, a large part of the sample is likely faculty members and staff rather than the general public. See Table 1 for additional participant demographics. Of the 481 who attended the play, 421 (88.8%) completed both the pre- and posttest surveys, and 166 (34.5%) participants completed open-ended questions online approximately one week after the play.

Survey responses were anonymous. Audience members were given two color-coded surveys that were stapled together along with a consent cover letter. Prior to the show, a member of the production team asked participants to only fill out the pre-test survey. After the show, the same person asked participants to fill out the post-test survey. Members of the research team collected the surveys after the play. Audience members were not assessed on any prior knowledge of the Havasupai case prior to attending the play. However, widely available information, including reviews of previous performances on Broadway (Isherwood 2015), clearly indicated the historical background and fictionalized nature of the story.

Respondents also were given the option to anonymously answer six open-ended questions through email. The email survey was sent to participants who provided contact information between 24 and 72 hours after the play and they had approximately one week to answer the questions. These questions asked respondents to explain the reasoning behind their responses to the three post-test questions about harm, consent, and ethics of investigators as well as the questions about group identity protection and donating biospecimens. A \$10 Amazon gift card was provided to each respondent who participated in the post-test qualitative survey.

Survey Development

The survey items were designed to respect respondents' limited availability before and after the play. Unable to address every ethical issue potentially included in the play, we developed

single-item questions that would be measureable and understandable in a short survey limited to the key ethical conflicts in the play. See Table 2 for a list of the questions. Questions were developed by the research team and were independently reviewed by all team members. Questions covered the ethics of genetic testing in children, the protection of group identity in research, willingness to donate biospecimens, beliefs about medical doctors' intentions, and level of trust in doctors who conduct medical research. There were a total of seven questions on the pre-test, with three additional questions included in the post-test survey regarding harm to the tribal group, consent provided by the tribal group, and the ethics of investigator behavior performed in the play. Attitudes were measured on a five point Likert scale from "1-Strongly Agree" to "5-Strongly Disagree" in reaction to the statements on the survey. In addition, the survey also included a short form *Trust in Medical Researchers* (Hall, Camacho et al. 2006).

Data Analysis

Paired samples t-tests were performed to assess differences between pre-play vs. post-play scores for *Trust in Medical Researchers* and individual items. Repeated Measures Analysis of Variance was used to explore the effect of demographics on pre-play and post-play scores. All items were reverse scored so higher scores indicated more trust.

Qualitative responses provided contextual data about response. All of the open-ended responses were analyzed using a content analysis within a qualitative descriptive framework (Sandelowski 2000; Sandelowski 2010). A member of the research team read all of the responses and created codes based on the participants' own words (Elo and Kyngas 2008). For example, many participants stated that the tribe in the play was not fully informed about the research. These responses were coded as "not fully informed." Additionally, responses were coded for the level of agreement with a given question (i.e. there was harm, or there was no harm). Finally, some participants reported several reasons for a given response to one question; each reason received its own code resulting in more codes than respondents. Another member of the team independently reviewed the codes for accuracy to ensure the codes represented what was reported in the open-ended questions. The codes were then linked based on similarity to form categories (Miles et al. 2014; Rothwell et al. 2016). For each question, the most commonly reported categories are presented below.

RESULTS

For the outcome of *Trust in Medical Researchers*, there was a significant decrease in post-play scores $m = 2.75$ ($SD = 0.67$) when compared with pre-play scores $m = 2.96$ ($SD = 0.70$), $t(420) = 8.09$, $p < 0.001$. Further, fewer individuals endorsed the survey item "Is it ethical for investigators to test children for adult-onset diseases?," post-play $m = 3.00$ ($SD = 1.17$) when compared with pre-play scores $m = 3.34$ ($SD = 1.14$), $t(413) = 7.41$, $p < 0.001$.

There was a significant increase in agreement to improve group identity protections in the conduct of genetic research with post-play scores $m = 3.81$ ($SD = 1.03$) vs. pre-play scores $m = 3.38$ ($SD = 1.12$), $t(411) = 8.89$, $p < 0.001$. There were no differences on willingness to donate biospecimens to research, post-play $m = 4.05$ ($SD = 0.99$) vs. pre-play $m = 4.06$ ($SD = 1.02$), $t(411) = 0.28$, $p = 0.777$.

Differences by demographics (education, income, student status, education, and race) were also included as co-variants in the analysis. Only one question, willingness to donate biospecimens, demonstrated significant differences with these covariates. When differences were analyzed by race of the participant, non-white participants ($n = 68$, $m = 3.76$, $SE = 0.11$) compared with white participants ($n = 344$, $m = 4.12$, $SE = 0.05$), were less willing to donate biospecimens in general $F(1/410) = 8.29$, $p = 0.004$ and white participants' willingness to donate was unchanged $F(1/410) = 3.94$, $p = 0.048$ (see Figure 1).

Post-test only questions also demonstrated that overall, participants strongly agreed that the tribal p (as presented in the play) was harmed $m = 4.21$ ($SD = 0.94$), that members of the tribal group did not give informed consent $m = 1.90$ ($SD = 0.85$), and the investigators had low ethical behavior toward the tribal members $m = 2.05$ ($SD = 0.93$). There were no significant differences by demographics for all three post-test only questions.

Each qualitative survey question was examined separately. In response to "Please explain how you think the tribal group was or was not harmed in this play?", 89.8% of the respondents indicated that the tribal group in this play was harmed, and 6.0% of respondents did not think the tribe was harmed. The three most common categories from all of the 246 coded responses included: cultural identity was harmed (41.9%), participants did not provide consent (21.5%), and investigators misled/violated/betrayed/exploited participants (15.4%).

For the qualitative survey question, "Please explain if you think the tribal informed consent or not?", two codes were created because of the high number of participants that responded with concepts of "legal consent" and "ethical consent" of respondents. 94.4% reported the tribal members gave "legal consent," but only 16.3% reported they gave "ethical consent." The most common categories explaining these perspectives included: participants consented to diabetes study, but not other studies (35.4%); the study was not fully explained and/or understood (22.5%); and participants were not adequately informed (15.3%). Some of the other codes included: tribe was manipulated, cultural/language barriers (13.9%), and vague consent form (5.7%).

In response to the question "Please explain if the investigator behaved ethically or unethically toward the tribal members in this play?", 89.8% of coded responses (total number of codes = 241) indicated that the investigators did not behave ethically. The three most common reasons provided included: the investigators did not get consent properly (22.4%), investigator believed key were acting ethically/trying to help/not malicious (17.8%), and investigators acted unethically or maliciously (17.8%). Some of the other codes included: cultural damage from investigator's actions (14.9%), investigator acted selfishly (12.0%), and tribe was not adequately informed/language barriers/vague paperwork (12.0%).

When prompted to "Please explain if you think it is okay or not to test children for adult onset diseases?", 50.0% of the 233 coded responses indicated that yes it is okay, while 21.3% indicated no, 26.2% reported that it depends and 2.4% wrote maybe. The three most common reasons included: only with parental permission (21.0%), only with child's consent (18.0%), and it is OK because of the risks for stigma or living in fear (15.5%). Other codes

included: only testing if a treatment exists (11.6%), only if early intervention is available (11.6%), and children's vulnerability (9.4%).

For the qualitative survey question, "Why should group identifiers such as race/ethnicity, or community be removed or not removed from biospecimens?", 32.5% indicated that yes race/ethnicity should be removed, 51.6% indicated race/ethnicity should not be removed, 15.9% indicated maybe, and 2.4% indicated that it depends. The three most common categories of explanation included: prevent damage to group/cultural identity (25.3%), group identity is important for population level medical interventions (25.3%), and removal is detrimental to research (19.1%). Other categories included: use DNA or other markers instead of race (10.5%), consent documents should be clear (8.6%), and depends on the demographic size of the group (8.0%).

Finally, in response to the qualitative survey question, "After watching this play, why would you or would you not donate your biospecimen for future research?", coded responses reported that 89.1% indicated that yes they would donate biospecimens, 4.8% indicated no, and 6.1% indicated maybe. The most common categories for why someone would donate biospecimens included: scientific advancement and the greater good (44.0%), if conducted ethically with restrictions (22.3%), and if donation would not harm respondents or their group identity (12.0%). Other categories included: play did not change mind about biospecimen donation (6.5%) and suspicious of research and researchers (5.4%).

DISCUSSION

The use of dramatic literature and performance as a vehicle for ethical inquiry can result in unpredictable reactions by an audience and hypothesizing a particular response is problematic. A theatrical or literary presentation of an ethical conflict may create emotional connections to the people involved in the conflict, broadening an individual's understanding of the issues at stake. As a result, the reader or audience member may be more likely to discuss the issues rather than promote a particular agenda, or their responses to characters might deepen their commitment to understanding impacts on individuals and specific groups of stakeholders. *Informed Consent* is a complex play that highlights a controversial use of biospecimens, based in part on the Havasupai case, as well as using a fictionalized story to highlight some of the ethical issues related to testing children for adult-onset diseases.

Results from this study indicate that, after viewing the *Informed Consent* play, people were less trusting of research and that non-white audience members were less likely to donate their biospecimens to research. More broadly the results raise questions about human subjects protections in general. Already, there is a gap between white and non-white representation in biomedical research, and minority participants have the lowest participation rate in biobanks and research (Remue 2011; Trinidad et al. 2011). Mistrust based on historical research practices and experiences may affect minorities' willingness to participate (Randall 1996; Pentz and Theriault 2001; Pentz et al. 2006). In retrospect, it seems logical that audience members would demonstrate reduced trust in researchers immediately after seeing a play in which a vulnerable population appears to have been taken advantage of—even if unintentionally and for the greater good—by a researcher. The public

presentation of plays such as this one in non-academic settings could have the result of furthering the challenge to recruit minorities for biomedical research. On the other hand, audience members encountering these issues for the first time in a theatrical setting might offer important insights into public understanding of real-world controversies surrounding genetic research. Once alerted to the importance of public input and participation, viewers of plays like *Informed Consent* may help to improve and promote the goals of truly informed consent.

Additionally and importantly, the lack of public awareness about biospecimen research may in itself foster negative attitudes. In 2009, two state public health programs, Minnesota and Texas were sued by parents who objected to the use of residual newborn screening dried bloodspots without parental knowledge or permission (Rothwell et al. 2016). Although the biospecimens were not used in a manner that violated federal regulations, the lack of awareness of this practice was problematic. Theatrical performances could be used to bring greater awareness of utilization of biospecimens as well as to demonstrate some of the benefits and risks of the use of biospecimens, allowing individuals to make an informed decision. However, how the public initially learns about this long-standing practice is important because biospecimen research is dependent on large populations to participate. If biospecimen research use by public health programs is presented in a negative angle, then participation is less likely and may negatively impact public health programs. Finding ways to present these issues in a balanced manner will be important for medical researchers and public support.

That said, the question remains how best to address concerns raised by an audience after viewing a theatrical performance of a bioethics situation. One option is to plan formal panel or group discussions after the play that can put the issues in context, including the strengths and weaknesses of existing safeguards for this type of research. Unfortunately, while the research community learned from the mistakes made in the Havasupai case, the issue of consent for secondary uses of biospecimens remains active (Guerrini et al. 2016). The Common Rule that guides consent practices does not require consent for de-identified biospecimens used in research and the newly adopted changes to the Common Rule do not impact that scenario, instead encouraging the use of broad consent (Federal Policy for the Protection of Human Subjects 2017). Many key stakeholders commented on the Notice of Proposed Rule Making against obtaining consent due to the minimal risk nature of biospecimen research and the logistics of obtaining informed consent from populations within the context of clinical care and competing clinical needs (Health and Human Services 2015). Some published research with varied populations supports these comments, indicating that the public does not want to be refer each research project that uses their biospecimens (Simon et al. 2011; Brown et al. 2016; Garrison et al. 2016). Yet, additional evidence supports a conclusion that the public wants to know about research with their biospecimens and more importantly, they want to be asked for their permission (Hendrix et al. 2013; Javitt 2013; Botkin et al. 2014, Hayeems et al. 2016). The current post-play attitude results further underscore the importance of seeking some type of consent for this type of research.

The results from this study also support the need to address investigator accountability and responsibility, an ethical area not covered by changes to the Common Rule. The Havasupai case and the recent newborn screening bloodspot controversies involve actions by investigators who were technically compliant with federal regulations, yet offended the public and, more importantly, caused decline in public trust. If project-specific consent is not required for use of arch, even in situations when expert panels are convened to ensure appropriate use of biospecimens (Grady et al. 2015), the public is expected to simply trust researchers to use those biospecimens in the manner that is consistent with their proposed use. When de-identified biospecimens are released to an investigator, there are no systematic processes in place to follow up on the actual manner of use, how the leftover biospecimens are stored and potential future uses for the biospecimens. This model of investigator independence leads to a “black box” conundrum in which there is neither accountability nor transparency of the investigator’s independent work. We need to identify ways to improve both recognition of the investigator’s responsibilities and accountability. Currently, much of the accountability falls to the institution where the investigator works. Solutions at the institutional level which promote investigator commitment to ethical conduct of research while respecting investigator intellectual independence are urgently needed.

In addition to exploring ethical issues around consent, *Informed Consent* also highlights the standing debate over genetic testing of children for adult-onset conditions. One of the major critiques of genetic testing of children is that it eliminates the option for children to make their own decisions to pursue knowledge about their genetic profile. Also, because there is large variation in the genotype-phenotype relationship, reporting genetic information back to parents of a healthy child may cause unnecessary worry and anxiety. The limited body of empirical data on how different types of genetic tests impact children and their families is a significant concern (Duncan and Delatycki 2006; Wade et al. 2010). It is unknown how and when parents might communicate to a child later in life about their risk for an adult-onset disease. How these challenges manifest psychosocially for the child and their future health behavior is also unknown. In general, current recommendations do not support genetic testing for adult onset disorders unless there are unusual circumstances, and do support allowing the child to reach the age of maturity to make their own decisions about testing (Botkin et al. 2015). The qualitative results of this play illustrate that these recommendations remain controversial.

In summary, recognizing that audiences are limited in their ability to respond to a presentation of any kind, theatrical performances that focus on ethical controversies in medicine offer an important opportunity to explore complex issues. The arts allow researchers to explore public understanding of, and attitudes toward, a variety of scenarios involving biospecimens, genetics, and other contemporary controversies. For instance, audience member responses could shed light on the implications of biospecimen donation and genetic testing among the public and among vulnerable groups. Many of the comments to the open-ended responses in this study indicated a need for additional protections for group identity, but the suggestions focused more on smaller populations of individuals than on broad demographic indicators such as race. Conversely, this question also received comments about the value of biospecimens when they do not have any type of information related to them (such as zip code or race) and how that additional anonymity limits scientific

integrity and generalizability. It appears the participants in this study greater protections for group identity, yet what this protection might entail was not clear

There are limitations with this type of research, most notably the makeup of the audience. Although it was advertised to the public as part of a season of professional performances on a university campus, most participants were likely part of the academic medical center, given the topic of the play and the sponsoring organizations. Other limitations include the briefness of the survey items and that the qualitative responses were not linked to survey responses.

Further evaluation of the impact of performances on attitudes about research and ethics is needed. Future research should tease out the impact of debriefing discussions on audience attitudes and intentions. Clearly, the experience of viewing a live performance can affect attitudes, and should be considered part of a larger program of education and outreach to communities rather than a single didactic event intended to convey a narrow message. To date, the research and regulatory communities have determined that the benefits of broad consent for biospecimen use justify the lack of specific consent from tissue sources. Finding ways to illustrate the potential benefits of this type of research is equally important as transparency about harms and risks. At the core of ethics is dialogue and discussion, which a play like *Informed Consent* inspires.

Conclusion

This play is particularly salient because it addresses contemporary issues in research ethics. Topics explored included the high-profile case of the Havasupai Tribe, elegantly fictionalized to explore relevant ethical issues, genetic research in children regarding adult-onset conditions, and whether or not consent should be obtained for secondary biospecimens obtained in clinical care and/or research. The robust opinions expressed by members of the audiences for this illustrate that there are rich opportunities to use theatrical performances to explore controversial bioethics issues.

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Figure 1 –.
Willingness to Donate Biospecimen vs. Race (White, Non-White)

Table 1.

Demographic Characteristics of Sample (N=472)

Characteristic	n or Mean	% or SD
Age (years)	37.62	16.79
Gender		
Male	168	39.3
Female	253	59.3
Declined to answer	6	1.4
Ethnicity		
Non-Hispanic	389	91.1
Hispanic	21	4.9
Declined to answer	17	3.9
Race		
American Indian	2	0.5
Asian	36	8.4
Black or African American	4	0.9
Multiracial	10	2.3
Native Hawaiian/Alaskan	2	0.5
Other	6	1.4
White	35	80.8
Declined to answer	22	5.2
Education		
Some high school or less	4	0.9
High school diploma or GED	3	0.7
Some college	57	13.5
Associates degree	16	3.7
Bachelor's degree	156	36.5
Graduate degree	186	43.6
Declined to answer	5	1.1
Student status (n = 196)		
Undergrad (1 st or 2 nd year)	32	16.3
Undergrad (3 rd or 4 th year)	28	14.3
Graduate (Masters or certificate)	13	6.6
Medical	106	54.1
Doctorate	17	8.7

Table 2.**Survey Questions**

<u>Study Specific Questions (1 = Strongly Disagree to 5 = Strongly Agree)</u>
Is it ethical for Investigators to test children for adult onset diseases.
Group identity is not protected in the same way as individual identity in research regulations. Group identity (e.g., tribe, race) needs to be protected in the same way as individual identities.
I would donate my biospecimen for future research.
<u>Trust in Medical Researchers Scale (5 = Strongly Disagree to 1 = Strongly Agree)</u>
Doctors who do medical research care only about what is best for each patient
Doctors tell their patients everything they need to know about being in a research study
Medical researchers treat people like “guinea pigs ”
I completely trust doctors who do medical research
<u>Post Survey Only (1 = Strongly Disagree to 5 = Strongly Agree)</u>
This tribal group was harmed in this play.
Members of the tribal group gave informed consent
Investigators behaved ethically toward the tribal members.