The Effectiveness of Eastern Michigan University’s Institutional Review Board

by

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Project

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Acknowledgement

This research process was not an easy task and it truly took me out of my element. I must thank my Savior, Jesus Christ, for giving me the strength to push through. There were many days where I wanted to quit. I want to thank my parents (Danny and Erma), my siblings (Danny, Jr. and Dominique) and my cousin Shereka for seeing the end of the tunnel when I could not. Thank you for your constant love, patience and support.

I would like to thank Dr. Irwin Martin for being patient and supportive as I balanced my work and school life. Dr. Martin, I have learned so much from you through this process. The skills I have learned through this project has made me a better clinical research coordinator at Karmanos Cancer Institute and I pray that it will make me an exceptional clinical research associate when the time comes.

Dr. Stephen Sonstein, thank you for taking a chance on me. You have given me an opportunity to have a second chance with my career path. The knowledge that you and Dr. Martin has given me has allowed me to part of Karmanos Cancer Institute Phase 1 team for almost 3 years.

Finally, to the Karmanos Cancer Institute Phase 1 team and Lindsay Casetta, thank you. Thank you for giving me an opportunity. This has been a humbling, learning experience. I love what I do and who I do it for. I pray for continued success at KCI.
Abstract

The Eastern Michigan University Human Subject Review Committee has made a commitment to upholding the ethical principles found in the Belmont Report. This commitment has a great responsibility to the academic society as well as those in the community surrounding Eastern Michigan University. This survey was conducted to assess how well the Eastern Michigan University Human Subject Review Committee had previously communicated with those who requested IRB approval. The participants of the study were academic researchers who varied in their field and education level. Due to the number of responses, the results of this survey could not definitively answer the research questions in this project.
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**Introduction**

The need for an Institutional Review Board was born during a time where individuals felt it was ethically sound to do “research” on human subjects without their consent. No one knows the number humans who have lost their lives for the sake of medicine. The complexity of the human body has sparked both positive and negative curiosity in the medical community. Their curiosity of the human body has led them to perform unnecessary experiments on the outcasts in the society of that time. Outcasts were individuals who owed a debt, institutionalized in a mental hospital, prisoners, and/or poor.

An early documented account of unethical human experimentation was during World War II. During this war, German medical doctors believed their research using Jewish men, women and children benefited the greater good of the German soldiers (Byman, 1989). These doctors’ horrible acts were brought to the public’s attention, and many were found guilty for their participation. Before the United States was at war with Germany, the Department of Public Health solicited participation from a vulnerable group of uneducated men in Macon County, Alabama. The project was called the Tuskegee Syphilis Experiment. For 40 years, the participants were not fully informed on why they were enduring the suffering that was inflicted on them (Jones, 1993). In 1972, the New York Times exposed the unethical clinical research practices in Tuskegee (Jones, 1993).

However, The Tuskegee Syphilis Experiment was not the first time the US experimented on their citizens without their consent, but it did force the United States Congress to pass the National Research Act in 1974. Out of the National Research Act came the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The job of the commission was to make recommendations to the Secretary of Health, Education, and
Welfare and Congress regarding the safety and welfare of human research subjects. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research believed that research was necessary to further science, but research subjects needed to be protected from bad science. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research developed the Institutional Review Board (IRB) concept and in 1978, the Belmont Report was published. The Belmont Report provided ethical principles and guidelines in which research involving human subjects should be conducted. The three ethical points that are core of the Belmont Report are beneficence, justice, and respect of persons (Health and Human Services, 1979).

The Eastern Michigan University Human Subject Review Committee has made a commitment to upholding the ethical principles found in the Belmont Report. This commitment has a great responsibility to the academic society as well as those in the community surrounding Eastern Michigan University. Since 1981, Eastern Michigan University Human Subject Review Committee and other universities’ IRB staff have progressively professionalized including training, national conferences, and certification (Droogsma Musoba, Jacobs, & Robinson, 2014).

Universities around the world are constantly pressured to improve in response to environmental influences and competitive forces (Mullen, Murthy, & Teague, 2008). Eastern Michigan University is no different when it comes to trying to remain relevant in a competitive atmosphere. This is why the Eastern Michigan University Human Subject Review Committee had asked applicants who had submitted an application to rate their level of satisfaction with the process. The goal of the survey was to provide a baseline of how well the review committee was performing.
Purpose

The purpose of the research project was to highlight relevant areas that were in need of improvement, so the university could make the necessary changes before the fall 2015 semester began. The applicants were given three weeks to respond to the survey. The university’s research compliance department had made some changes prior to the fall 2014 semester. “There were a few changes made in September 2014. The IRB was brought into compliance with federal regulations, and the submission/document management system was changed from Digital Commons to IRBNet. Additionally, online human subject training was made mandatory instead of optional” (S. C. Wright, personal communication, April 12, 2016). The research compliance department wanted to gauge the satisfaction of individuals who had previously submitted to the IRB. The survey was also designed to solicit data from participants to serve as a baseline to future surveys. This survey was the first time individuals were asked to rate their experience with the Eastern Michigan University Human Subjects Review Committee.
Research Questions

1) Is there a relationship between the communication and application response time provided by the IRB staff?

2) For the IRB tasks and/or interaction, is the perception of satisfaction consistent across the board?

3) Are there differences between the perception of satisfaction with the IRB staff between faculty and students?
EMU UHSRC

Methods

In the second week of March 2015, 377 participants received the Human Subject Review Satisfaction Survey via email. The participants were individuals who had previously applied for research approval to the University Human Subjects Review Committee through the fall of 2014 at Eastern Michigan University. The academic background of the participants was faculty, staff, doctoral students, master’s students, or undergraduate students. For this project, faculty and staff were labeled as faculty and three remaining academic backgrounds were labels as students. (See Appendix.)

The main component of the survey consisted of 15 questions that participants were asked to rate using a 5-point Likert scale. The range of the Likert scale was not at all satisfied to completely satisfied. The 15 questions were divided into five categories: communication (3 questions), application completion (3 questions), application response time (2 questions), CITI online training (4 questions) and workshops and training (3 questions).
Results

Of the 337 emails that were sent out, 102 participants responded to the research compliance department’s survey. Once the all the responses were received from the participants, the data was analyzed using Statistical Package for the Social Sciences or SPSS for short. Using SPSS, a Mann-Whitney U test was conducted to assess if there were differences in satisfaction with the survey questions (Appendix) from the IRB staff between faculty and students (see Table 1).

Communication

A Mann-Whitney U test was conducted to assess if there were differences in satisfaction with the amount of communication from the IRB staff between faculty and students. Distributors, as assessed by visual inspection, were determined to be approximately similar. Median satisfaction with the amount of communication was significantly higher for students (5.0) than for faculty (4.0), $U = 138, z = -2.541, p = 0.011$.

The differences in satisfaction with the promptness of communication from the IRB staff between faculty and students were assessed by using the Mann-Whitney U test. Distributions of the promptness of communication, as assessed by visual inspection, were determined to be approximately similar. Median satisfaction with the promptness of communication was significantly higher for students (5.0) than for faculty (4.0), $U = 154, z = -2.254, p = 0.024$.

Median satisfaction with the quality or helpfulness of communication was significantly higher for students (5.0) than for faculty (4.0), $U = 155, z = -2.18, p = 0.143$. To determine if there were differences in the satisfaction with the quality or helpfulness of communication from the IRB staff between faculty and students. Distributors, as assessed by visual inspection, were determined to be different.
Application Completion

Median satisfaction with the ease of use – IRBnet was significantly higher for students (4.0) than for faculty (3.0), $U = 191, z = -1.22, p = 0.22$. To determine if there were differences in the satisfaction with the ease of use – IRBnet from the IRB staff between faculty and students. Distributors, as assessed by visual inspection, were determined to be different.

To determine if there were differences in satisfaction with the ease of completing application from the IRB staff between faculty and students, a Mann-Whitney U test was conducted. Distributors, as assessed by visual inspection, were determined to be different. Median satisfaction with the turnaround time was significantly higher for students (4.0) and for faculty (3.0), $U = 169, z = -1.52, p = 0.13$.

Application Response Time

To determine if there were differences in satisfaction with the turnaround time from the IRB staff between faculty and students, a Mann-Whitney U test was conducted. Distributors, as assessed by visual inspection, were determined to be the similar. Median satisfaction with the turnaround time was the same for students (4.0) and for faculty (4.0), $U = 234.5, z = -0.137, p = 0.891$.

The differences in satisfaction with the quality of online assistance documents from the IRB staff between faculty and students were assessed by using the Mann-Whitney U test. Distributions of the quality of online assistance documents, as assessed by visual inspection, were determined to be approximately similar. Median satisfaction with the quality of online assistance documents was significantly higher for students (4.0) than for faculty (3.0), $U = 177, z = -1.52, p = 0.13$. 

A Mann-Whitney U test was conducted to determine if there were differences in the level of detail or clarity of revision from the IRB staff between faculty and students. Distributors, as assessed by visual inspection, were determined to be different. Median satisfaction with the level of detail or clarity of revision was significantly higher for students (5.0) than for faculty (4.0), $U = 171.5$, $z = -1.72$, $p = 0.09$.

**CITI Online Training**

The differences in satisfaction with the quality of CITI online training from the IRB staff between faculty and students was assessed by using the Mann-Whitney U test. Distributions of the quality of CITI online training, as assessed by visual inspection, were determined to be approximately similar. Median satisfaction with the quality of CITI online training was significantly higher for students (4.0) than for faculty (3.0), $U = 152.5$, $z = -2.33$, $p = 0.02$.

A Mann-Whitney U test was conducted to determine if there were differences in the satisfaction with the usefulness of CITI online training from the IRB staff between faculty and students. Distributors, as assessed by visual inspection, were determined to be different. Median satisfaction with the usefulness of CITI online training was significantly higher for students (4.0) than for faculty (1.0), $U = 162.5$, $z = -2.08$, $p = 0.04$.

Median satisfaction with the applicability of CITI online training was significantly higher for students (4.0) than for faculty (3.0), $U = 171.5$, $z = -1.89$, $p = 0.06$. To determine if there were differences in the satisfaction with the applicability of CITI online training from the IRB staff between faculty and students. Distributors, as assessed by visual inspection, were determined to be different.

The differences in satisfaction with the appropriateness of CITI online training from the IRB staff between faculty and students was assessed by using the Mann-Whitney U test.
Distributions of the appropriateness of CITI online training, as assessed by visual inspection, were determined to be approximately similar. Median satisfaction with the appropriateness of CITI online training was significantly higher for students (4.0) than for faculty (3.0), $U = 175, z = -1.80, p = 0.07$.

**Workshops and Training**

To determine if there were differences in satisfaction with the availability and variety of training workshops from the IRB staff between faculty and students, a Mann-Whitney U test was conducted. Distributors, as assessed by visual inspection, were determined to be the similar. Median satisfaction with the availability and variety of training workshops was the same for students (1.0) and for faculty (1.0), $U = 227.5, z = -0.31, p = 0.75$.

A Mann-Whitney U test was conducted to determine if there were differences in the satisfaction with the convenience of training workshops from the IRB staff between faculty and students. Distributors, as assessed by visual inspection, were determined to be different. Median satisfaction with the usefulness of convenience of training workshops was significantly higher for students (1.5) than for faculty (.5), $U = 218.5, z = -0.54, p = 0.59$.

A Mann-Whitney U test was conducted to determine if there were differences in the satisfaction with the quality of training workshops from the IRB staff between faculty and students. Distributors, as assessed by visual inspection, were determined to be different. Median satisfaction with the quality of training workshop was significantly higher for students (1.0) than for faculty (0.0), $U = 184, z = -1.465, p = 0.143$. 
**Table 1**

*Descriptive Statistics Between Ratings of Satisfaction Among Faculty and Students Participating in the IRB Review Process*

<table>
<thead>
<tr>
<th>Measures</th>
<th>Faculty</th>
<th>Student</th>
<th>Z</th>
<th>U</th>
<th>P</th>
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<td>Amount of Communication</td>
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<tr>
<td>Quality of online assistance documents</td>
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<td>177.00</td>
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<td>4</td>
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<td>Ease of completing application</td>
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<td>4</td>
<td>-1.52</td>
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<tr>
<td>Turnaround time for review</td>
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<td>4</td>
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<td>234.50</td>
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</tr>
<tr>
<td>Level of detail or clarity of revision</td>
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<td>5</td>
<td>-1.72</td>
<td>171.50</td>
<td>0.09</td>
</tr>
<tr>
<td>Quality of CITI online training</td>
<td>3</td>
<td>4</td>
<td>-2.33</td>
<td>152.50</td>
<td>0.02</td>
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<tr>
<td>Usefulness of CITI online training</td>
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<td>4</td>
<td>-2.08</td>
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<td>Applicability of CITI online training</td>
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<tr>
<td>Appropriateness of CITI online training</td>
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<td>Availability and variety of training workshops</td>
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<td>1</td>
<td>-0.31</td>
<td>227.50</td>
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<td>Convenience of training workshops</td>
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<td>1.5</td>
<td>-0.54</td>
<td>218.50</td>
<td>0.59</td>
</tr>
</tbody>
</table>
Discussion

Research Question 1: Is there a relationship between the communication and application response time provided by the IRB staff?

The correlation matrix table (Table 2) supported there was a significant relationship between communication and application response time with the IRB staff between the faculty and students. The results showed the faculty and students were satisfied with the application response time provided by the IRB staff. There was also found a significant relationship between communication and workshop and training between the IRB staff and the participants. This finding showed that the IRB staff was making the department available to train those who were not familiar with research and provide extra support when needed. A significant relationship between communication and CITI online training was not found. It was not clear why there was not a relationship. One can assume because CITI online training was not an Eastern Michigan University program, any question a researcher may have, CITI would be their first point of contact.

The average turnaround time for the EMU HSRC was around three weeks (Human Subjects Review, personal communication, January 19, 2016). The three-week turnaround time is standard for most academic institutions, because most IRBs meet once a month to the review submitted studies. The “turnaround time for review” question should be expanded to include time the participants originally submitted their proposal and the time it took after they had to resubmit their proposal, if applicable. Questions that can include how the participants felt about the advertised turnaround time, time until feedback from IRB on submitted proposal, time for IRB to communicate need of revision, respondent’s revision time, IRB’s response time to revision, total elapsed IRB time excluding respondent’s revision time, fastest experienced
turnaround, slowest experienced turnaround and IRB time on slowest experience (Ashcraft & Krause, 2007). Some of these questions are addressed in the survey, but asking these questions can provide a better understanding how the researchers perceived the “turnaround time for review”.

In the article, *Social and Behavioral Researchers' Experiences With Their IRBs*, the authors state that “Researchers who receive timely feedback and approval are reasonably content with the IRB approval process and are unlikely to violate the regulations concerning the need for prior approval. Slow turnaround, especially for those who are doing minimal risk work, is a primary source of frustration and is rather closely related to going solo on a project and introducing modifications without notifying the IRB.” This idea of going solo can cause more problems than one would think. This can create a culture in the research community that can be seen as unethical. Though the research motives were “good”, their unapproved change to the proposal or protocol could have negative effect on a participant in the research.

**Research Question 2: For the IRB tasks and/or interaction, is the perception of satisfaction consistent across the board?**

In Table 1, the overall perception of the satisfaction was consistent across the board. The respondent median, between the faculty and students, showed the students were significantly satisfied with the tasks and/or interaction with the IRB. There was not a significant difference of satisfaction in the questions pertaining to the turnaround time and availability and variety of training workshops. It is unclear why the data did not provide a difference, one can assume the participants were equally satisfied or equally dissatisfied with turnaround time and variety of training workshop.
Research Question 3: Are there differences between the perception of satisfaction with the IRB staff between faculty and students?

It is unknown if there were differences between the perception of satisfaction with the IRB staff between faculty and students. The results provided in Table 1 and Table 2 do not provide enough information to provide evidence for this question. This survey was sent out to 377 emails and only 102 responded. It was not known, if all 337 emails were active faculty and students.

This was the first time a survey has been provided to participants who have submitted a study for review. Due to the lack of data from previous years, it was difficult to see if there are differences between the perception of satisfaction with the IRB staff between faculty and students. A survey should have been provided again in the March 2016 period to see if there were differences between the perception of satisfaction with the IRB staff between faculty and students. This survey could be beneficial to the committee, because it can provide feedback in the areas the participants were not satisfied and look for ways to improve their services to the EMU community. The survey should ask participants to state what year they had submitted a study for review. This window of time could provide more reliable idea of how the committee is doing.

Limitation

A primary limitation of this project was not being able to compare the Eastern Michigan University Human Subjects Review Committee to similar universities in Michigan. Central Michigan University and Northern Michigan University were schools selected because they have
similar academic profiles. Both universities were contacted to learn if their IRB conducted annual surveys. Neither schools conduct annual surveys, but a representative for Central Michigan University stated, “At one time, the IRB was thinking about putting together a survey, it was never completed.” This lack of information made it difficult to compare the Eastern Michigan University Human Subjects Review Committee with other academic IRBs. Based on the results of this survey, it is unclear if the changes made in the research compliance office have met the needs of the individuals who had submitted studies for review. This question could have been better answered if the research compliance had submitted a survey to the participants at the end of the winter 2014 and winter 2015 semesters.

The second limitation to this study was the lack of scholarly articles available concerning communication between participants and an academic IRB. In the article, *A Survey of University Institutional Review Boards: Characteristics, Policies, and Procedures*, the authors created a survey that focused more on the demographic make-up of the IRB and how well it represented the community at large. The results of the this survey showed that the data reflected a predominately white and male representation. The federal regulations appear to underline this requirement in stating that an IRB should be “sufficiently qualified through… the diversity of the members’ background including consideration of the racial and cultural background of members (Hayes, Hayes, & Dykstra, 1995). The cultural background of the Eastern Michigan University Human Subjects Review Committee is very diverse. The committee, as of May 1, 2016, has 9 females, 4 males and 4 vacant seats (S. C. Wright, personal conversation, May 1, 2016).

In 2012, Robert Klitzman wrote an article called *From anonymity to “open doors”: IRB responses to tensions with researchers*. In this article, Klitzman found that the information the IRBs use to communicate to the researchers was important, including how (i.e., the tone and the
nature of interactions) the information is presented to the researchers. The author suggested the following ways IRBs can potentially improve their relationship with PIs: using more “open doors” rather than anonymity, engaging in outreach (e.g., through clinics), enhancing the tone as well as content of interactions, educating PIs about underlying ethics, and helping PIs as much and proactively as possible. IRBs should provide a single point of contact and develop a relationship with researchers to track down needed information, and enable them to take action quickly, as needed (Adams, et al., 2014). The Eastern Michigan University Human Subjects Review Committee activities are coordinated by Sonia Chawla Wright. Ms. Wright is the Research Compliance Officer for Eastern Michigan University. She provides access to resources and workshops for individuals and groups who want to do research at Eastern Michigan University (Eastern Michigan University, 2016).

Effective communication can help alleviate tension for both researchers and the IRB. Earlier in the project, the data provided from the survey reflected how researchers felt about communication between them and university human subject review committee. One way to improve the tension between researchers and the IRB is for universities to create a self-assessment tool (Adams, et al., 2014). Mahidol University, in Thailand, created an IRB Metric to assess the efficiency and perceived effectiveness of its ethics committee. Quantitative information based on IRB Metrics structured-8 point process-outcome illuminates different areas for internal-process improvement (Adams, et al., 2014).

At the 2004 Annual IRB Conference, IRB members, researchers, sponsors and others attending discussed how communication problems contribute to the problem of delayed clinical trials and misunderstanding among those who are working toward the same goals (AHC Media: Continuing Medical Education Publishing, 2004). An attendee of the conference stated, “Too
often IRBs don’t make their requirements clear, what materials they need to review, what the review process will look like, so folks don’t know what to expect and this sets up an uneven dynamic”. This statement goes along with what Robert Klitzman had written in his article. The IRB needs to be transparent, but the researcher also needs to frame the requests in a problem-solving and conciliatory fashion (AHC Media: Continuing Medical Education Publishing, 2004). When there are unexpected delays with the IRB process, know who to contact as well as how you communicate can help alleviate tension among the two groups.

Another topic to take into consideration is the HSRC effectively communicating changes in policies. Kristine L. Fitch, author of *Difficult Interactions between IRBs and Investigator: Applications and Solutions*, mentioned how difficult it was for the board and Human Subjects Office at Iowa to come up with effective ways of getting information about changes to those who do research. The changes included but were not limited to application process, review procedures and regulations (Fitch, 2006). Ms. Fitch states, “most individuals see there is a communication attempt from the IRB and delete the email are the same ones who later come to committee meetings complaining about not being informed about the “senseless changes in procedures.”
## Descriptive statistic and correlation matrix for study variables – correlation matrix

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**Notes:** * correlation is significant at the 0.05 level (two-tailed); ** correlation is significant at the 0.01 level (two-tailed); *** correlation is non-significant. Univ Affil = University Affiliation; College = College; Review Stat = Review Status; Amt of com = Amount of Communication; POC = Promptness of Communication; QOC = Quality or helpfulness of Communication; QOAD = Quality of online assistance documents; EOU IRBnet = Ease of use – IRBnet; EOCA = Ease of completing application; TTFR = Turnaround time for review; LODL = Level of detail or clarity of revision; QCITI = Quality of CITI online training; U of CITI = Usefulness of CITI online training; Appr CITI = Appropriateness of CITI online training; AVTW = Availability and variety of training workshops; CTW = Convenience of training workshops.
Conclusion

Overall, this survey has provided the Eastern Michigan University Human Subjects Review Committee valuable information as a baseline to future surveys. The data provided from the survey was not sufficient enough to gauge the level of satisfaction from the faculty and student with the IRB staff. Also, more universities should provide end of the year surveys for those who participate in research. Understanding how to serve better their researchers can be a benefit to the university as well as the community.

Most researchers already feel the IRB is too involved or do not completely understand what their research entails (Getz, 2011). As criticism and dissatisfaction grows, our national IRB system has been losing credibility and respect among professionals and patients (Getz, 2011). The Eastern Michigan University Human Review Committee should implement internal IRB Metrics so they can see how they can improve internally as well as externally. Communication is complicated because it is important (and vice versa: important because it is complex) (Fitch, 2006).
References


# Human Subject Research Program Evaluation

1. What is your affiliation with Eastern Michigan University?
   - Faculty
   - Staff
   - Doctoral Student
   - Masters Student
   - Undergraduate Student

2. Which College are you in?
   - College of Arts and Sciences
   - College of Health and Human Services
   - College of Education
   - College of Business
   - College of Technology

   Other Affiliation (please specify)

3. Have you submitted a study for human subject review *during* the fall 2014 semester?
   - Yes
   - No

4. How was your study reviewed?
   - Full Board
   - Expedited (UHSRC reviewers)
   - Exempt (College reviewers)
   - I’m not sure
## Human Subject Research Program Evaluation

5. Please indicate how satisfied or dissatisfied you are with the following.

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