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Therapeutic misunderstanding among
future clinicians and researchers;
Attitudes towards increased exposure to
clinical research ethics in undergraduate
medical education a pilot study

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BOSTON UNIVERSITY
SCHOOL OF MEDICINE

Thesis

**THERAPEUTIC MISUNDERSTANDING AMONG FUTURE CLINICIANS AND
RESEARCHERS; ATTITUDES TOWARDS INCREASED EXPOSURE TO
CLINICAL RESEARCH ETHICS IN UNDERGRADUATE MEDICAL
EDUCATION
A PILOT STUDY**

by

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B.S., University of Massachusetts Amherst, 2003

Submitted in partial fulfillment of the
requirements for the degree of
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ABSTRACT

Background: Therapeutic misunderstanding (TMU) and its three facets: therapeutic misconception, therapeutic misestimation, and therapeutic optimism have been identified as major challenges to the ethical conduct of clinical research and obtaining informed consent from research participants. However, the prevalence of TMU among clinicians and researchers has not been explored. Since most physicians will be exposed to clinical research over the course of their career, the understanding of clinical research procedures is important. In this study we attempted to determine the prevalence of TMU among medical students: future clinicians.

Methods: Twenty-two BUSM undergraduate medical students took part in a two-part, survey evaluating the prevalence of therapeutic misunderstanding using “The Therapeutic Misunderstanding Scale”. The attitudes of the students towards

increasing the exposure to clinical research topics through the medical school curriculum were also determined.

Results: The majority of the medical students exhibited therapeutic misunderstanding, particularly in the area of therapeutic misconception. In particular, the misunderstanding the difference between evidence-based clinical care versus hypothesis driven clinical research was exhibited. Although there was strong agreement that education in clinical research and clinical research ethics was important, the participants though increases of clinical research topics in the curriculum was not needed.

Conclusions: The increased prevalence of TMU among future physicians underscores the need to teach clinical research and research ethics. Further research on a larger sample needed to validate the findings.

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ABBREVIATIONS

BUSM	Boston University School of Medicine
IRB	Institutional Review Board
RCT	Randomized Clinical Trial
TE	Therapeutic Misestimation
TM	Therapeutic Misconception
TMU	Therapeutic Misunderstanding
TMU Scale	Therapeutic Misunderstanding Scale
TO	Therapeutic Optimism

1.0 BACKGROUND

Over the course of their careers, almost every clinician will have a role in balancing both clinical care of their patients as well as clinical research. Regardless of direct participation in research by a clinician, a general understanding of the basic principles, both functional and ethical, of clinical research is needed. Every clinician must read and interpret the biomedical literature in order to practice evidence based medicine. Many clinicians will have to answer questions from their patients concerning participation in clinical research studies. With an ever increasing number of clinical trials, and advertisements on TV, in newspapers, and on the internet, it is almost certain that clinical research will make its way into every clinical practice at some point.^{1,2} For clinicians who will not go through formal training in clinical research, the basic functional and ethical issues must be covered somewhere in their medical education. Because advising patients on research participation is an important part of the physician-patient relationship, improvements to undergraduate medical curricula need to be made, and this has been recognized by the medical students themselves.^{3,4}

The goal of clinical research and clinical research ethics education should be to educate medical students in the fundamentals and major ethical issues they will face when conducting or advising on participation in clinical research, as well as reading and interpreting the biomedical literature or performing the informed consent process. The differences between clinical care and clinical

research, clinical equipoise, clinician/researcher duality of role, and the general all-encompassing misunderstanding of clinical research among research participants, are concepts about which every clinician must have a general understanding. Beginning in 1982, misunderstanding of these concepts in research participants as well as clinicians is what has been termed therapeutic misconception.⁵ This term has undergone some revision and much controversy over the last 30 years. Therapeutic misconception has come to be recognized as just one of three facets of the greater construct, therapeutic misunderstanding.⁶

1.1 Therapeutic Misunderstanding

Clinical Care versus Clinical Research

Clinical care is the evidence-based, individualized care of a patient by their physician. It encompasses the whole of diagnostic procedures and treatments with the sole goal of maintaining or improving the health of the current patient whereas clinical research is hypothesis-based process, mostly (with some exceptions) geared towards generating newer data, and helping future patients.¹

Clinical equipoise

Clinical equipoise is a basic concept in clinical research ethics. Equipoise is defined as “the genuine uncertainty about the risks and benefits of the test treatment. That is, there must be sufficient certainty that the test treatment might be beneficial in order to administer it to some individuals while, at the same time,

sufficient doubt about its benefits in order to withhold it from others.”⁷ It is this concept that provides us with the ethical footing to randomly assign research participants to separate treatment groups. These groups usually comprise a group receiving the treatment/intervention under study, and a comparison group that may be a placebo, standard of care, or sham device/surgery. Clinical equipoise is where ethically, we can make the greatest distinction between clinical research and clinical therapy. In clinical research the goal is to answer a specific scientific question to add to “generalizable knowledge” about a condition and its treatment through experimentation.

Clinician/Researcher Duality of Role

Increasingly in the United States, and elsewhere, industry based clinical research is moving away from the academic medical center model and a much higher number of clinical trials are moving into the private practices of active clinicians.^{8,14}

Between 1980 and 2004 the percentage of clinical trial sites based in academic medical centers decreased from 80% to 30%.⁹ Since 1990 the number of private practice based clinicians conducting clinical trials has increased from 4,000 to over 20,000.^{1,9} In 2008, clinical trial spending broke \$11 billion, and as much as 36% of that spending was in private practice-based trials.¹⁰ A recent study of private practice based physicians identified one of the major reasons for this shift is the financial incentives: “We’re paid less and less for the work we do.

In fact, we're paid about 50% of what we made 20 years ago...So one of the ways we offset that [trend] is to find an alternative source of revenue, and getting into research was a way to do that.”⁹ With the rising costs of healthcare for both patients and clinicians, the role of the financial interests that come along with participation in clinical research studies by clinicians provides increasing conflicts within the doctor-patient relationship.⁹

In both private practice and academic medical/research centers, this “duality of role” and the inherent differences and goals of the clinician versus the researcher must be fully understood by research subjects for them to give complete informed consent. In the setting of a dedicated research clinic, this difference is easier to show. A dedicated clinical researcher is not a research subject's regular primary care physician or specialist and is not regularly recommending or prescribing treatment for the research subject in an ongoing manner. It is easier for the research subject to see the temporary relationship (the instances where a researcher may see the research subject in another setting such as a separate clinic setting at the same institution is a separate case that falls under the following example).

Outside of the dual role of the clinician/researcher is the potential of a clinician helping their patient make decisions about participating in clinical research. This could come from referring their patients to a research study because of lack of treatment options, or to answer questions about the risk versus benefits of participating in a research study conducted elsewhere. A

potential research subject's regular clinician(s) is more poised than the researcher to understand the broad implications of a particular research intervention on the subject's health. Most importantly, how participating in the study may adversely affect their health, from interactions of medications, necessary changes to their current therapy, or the multitude of tests, blood work and questionnaires that go along with the data collection of research, many of which may have risks beyond that of the particular intervention itself. The subject's clinician can also provide a more unbiased view of the research study than that of the researcher, who even though well-intentioned has financial conflicts and recruitments deadlines.^{1,11,12}

The misunderstanding of the dual role of the clinician/researcher, the general misunderstanding of differences between clinical care and clinical research and the effects these issues have on informed consent has been labeled therapeutic misconception when it exists in research subjects.

Therapeutic Misunderstanding and Therapeutic Misconception

Therapeutic misconception (TM) was first described in by Appelbaum et al. in 1982 as the assumption of research subjects that "decisions about their care are being made solely with their benefit in mind" in relation to the subjects' participation in research activities. Appelbaum anecdotally expressed this in the following back and forth between a researcher and their subject:

Gray: “How did you think they were going to decide which drug to give you? Did you know?”

Subject: “Well, I figured they would take into consideration, you know, my condition and what was happening to me.”

Gray: “That’s what I was wondering, because several people told me they figured they would get the best drug for them.”

Subject: “Yeah. I certainly thought *I* was taken into consideration.”

demonstrating the therapeutic misconception, in this case the lack of understanding of randomization and blinding in the study participated in.⁵

In 2007, Jonathan Kimmelman discussed TM at 25.¹³ Kimmelman defined TM as “the failure of research subjects to appreciate the ways that study procedures interfere with individualized care.” Kimmelman notes the growing acknowledgement of TM as a research ethics issue, especially since 2000, highlighting the increasing number of publications in PubMed referencing TM, as well as the number of articles citing Appelbaum 1987 on TM, where the concept was brought to a larger audience.

Despite its 30-year existence in the medical terminology the exact nature of TM is still debated and some have proposed that it is really one of three facets of a greater subject, Therapeutic misunderstanding (TMU) which also covers Therapeutic misestimation (TE), and Therapeutic optimism (TO).⁶ The concept of TM was relegated to the simple conflation of research with clinical care while TE is described as the underestimation of risk to the research subject and/or the overestimation of the benefit to the subject. TO on the other hand is a more

emotional response wherein the research subject “hopes for the best personal outcome.” TM and TE together are seen as the greater threat to the informed consent process in research. It is with these two concepts that research subjects really misunderstand the differences between research and clinical care or therapy. TO, on the other hand, is much less of a misunderstanding than an emotional response, ‘hope’ that they will have improvement in their condition. As Horng and Grady suggest, “An optimistic outlook likely makes a positive contribution to the healing process.” TO alone does not constitute the greater TMU, however it can magnify the effects of TM and TE.⁶

Henderson et al. postulate a different definition of therapeutic misconception, focusing solely on the understanding of clinical care versus research. That the purpose of research is to gain generalizable knowledge and any potential therapeutic benefit is merely a secondary concern.¹⁴ Henderson goes on to list 5 dimensions that research participants should understand for true informed consent: scientific purpose of the research, study procedures, uncertainty (equipoise), adherence to the protocol, and clinician as investigator (duality of role).

Miller explains that therapeutic misconception is not limited to research subjects but also applies to clinicians and clinician-researchers.¹⁵ Various authors have estimated that TM among clinicians may be as high as 60%, however the reasons or area of TM are not always the same for researchers and research subjects.^{12,16} If researchers conflate the ethics of clinical research with

the ethics of therapeutic medicine, they may implicitly “foster the therapeutic misconception among their research participants.”¹⁵ This has been termed “Therapeutic Misdirection” and may be unintentional. It is especially concerning when although well-intentioned, researchers attempt to personalize care of research subjects.^{17,18} Green’s analysis of IRB exception requests, requests to deviate from the study protocol, showed the most frequently given reason was to enable the research subject to receive the treatment instead of being randomized to treatment or placebo, or for subjects who did not meet inclusion/exclusion criteria.¹⁸

The Therapeutic Misunderstanding Scale

The Therapeutic Misunderstanding Scale (TMU scale) was developed and validated by Chou and O’Rourke in response to the need for an instrument of sufficient breadth to evaluate TMU, but without being overly long and too unwieldy to be widely utilized. The TMU scale was designed using psychometric procedures unlike previous scales developed by Appelbaum et al.¹⁹ However, “The Therapeutic Misconception Scale”, a 6-item T/F instrument from Dunn and Appelbaum was the starting point for question content and survey design. The original Therapeutic Misconception Scale was scored 0 to 6 with a full score of 6 required to show no TM. After the presence of TM is determined, the specific questions answered incorrectly can be evaluated for areas where focus in informed consent can be improved.²⁰

The validation population for the TMU scale was an older, computer literate, Canadian and American population, mean age 59.8 years, well educated, mean 13.9 years of formal education, exclusively with internet data collection techniques. The study was in two parts, generating the useable items from a larger pool using psychometric methodology, and then validation by analog methodology using a defined hypothetical clinical trial situation. The study participant population consisted of individuals who had previously participated in randomized clinical trials as well as those who never had participated in research. Chou et al. note that analog methodology is useful because it allows participants to respond based on their perceptions of the hypothetical situation rather than their past experiences.¹⁹

The Therapeutic Misunderstanding Scale itself consists of 20 items that can be administered with short Likert-type scales or with a briefer True or False answer. (See Appendix B) Each individual item covers concepts related to the three-facet TMU construct of Horng and Grady, TM (9), TE (6), and TO (5). These concepts range from understanding the differences between clinical care and clinical research, clinical equipoise, and the differences between a practicing clinician and a research clinician. Ultimately, it can be used to judge the effectiveness of the informed consent process outside of the clinical specifics of the intervention and its risks in a particular study, and the general understanding of the research participant.

Responses can be averaged or summed, depending on if utilized with a likert scale or binary true or false response respectively, in total to yield a raw score that can be linked to a certain degree of Therapeutic Misunderstanding, or average per item scores can be analyzed against a variety of demographic or life/educational experience information collected to show areas of greatest misunderstanding.

The TMU scale was designed to be used with research subjects, administered at some point after informed consent was obtained for participation in a clinical trial. Subjects would answer the questions based on reading the hypothetical scenario presented at the beginning of the survey, and the survey would be scored based on the generalized structure of a randomized clinical trial (RCT) and choosing *the best answer*. The basic structure of a randomized, double blind, placebo controlled study is designed around a strict protocol for generalizable results, not individual benefit, which cannot be guaranteed. Adjustments to the study drug, and individualized treatments are not allowed in the general RCT study design.

1.2 Clinical Research and Clinical Research Ethics in Undergraduate

Medical Education

A 2000 survey of U.S. and Canadian medical schools showed that 70% of schools allotted 20 or more hours of ethics instruction in their curricula. The largest focus of instruction was in clinical situations (informed consent, health

care proxy etc.) at 96% of responding schools. Research ethics topics were only reported to be part of the curricula at 54% of the schools, and the role of ethics committees, was discussed in only 42% of curricula.²¹

At BUSM formal instruction in clinical research and research ethics topics such as TM takes place early in the first year in the “Evidence-based Medicine” course, covering approximately 12 instructional hours. Medical and research ethics related topics are taught through the “Essentials in Public Health” course and have also been integrated in to the general curriculum. It is expected that these topics will also be learned through clinical rotations, discussions with mentors, journal clubs as well as integrated into applicable didactic lectures.

Roberts et al over the last decade have conducted numerous cross-sectional surveys as well as interventional studies at the Universities of New Mexico and Wisconsin exploring ethics curricula, and medical students’ expectations regarding the curricula with a later focus on clinical research topics and education. Their studies have shown positive attitudes among the students about the need for increased education in clinical research related topics as well as improved ethical reasoning in medical students who are taught to recognize ethical dilemmas.^{3,4,22} A 2004 cohort study followed undergraduate medical students through their education, asking about a broad range of medical ethics topics and mapping changes in those attitudes over a three year period. Most criteria measured, including those on ethical topics, showed a general decrease in positive attitudes over a student’s time in school. It was agreed in general, that

subject matter in these areas was seen as less important than basic and clinical sciences and skills.²³ In a 2001, 3-arm, interventional study of medical students, it was shown that students who were taught to use the Research Protocol Ethics Assessment Tool or who viewed a presentation on personal perspectives and experiences of seriously ill individuals who participated in research studies were better able to answer questions about ethical dilemmas' than the control group who answered the same questionnaire without any ethics instruction.²²

Students entering undergraduate medical education have a preexisting perception of healthcare and the practice of clinical medicine. These preexisting perceptions are derived from their life experiences and may include influences from medical histories related to their personal lives, as well as previous educational and research exposures. It has been shown in numerous studies that women demonstrate a greater perception of the need for ethics education, as well as a decrease in this perception among all groups as the students progress through medical school.^{3,4,22,23} As Woloschuk discussed, these attitudes can be overshadowed by more discrete science and clinical portions of the education. There is also a loss of the higher idealism that students may enter medical school with, replaced with a more realistic view of medical practice and a general desire to finish school and get out into the real world. This needs to be considered in the design and temporal positioning of coursework over the course of medical school.²³

Focus groups with medical students who conducted undergraduate research, both basic and clinical, have shown that students are aware of research and its importance. However, students are not always clear what constitutes various forms of research, or how it differs from clinical care in the case of clinical research, leading to therapeutic misunderstanding among students and clinicians. Students also came out of undergraduate research with more of a feeling of “hired help” as opposed to active researchers.² These experiences can augment the preconceived notions of research, which could in turn affect their willingness to address research and research ethics-related topics, making formalized training in research and research ethics related topics essential. Murdoch-Eaton states, that “All clinicians need to understand research and the research process, even if they are not actively engaged in research itself.² Evidence-based medicine requires clinicians to make informed judgments on the best possible care for their patients or populations, and base this upon the best available evidence.” Thus it is not only important for a clinician to have a good foundation in the basic science and clinical skills, but a thorough understanding of the biomedical literature, which can only come from understanding the underlying research, and ethical principles that govern how and why research is conducted.

Attitudes Towards Clinical Research Ethics education Survey

The Attitudes Towards Clinical Research Education survey (Attitudes) is a 12 item questionnaire assessing the interests of ethics education among medical students, with a focus on clinical research topics. (See Appendix C) Questions were adapted from surveys developed by Roberts et al., as well as questions developed for the purposes of this survey. The survey consists of 24 major items in 12 groups scaled on a 9 point Likert-type scale, 1= strongly disagree, 9= strongly agree. Individual item means can be compared across a variety of demographic or life/educational experiences collected as part of the demographics and predictor variable questionnaire. In addition several items evaluate attitudes towards similar clinical versus research related concepts.

Previous studies by Roberts et al and Woloschuk et al have shown that there is moderate to high agreement towards the need for increased ethics training in the undergraduate medical curriculum.^{3,4,22,23,24}

2.0 METHODS AND MATERIALS

This was a two-part, survey-based, cross-sectional pilot study of undergraduate medical students at Boston University School of Medicine in the 2012-2013 academic year.

2.1 Study Hypotheses

Hypothesis 1

A majority of BUSM undergraduate medical students will demonstrate therapeutic misunderstanding, as defined by a score of ≤ 14 on The Therapeutic Misunderstanding Scale.

Hypothesis 2

A majority of BUSM undergraduate medical students will agree with a mean score of ≥ 7 that clinical research and clinical research ethics education is important (question 12 on the Attitudes Towards Clinical Research Ethics Education Survey).

Hypothesis 3

A majority of BUSM undergraduate medical students will agree with a mean score of ≥ 7 that there should be increased focus on clinical research and clinical research ethics education in the medical school curricula (question 13 on the Attitudes Towards Clinical Research Ethics Education Survey).

2.2 Study Population

The eligible population consisted of all undergraduate medical students, BUSM I through BUSM IV, including dual degree students currently in their PhD or master's degree year. There were approximately 730 students enrolled during the 2012-2013 academic year. For the pilot study, it was intended to recruit up to 50 undergraduate medical students: 25 BUSM I and II's, and 25 BUSM III and IV's. Dual degree students currently in their PhD, MPH, or Masters year were included in the BUSM III and IV cohort (post-didactic).

2.3 Study Surveys

The study surveys consisted of two parts: The Therapeutic Misunderstanding Scale (See Appendix B) and the Attitudes Towards Clinical Research Education Survey. (See Appendix C) In addition, a short demographic and personal history questionnaire was included as part of the Attitudes survey. The surveys were completed anonymously. No identifying information was collected. The surveys included an institutional review board-approved cover letter to serve as assent to participate in the study in place of a signed informed consent form.

The Therapeutic Misunderstanding Scale

The Therapeutic Misunderstanding Scale consists of 20 items in one of three facets, therapeutic misconception, therapeutic misestimation, or therapeutic

optimism. For this study, the questions administered with true or false responses. Six sham questions were added to the survey to help negate the bias towards the false in the responses. This was done in correspondence with Chou and O'Rourke who designed the TMU scale.

For Hypothesis 1, only the responses to the therapeutic misconception and therapeutic misestimation questions were scored. Questions pertaining to the therapeutic optimism facet were analyzed for exploratory purposes only. In accordance with previous studies with similar scales, a single incorrect response was deemed to show therapeutic misunderstanding. Individual items were then examined for specific areas of therapeutic misunderstanding.

The Attitudes Towards Clinical Research Ethics Education Survey

The Attitudes Towards Clinical Research Ethics Education Survey is a 24 item questionnaire arranged in 12 questions, assessing the interests of ethics and research ethics education among medical students. Questions for this short survey were adapted from surveys developed by Roberts et al. and questions developed for the purposes of this pilot study. Survey items were answered on a 9 point Likert-type scale, 1= strongly disagree, 9= strongly agree.

Demographics and Personal History Questionnaire

A short demographics questionnaire was administered with the Attitudes survey. This questionnaire included questions concerning the educational, and

employment (or volunteer) history in areas that relate to clinical care or research related activities.

2.4 Institutional Review Board Approval

The study protocol was submitted to the Boston University Medical Center Institutional Review Board (IRB) for review. The study was approved by the IRB on March 26, 2013.

2.5 Study Recruitment and Data Collection

Study participants were recruited through use of flyers, electronic display boards, school-wide electronic newsletters and participant referral. Two group administrations of the study surveys were undertaken approximately 2 weeks apart.

A total of 22 participants were recruited between the two recruitment events.

Study participants were given instructions to answer all the questions. They were also instructed to choose “the best” answer to questions on the TMU Scale, and to not overthink their responses.

2.6 Data Entry and Quality Control

The TMU Scale was scored by the principal investigator and the scoring was reviewed by a research assistant.

The responses to the surveys and questionnaire were then entered into two prepared excel spreadsheets by the principal investigator, and by a research assistant. The two spreadsheets were then merged and checked for discrepancies between the two entries. A final spreadsheet was prepared and locked from editing for use with a statistical analysis package.

2.7 Statistical Analysis Plan

Data were described using means, standard deviations, and ranges for overall scores and using counts and proportions for individual items. For analyses of association, a subject's expressing therapeutic misunderstanding was indicated by an individual score of 14 or less (the greatest possible score is 15). Prevalence and odds ratios were calculated for presence of therapeutic misunderstanding where possible. The association of items scores of the TMU with demographic and predictor variables were analyzed by chi-square tests and Fisher's exact tests. Multiple logistic regressions were not performed as planned due to inability to calculate odds ratios for all items resulting from small sample size. Responses to attitude items were rated on a 9-point Likert type scale (treated as a continuous outcome), and were analyzed by Students t-tests, and ANOVA. Due to small sample size, general trends were explored through descriptive statistics.

3.0 RESULTS

3.1 Study Sample

A total of 22 students participated in the pilot study and made up the study sample. (See Tables 1.1 and 1.2, Demographic Characteristics and Primary Outcomes)

The study sample was split evenly between men (n=11) and women (n=11). Fourteen participants were aged ≤ 24 (64%), 7 were aged 25-29 (32%), and 1 was aged ≥ 30 (5%). Twenty (91%) were either BUSM I or II, and 2 (9%) were BUSM III or IV or in their dual degree year. Seven (33%) intended to pursue primary care as their specialty, 14 (67%) intended to pursue surgery or other specialties, no participants anticipated pursuing psychiatry as their specialty.

Four participants (18%) had previously completed graduate degrees, and 8 (36%) had previous clinical experience

Twenty one participants (95%) had previous research experience; of which 13 (63%) had basic or “bench” research experience, 7 (34%) had research experience involving animals, and 12 (58%) had clinical research experience. Eight (36%) participants anticipated research as part of their future medical career; of which 2 (9%) planned on basic or bench research, 1 (5%) planned on animal research, and 6 (27%) planned on being involved in clinical research.

TABLE 1.1 DEMOGRAPHIC CHARACTERISTICS AND PRIMARY OUTCOMES (n=22)									
n (%)	Total	Gender		TMU		Clinical Research and Ethics Education		Increase Focus on Clinical Research and Ethics	
		Male	Female	Yes	No	≥7	<7	≥7	<7
Gender (%)									
Male	11 (50)			11 (100)	0 (0)	10 (91)	1 (9)	7 (64)	4 (36)
Female	11 (50)			10 (91)	1 (9)	9 (82)	2 (18)	6 (55)	5 (45)
TMU (%)									
Yes	21 (95)	11 (52)	10 (48)			18 (86)	3 (14)	13 (62)	8 (38)
No	1 (5)	0 (0)	1 (100)			1 (100)	0 (0)	0 (0)	1 (100)
Age (%)									
≤24	14 (64)	6 (43)	8 (57)	14 (100)	0 (0)	13 (93)	1 (7)	9 (64)	5 (36)
25-29	7 (32)	4 (57)	3 (43)	6 (86)	1 (14)	5 (71)	2 (29)	3 (43)	4 (57)
≥30	1 (5)	1 (100)	0 (0)	1 (100)	0 (0)	1 (100)	0 (0)	1 (100)	0 (0)
BUSM Year (%)									
I or II	20 (91)	9 (45)	11 (55)	19 (95)	1 (5)	17 (85)	3 (15)	11 (55)	9 (45)
III or IV	2 (9)	2 (100)	0 (0)	2 (100)	0 (0)	2 (100)	0 (0)	2 (100)	0 (0)
Anticipated Specialty (%) (n=21)									
Primary Care	7 (33)	2 (29)	5 (71)	7 (100)	0 (0)	6 (86)	1 (14)	4 (57)	3 (43)
Other/ Surgery	14 (67)	9 (64)	5 (36)	13 (93)	1 (7)	13 (93)	1 (7)	9 (64)	5 (36)
Graduate Degree (%)									
Yes	4 (18)	4 (100)	0 (0)	4 (100)	0 (0)	4 (100)	0 (0)	3 (75)	1 (25)
No	18 (22)	7 (39)	11 (61)	17 (94)	1 (6)	15 (83)	3 (17)	10 (55)	8 (45)
Previous Research Exp. (%)									
Bench	13 (63)	5 (38)	8 (62)	12 (92)	1 (8)	12 (92)	1 (8)	8 (62)	5 (38)
Animal	7 (34)	2 (29)	5 (71)	7 (100)	0 (0)	6 (86)	1 (14)	4 (57)	3 (43)
Clinical	12 (58)	8 (67)	4 (33)	12 (100)	0 (0)	11 (92)	1 (8)	9 (75)	3 (25)
None	1 (5)	1 (100)	0(0)	1 (100)	0(0)	1 (100)	0(0)	0 (0)	1 (100)

n (%)	Total	Gender		TMU		Clinical Research and Ethics Education		Increase Focus on Clinical Research and Ethics	
		Male	Female	Yes	No	≥7	<7	≥7	<7
Future Research Career? (%)									
Bench	2 (9)	1 (50)	1 (50)	2 (100)	0 (0)	2 (100)	0 (0)	2 (100)	0 (0)
Animal	1 (5)	1 (100)	0 (0)	1 (100)	0 (0)	1 (100)	0 (0)	1 (100)	0 (0)
Clinical	6 (27)	2 (33)	4 (67)	5 (83)	1 (17)	6 (100)	0 (0)	5 (83)	1 (17)
None	14 (64)	8 (57)	6 (43)	14 (100)	0 (0)	11 (79)	3 (21)	6 (43)	8 (57)
RCT Participation? (%)									
Yes	2 (9)	1 (50)	1 (50)	2 (100)	0 (0)	1 (50)	1 (50)	1 (50)	1 (50)
No	20 (91)	10 (50)	10 (50)	19 (95)	1 (5)	18 (90)	2 (10)	12 (60)	8 (40)
Previous Clinical Exp. (%)									
Yes	8 (36)	3 (38)	5 (63)	8 (100)	0 (0)	8 (100)	0 (0)	6 (75)	2 (25)
No	14 (64)	8 (57)	6 (43)	13 (93)	1 (7)	11 (79)	3 (21)	7 (50)	7 (50)
Informed Consent? (%) (n=8)									
Yes	2 (25)	0 (0)	2 (100)	2 (100)	0 (0)	2 (100)	0 (0)	1 (50)	1 (50)
No	6 (75)	3 (50)	3 (50)	6 (100)	0 (0)	6 (100)	0(0)	5 (83)	1 (17)
Medical Ethics Course? (%)									
Yes	9 (41)	5 (56)	4 (44)	8 (89)	1 (11)	8 (89)	1 (11)	5 (55)	4 (45)
No	13 (59)	6 (46)	7 (54)	13 (100)	0 (0)	11 (85)	2 (15)	8 (62)	5 (38)
Other Ethics Course? (%)									
Yes	12 (55)	5 (42)	7 (58)	11 (91)	1 (8)	11 (92)	1 (8)	7 (58)	5 (42)
No	10 (45)	6 (60)	4 (40)	10 (100)	0 (0)	8 (80)	2 (20)	6 (60)	4 (40)
Difference Between Clinical and Non Clinical Research? (%)									
Yes	21 (95)	11 (52)	10 (48)	21 (100)	0 (0)	18 (86)	3 (14)	13 (62)	8 (38)
No	1 (5)	0 (0)	1 (100)	0 (0)	1 (100)	1 (100)	0 (0)	0 (0)	1 (100)

Two participants (9%) had participated or had had a close relative who had participated in a RCT. Nine (41%) had taken a medical ethics course prior to enrolling in medical school, and 12 (55%) had taken another type of course in ethics. Twenty-one participants (95%) indicated they understood the difference between clinical and non-clinical research.

3.2 Prevalence of Therapeutic Misunderstanding among the BUSM Undergraduate Medical Student

Of the 22 participants who completed the TMU Scale, 21 (95%) exhibited some level of Therapeutic Misconception. One participant, female, aged 24-29, BUSM I or II, no previous graduate degree, previous basic or “bench” research but anticipating a career involving clinical research responded correctly to all items of the TMU scale. This student also had not participated in a RCT in the past, had previous clinical experience without informed consent experience, and had previously taken both a medical ethics course and other ethics courses. This student also highly agreed that education in clinical research and clinical research ethics is important (≥ 7 on 9 item Likert scale, 9= strongly agree), but did not highly agree with the need for increased focus on clinical research or clinical research ethics education in the medical school curricula. (See Tables 1.1 and 1.2, Demographic Characteristics and Primary Outcomes) Of the remaining participants, 4 (18%) answered only 1 survey item incorrectly, and 3 (14%) answered only 2 survey items incorrectly. One (5%) participant scored a total of

five correct responses; otherwise the next lowest score was 10/15. (See Figure 1)

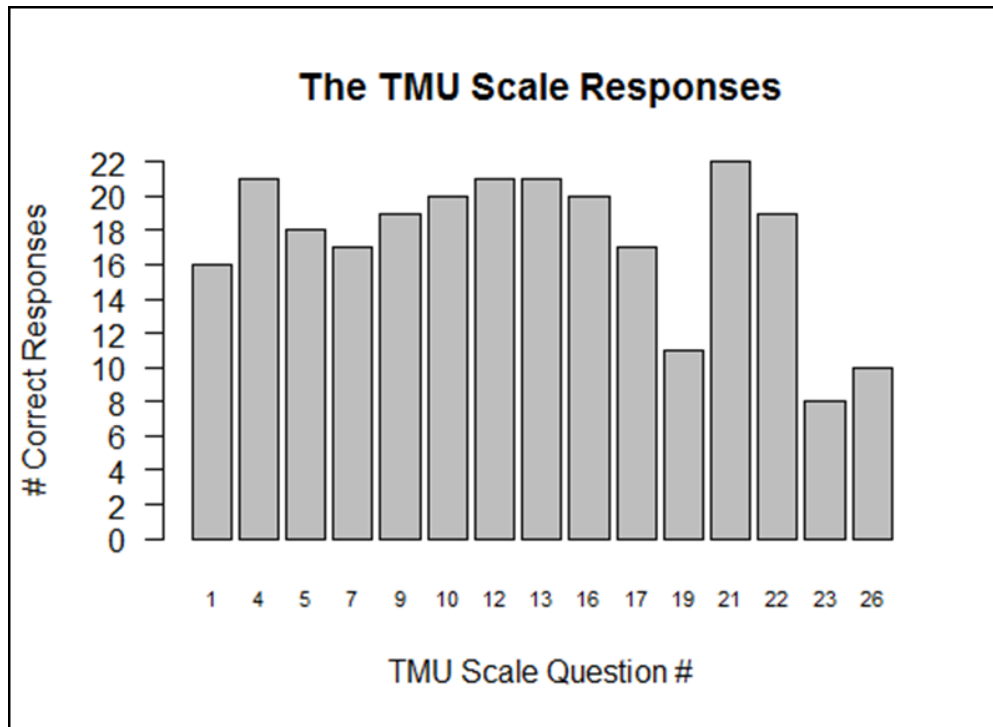


Figure 1: The number of correct responses to The Therapeutic Misunderstanding Scale (Therapeutic Misconception and Therapeutic Misestimation) by question number. Omitted questions were non-scored Therapeutic Optimism and filler questions.

The most commonly correct answered item was #21, “My participation in this clinical trial will prolong my life.” with all 22 participants answering “false” correctly. Three items, #4, #12, and #13 received 21/22 correct responses and 2 items, #10 and #16 received 20/22 correct responses. The most commonly incorrect item was item #23, “This trial is conducted mostly to gather knowledge about my condition.” The answer is false; the trial is conducted to gather

knowledge about the intervention, though this is the one of the most ambiguous questions in the survey.

Therapeutic Misconception

Nearly all the incorrect responses to the TMU Scale were in the TM questions, 1, 5, 7, 9, 12, 17, 19, 23, and 26.

Study participants were able to correctly respond to questions regarding clinical equipoise, such as questions 9 (86%) *Medical researchers are only allowed to do things that would benefit all patients*, and question 5 (82%) *The researchers in this study know that one of the treatments or interventions in this study will have better results than the others*.

Responses to questions regarding the physician/researcher duality of role, and the differences between researchers and practicing clinicians were mixed. Question 19 was answered correctly by only 11 (50%) of the participants; *My doctor could access the information obtained during the course of this study*, but question 17 was answered correctly by 17 (77%); *My doctor would adjust the treatment I receive (e.g. medication dosage) to ensure that I receive the best possible care*.

Questions regarding the differences between clinical care and clinical research posed the most difficulty with the study participants. Question 26 was answered correctly by 10 (45%) of the participants; *The treatment/intervention I would receive may be changed in response to the way my medical condition*

changes, and question 23 was answered correctly by 8 (36%) of the participants; *This trial is being conducted to mostly gather knowledge about my condition*. However, nearly all the participants, 21 of 22 (95%) responded correctly to question 12; *The treatment I would receive is based on my medical needs*.

Therapeutic Misestimation

The TE questions included questions 4,10,13,16,21, and 22. All of the study participants answered most of these questions correctly, not overestimating the potential benefits, or lack thereof of participating in a RCT. Question 21 was answered correctly by all the study participants, while questions 4 and 13 were answered by 21 of 22 (95%) participants correctly. Questions 10 and 16 were answered by 20 of 22 participants correctly (91%) and question 22 was answered correctly by 19 of 22 participants (86%).

Therapeutic Optimism

Survey participants showed generally positive optimism towards their previous experiences preparing them to take part in a research study (73%), and the majority of the participants looked forward to participation (68%), and expressed hope and enthusiasm (73%).

The survey participants showed no optimism (or indifference) to the chances for successful treatment (14% optimistic), or that participating would help them (36% optimistic).

3.3 Attitudes Towards Clinical Research and Clinical Research Education

Refer to tables 1.1 and 1.2 pages 21-22, and tables 3.1-3.6 in appendix D. All means are based on responses to a 9 point likert type scale (1= strongly disagree, 5 = neither agree nor disagree, 9 = strongly agree).

Importance of Clinical Research and Research Ethics Education

Of the 22 participants in the study, 19 (86%) highly agreed with a score ≥ 7 that clinical research and research ethics education is important. Overall, Study participants highly agreed that clinical research and research ethics is important with a mean of 7.95 (SD 1.0, range 6-9).

Attitudes to Increased Focus on Clinical Research and Research Ethics in the Medical School Curriculum

Of the 22 participants in the study, 13 (59%) highly agreed with a score ≥ 7 that there should be increased focus on clinical research and research ethics. Study participants overall only mildly agreed that there should be increased focus on research related topics, mean 6.72 (SD 1.6, range 2-9).

Attitudes Towards Clinical Medicine versus Clinical Research Goals of Ethics Education

Study participants highly agreed in interest in learning about ethics in clinical medicine, mean 7.78 (SD 1.1, range 5-9), but only mildly agreed that there is an interest in learning about ethics in clinical research, mean 6.95 (SD 1.3, range 5-9). In terms of ethics education the highest agreement was that the goal of ethics education is to help professionals to improve patient care and clinical decision making, mean 8.00 (SD 1.5, range 2-9), while they least agreed that the goal of ethics education is to acquire a working knowledge of social science, philosophy, religion and law as they apply to clinical research, mean 6.55 (SD 2.3, range 2-9).

Study participants highly agreed that both ethics in clinical medicine, mean 8.14 (SD 1.2, range 5-9), and ethics in clinical research, mean 7.32 (SD 1.3, range 4-9), should be formally taught in medical training. They also highly agreed equally that ethics training helps physicians, mean 7.59 (SD 1.2, range 5-9), and helps researchers, mean 7.59 (SD 1.1, range 5-9).

The study participants highly agreed that ethics can be taught and learned, mean 7.27 (SD 1.5, range 4-9), but only had mild agreement in the need for researchers to have more ethics training than is already provided, mean 6.41 (SD 1.8, range 2-9). The study participants most highly agreed that ethics training should take place in journal clubs and seminars, mean 7.95 (SD 1.8, range 2-9), versus during formal didactic (classroom) training, mean 6.64 (SD 1.7, range 2-8) or post didactic training (clerkship) training, mean 6.95 (SD 1.8, range 2-9)

Unlike previous studies, no major trends were seen among the various participant characteristics. Age, sex and BUSM year showed no observable trends in responses between matched clinical medicine and clinical research questions. Other areas that were thought to affect attitudes towards ethics education such as prior clinical or research experience, anticipation of a research career, history of participation in a RCT or previous medical ethics or other ethics coursework also showed no consistent trends towards difference in responses to the attitudes survey questions.

4.0 DISCUSSION

The Prevalence of Therapeutic Misunderstanding and What it Means

Ninety-five percent of the surveyed medical students showed some level of TMU. But the presence or absence of TMU is not as important as the specific areas of misunderstanding. In the three-facet model of TMU, the area that is of most concern in terms is TM. In this survey, the questions were designed to be answered based on a typical RCT study design without respect for special cases. Most of the survey questions answered incorrectly fell within the TM category. These questions deal with mostly the design and conduct of clinical trials.

Specific areas of misconception were focused in the areas of individualization of care, such as the differences between clinical care and clinical research, clinician/researcher duality of role, and equipoise, for example, questions 17 (adjustment of treatment for best possible care), and 26 (adjustment in medication dose as condition changes) both concern adjustments and changes to treatment while in a study. Though nearly all respondents answered the more straight forward question 12 (treatment based on medical needs), question 26 can be seen as the one of the most ambiguous in the survey. The use of the word “may” could cause some confusion in the interpretation of the question when used in an absolute context of true or false. As there is no indication in the scenario preceding the survey that this would be a dose escalation study or a cross-over design, it should be assumed that the intervention would remain the same throughout the study. The survey questions

were not written specific enough to make the assumption that this question may include special cases such as discontinuation of the intervention because of an adverse effect. This is in contrast to the similar questions 7 or 17, which have more definitive wording and were answered correctly by nearly all participants.

The area of TE showed much better understanding. These questions were more focused on the risk/benefit ratios of clinical trials. Here, nearly all the participants answered the questions correctly, not overestimating the possible benefits of participating in the study.

In contrast between the TM and TE areas, the medical students had a better understanding of the ultimate goals of the research study versus anticipated outcomes for individual clinical trial subjects. The third facet of TMU, TO, was examined, but not scored with the other two facets. It was believed that within this population that the emotional response of participating in a RCT would be difficult to replicate with participants not actively participating in a RCT as the survey was initially designed for. The medical students did show a generally positive optimism towards participating in a study though. Also, consistent with the understanding of the risk/benefit ratio shown by the responses to the TE questions, the questions (6, and 14) concerning successful treatment outcomes had less positive optimism with many more false responses.

There were several characteristics that were thought to have possible effects on how the questionnaire was answered, among them, previous experience in research, especially clinical research, and previous participation in

a RCT. However, there were no observable, consistent trends among the various demographic and personal history predictors versus responses to the TMU scale. A larger sample size would be needed to see if any trends exist.

Attitudes Towards Clinical Research and Clinical Research Ethics Education

A substantial number of the study participants highly agreed that education in clinical research and clinical research ethics is important. Previous work by Roberts et al showed similar results in medical students at other institutions.^{3,4,24,25} In this survey, unlike previous research which showed higher agreement among female medical students, a slightly larger percentage of male students with higher agreement to the importance of education in clinical research and clinical research ethics topics. Also, younger medical students were more likely to have higher agreement than older students. As expected, students with previous research experience highly agreed with the importance of education in these areas, however there was not a large enough sample of students without research experience to determine if this was a significant characteristic. Unexpectedly, students with previous participation in a clinical trial, or previous medical ethics coursework did not show higher agreement than those without. It was hypothesized that students with these types of past experiences would be more likely to agree with the importance of clinical research and clinical research ethics education.

Increasing the Focus of Clinical Research Education in the Undergraduate Medical Curriculum at BUSM

Despite study participants highly agreeing with the importance of education in clinical research and clinical research ethics, the study participants did not highly believe that there should be an increased focus on clinical research and research ethics education beyond what is currently in the curriculum at BUSM. Here male students were more likely than female students to highly agree that there should be an increased focus on clinical research education. This differs from previous studies that showed female students had higher agreement amount increasing education in these areas. In addition, there was also higher agreement in students who had previous research experience, especially those that had experience in clinical research. Participants in later stages of medical school, BUSM III or IV, showed higher agreement. In the past older age, or later stage of training were correlated with lower agreement to similar focus and changes to the curriculum, and this is consistent with the results in this study. This has been attributed to decrease in idealism, which is typically higher at the earlier ages and stages, as well as a perceived lack of need of further training and education as students' progress through the curriculum. Unlike the previous studies, age did not seem correlated with this agreement, younger and older were nearly equal in their agreement towards increasing clinical research education. Again, students with previous experience participating in a clinical trial, or who had prior medical ethics coursework showed

less agreement than those who had not. A larger sample size would likely be needed to determine if these are true trends or aberrations of the small sample size.

General Attitudes to Clinical Medicine versus Clinical Research Goals of Ethics Education

Medical student participants were generally more agreeable to the goals of ethics education in clinical medicine than clinical research. Unlike previous studies, there were no observable differences between male and female participants, and no consistent differences between age groups and training stage. There were some positive trends among those intending a research career, but not among those who had previous research experience or who had previously participated in a clinical trial. In terms of where students believe that this clinical research and research ethics education should be taught, the greatest area of agreement was in journal clubs and seminars. This is where most of the instruction in these topics currently exists.

4.1 Limitations of Study

This study is limited by the small sample size and the distribution across the age groups and BUSM year. Odds ratios were not able to be calculated for many of the characteristics with the TMU scale because of the presence of many groups with zero data points, and those that were are unreliable due to small the

sample size. Statistical analysis of a more adequate sample size may lead to more obvious trends and statistical significance. Many of the statistical tests planned were not able to be completed because of the small sample size and distribution. A larger sample size would also better define the trends in the Attitudes Towards Clinical Research Ethics Education Survey

Reconsideration of how to interpret the score of the TMU scale may also be practical; eliminating the absolute nature of the score in favor of a small leeway of incorrect responses may be a more accurate indicator to the level of therapeutic misunderstanding, but may also mask the prevalence of TMU if there is a specific question or area that is commonly misunderstood. As noted before, this is why analysis of individual questions in the TMU scale is as important if not more important than the absolute presence or absence of TMU. Also, expansion of the hypothetical scenario may also allow for some of the ambiguous questions to be interpreted by the survey participant more easily. A similar survey, with questions written more for this population of undergraduate medical students (or any group of biomedical students) may also be needed. The TMU scale was written to be used with research participants who had already gone through a full informed consent process for participation in a RCT, the assumption that medical students would be able to answer the questions based on previous education, or lack thereof, of basic research design and conduct may not be valid. No other validated tools exist to measure therapeutic

misunderstanding or any of its three facets, and only one other validated tool exists to measure therapeutic misconception itself, which was used for the basis of this expanded questionnaire.

If the TMU scale or other similar scales were to be used in the future, a re-examination of the presentation may be warranted. Many of the questions may seem ambiguous to participants, in that in the real world of clinical research studies every study has its own protocol, potential benefits, and may not lend itself to absolute yes/no, true/false answers. Each clinical trial has its own nuances to its study design, and what may be true in one study may not be applicable in another. In this study, it was intended that the TMU scale would test the knowledge (or lack thereof) of the most basic blinded, randomized clinical trial design.

4.2 Further Research Recommendations

Further research with larger sample size, as well as comparisons between multiple medical school programs and curricula would be necessary to define the true nature and extent of therapeutic misunderstanding in medical school students. Comparisons with other medical schools programs and curricula would allow researchers to find areas of the curricula that may be added too. Modifications to current courses may be preferable to new course additions. The ethics curriculum at Boston University School of Medicine has already been largely integrated into other coursework; further education in clinical research

conduct and research ethics could be integrated in the same way. For example, there could be increased focus on design and analysis of clinical research studies early on in meetings of journal clubs or in seminars dealing with the literature. Also, clinical rotations could include some time spent in clinics conducting research studies. Outside of the undergraduate medical curricula, there could be a push for more education in clinical research or clinical research ethics with the pre-medical education prior to matriculating to medical school. Many undergraduate programs include third or fourth year writing courses that focus on the student's area of study, as opposed to the general writing courses that most first year undergraduates must take. In the case of pre-medical students (or other students going into biomedical research fields), there could be more focus on the literature and study design. This would complement the coursework in writing scientific papers.

5.0 CONCLUSIONS

Results of this pilot study indicate that as measured by the TMU Scale, Therapeutic Misunderstanding exists in the undergraduate medical student population. The absolute presence or absence of TMU is less important than the individual areas where the misunderstanding exists. Initial indications are that most of the misunderstanding is in the area of therapeutic misconception. In order to minimize therapeutic misunderstanding and promote the ability of medical students and future clinicians to understand and interpret the biomedical literature, give proper guidance to their patients about research participation, or become involved in the clinical research process, there needs to be basic education in clinical research and clinical research ethics. This is supported by the medical students themselves, however, there is disagreement as to whether this topic is adequately covered and where in the undergraduate medical curriculum it should exist.

APPENDIX A APPROVED INFORMED CONSENT DOCUMENT

BOSTON UNIVERSITY SCHOOLS OF MEDICINE,
PUBLIC HEALTH, DENTAL MEDICINE AND
THE BOSTON MEDICAL CENTER



THE “THERAPEUTIC MISCONCEPTION” AMONG FUTURE CLINICIANS AND RESEARCHERS; ATTITUDES TOWARDS INCREASED EXPOSURE TO CLINICAL RESEARCH AND RESEARCH ETHICS IN UNDERGRADUATE MEDICAL EDUCATION A PILOT STUDY

You are being invited to participate in a short survey research study about your experiences as students at Boston University School of Medicine. This study is being conducted by Matthew S. Gregorio in partial fulfillment of the thesis requirement for the dual master's degrees in Medical Sciences and Clinical Investigation from the Division of Graduate Medical Sciences at the Boston University School of Medicine with Faculty Advisors: Lindsay A. McNair MD, MPH and Susan S. Fish PharmD, MPH of Boston University School of Medicine, Division of Graduate Medical Sciences.

There are no known risks if you decide to participate in this research study. There are no costs to you for participating in the study. The information you provide will be used to explore the ethics curriculum at Boston University School of Medicine. The questionnaire will take about twenty to thirty minutes to complete. You will be compensated for your time through refreshments served at the completion of this survey. The information collected may not benefit you directly, but the information learned in this study may provide more general benefits to future medical students.

This survey is anonymous. Do not write your name on the survey. No one will be able to identify your answers, and no one will know your individual responses to the survey. Individuals from Boston University School of Medicine and the Institutional Review Board of Boston University Medical Center may inspect these survey records. Should the data be published, no individual information will be disclosed.

Your participation in this study is voluntary. By completing this survey you are voluntarily agreeing to participate. You are free to decline to answer any particular question you do not wish to answer for any reason.

If you have any questions about the study, please contact Matthew S. Gregorio BS; msgregor@bu.edu; 670 Albany St. 2nd Floor, Boston University Medical Center, Boston, MA 02118 or Susan S. Fish PharmD, MPH; sfish@bu.edu; 801 Massachusetts Avenue, CT-330, Boston, MA 02118.

The Boston University Medical Center Institutional Review Board has reviewed my request to conduct this project. If you have any concerns about your rights in this study, please contact the Institutional Review Board of Boston Medical Center at 617-638-7207.



BUMC/BMC Institutional Review Board
IRB NUMBER: H-32212
IRB APPROVAL DATE: 03/21/2013
IRB EXPIRATION DATE: 03/20/2014

APPENDIX B “THE THERAPEUTIC MISUNDERSTANDING SCALE” SURVEY

For the whole of your life up to this point you have been relatively healthy but at a routine physical with your family physician you have been diagnosed with a new medical condition. After further discussing your medical condition with your family physician and/or specialist, you have been told that there is new experimental treatment. It is not known whether or not this new treatment would provide any benefits above and beyond currently available treatments. A physician or clinical nurse has asked you to consider enrolling in this randomized clinical trial. Depending on the group to which you are assigned, you may receive an inactive treatment (i.e. placebo) or the experimental treatment. The likelihood of being assigned to these two groups is equal (i.e. 50/50). With this in mind, please answer the following questions as if you were faced with this decision.

Based on the above description, please respond to each of the following statements with the best answer.

- | | |
|---|------------------------------|
| | Do not
mark this
space |
| 1. The main reason that people will be recruited for this study is so that they can benefit from the special treatment in this research project. | |
| _____ True <input type="checkbox"/> _____ False <input type="checkbox"/> | |
| 2. According to the rules of research studies like this, doctors do not choose the treatment or intervention I receive based on what best suits my needs. | |
| _____ True <input type="checkbox"/> _____ False <input type="checkbox"/> | |
| 3. Participating in this clinical trial might only benefit others. | |
| _____ True <input type="checkbox"/> _____ False <input type="checkbox"/> | |
| 4. The treatment I would receive in this clinical trial would cure my illness. | |
| _____ True <input type="checkbox"/> _____ False <input type="checkbox"/> | |
| 5. The researchers in this study know that one of the treatments or interventions will have better results than others. | |
| _____ True <input type="checkbox"/> _____ False <input type="checkbox"/> | |
| 6. My physician will not tell me which treatment I receive. | |
| _____ True <input type="checkbox"/> _____ False <input type="checkbox"/> | |
| 7. The treatment/intervention I would receive in this study will be adapted according to my needs, like the treatment from any other doctor. | |
| _____ True <input type="checkbox"/> _____ False <input type="checkbox"/> | |
| 8. There are many ways my participation in this study would help me. | |
| _____ True <input type="checkbox"/> _____ False <input type="checkbox"/> | |
| 9. Medical researchers are only allowed to do things that would benefit all patients. | |
| _____ True <input type="checkbox"/> _____ False <input type="checkbox"/> | |
| 10. My participation in this study will improve my quality of life. | |
| _____ True <input type="checkbox"/> _____ False <input type="checkbox"/> | |
| 11. There is a chance that my condition could worsen during the course of this study. | |
| _____ True <input type="checkbox"/> _____ False <input type="checkbox"/> | |
| 12. The treatment I would receive is based on my medical needs. | |
| _____ True <input type="checkbox"/> _____ False <input type="checkbox"/> | |

Do not
mark this
space

13. Taking part in this research study would cure my illness.
_____ True False
14. I am very optimistic about my chances for successful treatment.
_____ True False
15. I look forward to participating in this study with hope and enthusiasm.
_____ True False
16. My participation in this clinical trial would boost my immune system.
_____ True False
17. My doctor would adjust the treatment I receive (e.g. medication dosage) to ensure that I receive the best possible care.
_____ True False
18. I look forward to being in this study.
_____ True False
19. My doctor could access the information obtained during the course of this clinical trial.
_____ True False
20. There was something different about my condition or circumstances as compared to others that led doctors to ask me to be in this study.
_____ True False
21. My participation in this clinical trial will prolong my life.
_____ True False
22. I'm more likely to benefit than the average person.
_____ True False
23. This clinical trial is conducted mostly to gather knowledge about my condition.
_____ True False
24. My past medical experiences have prepared me well for participation in this study.
_____ True False
25. My doctor would discourage my participation in this clinical trial if there would be no direct benefit for me.
_____ True False
26. The treatment/intervention I would receive may be changed in response to the way my medical condition changes.
_____ True False

**APPENDIX C “ATTITUDES TOWARDS CLINCIAL RESEARCH ETHICS
EDUCATIONSURVEY”**

Please answer the following questions based on the following scale:

1= Strongly Disagree
 2= Disagree
 3=Moderately Disagree
 4= Mildly Disagree
 5= Undecided
 6= Mildly Agree
 7= Moderately Agree
 8= Agree
 9= Strongly Agree

1. I am interested in learning about:
 - a. Ethics in clinical medicine. _____
 - b. Ethics is clinical research. _____

2. The goal of ethics education in medical training is to help professionals:
 - a. To improve patient care and clinical decision making. _____
 - b. To improve ethical practices in clinical research. _____
 - c. To acquire a working knowledge of social science, philosophy, religion and law as they apply to clinical care. _____
 - d. To acquire a working knowledge of social science, philosophy, religion and law as they apply to clinical research. _____

3. Professional attitudes are an appropriate focus for medical education. _____

4. Clinical medicine ethics should be formally taught in medical training. _____

5. Clinical research ethics should be formally taught in medical training. _____

6. Training in ethics does help physicians to deal with ethical problems. _____

7. Training in ethics does help researchers to deal with ethical problems. _____

8. Ethics can be taught and learned. _____

9. Researchers in medicine need more ethics training. _____

10. I would like more ethics training in:
 - a. Informed consent. _____
 - b. Risk / benefit assessment. _____
 - c. Participant recruitment and Selection. _____
 - d. Institutional Review Board processes. _____

APPENDIX D Data Tables

TABLE 2.1.1 THERAPEUTIC MISCONCEPTION (1)		Gender		Age		BUSM Year		Anticipated Specialty	
	n= correct n (%) [OR]	Male	Female	≤24	≥25	I & II	III & IV	1° care	Other
1. The main reason that people will be recruited for this study is so they can benefit from the special treatment in this research project.		7 (64) [0.41]	9 (81)	10 (71) [0.84]	6 (75)	15 (75) [2.85]	1 (50)	6 (85) [3.13]	9 (64)
12. The treatment I would receive is based on my medical needs.		10 (90) [0.0]	11 (100)	13 (93) [0.0]	8 (100)	19 (95) [0.0]	2 (100)	7 (100) [INF]	13 (93)
17. My doctor would adjust the treatment I receive (e.g. medication dosage) to ensure that I receive the best possible care.		9 (81) [1.65]	8 (73)	9 (64) [0.0]	8 (100)	15 (75) [0.0]	2 (100)	7 (100) [INF]	9 (64)
19. My doctor could access the information obtained during the course of this clinical trial.		8 (27) [0.16]	3 (72)	5 (36) [0.20]	6 (75)	2 (100) [INF]	9 (45)	3 (43) [0.58]	8 (57)
23. This trial is conducted mostly to gather knowledge about my condition.		4 (36) [1.0]	4 (36)	8 (38) [INF]	0 (0)	8 (40) [INF]	0 (0)	3 (43) [1.33]	5 (36)
26. The treatment/intervention I would receive may be changed in response to the way my medical condition changes.		5 (45) [1.0]	5 (45)	6 (43) [0.46]	4 (50)	9 (45) [0.83]	1 (50)	5 (71) [4.17]	5 (36)
5. The researchers in this study know that one of the treatments or interventions in this study will have better results than others.		9 (82) [1.0]	9 (82)	11 (79) [1.86]	7 (75)	16 (80) [0.0]	2 (100)	6 (86) [1.61]	11 (79)
7. The treatment/intervention I would receive in this study will be adapted according to my needs, like the treatment of any other doctor.		9 (81) [1.1]	8 (80)	10 (77) [0.49]	7 (88)	15 (79) [0.0]	2 (100)	6 (100) [INF]	10 (71)
9. Medical researchers are only allowed to do things that will benefit all patients.		9 (82) [0.46]	10 (91)	13 (93) [4.0]	6 (75)	17 (85) [0.0]	2 (100)	7 (100) [INF]	11 (79)

TABLE 2.1.2 THERAPEUTIC MISCONCEPTION (2)									
	Graduate Degree?		Prior Research Experience?		Future Research Career?		Past RCT Participant?		
	Yes	No	Yes	No	Yes	No	Yes	No	
1. The main reason that people will be recruited for this study is so they can benefit from the special treatment in this research project.	3 (75) [1.14]	13 (72)	15 (71) [0.0]	1 (100)	6 (75) [1.19]	10 (71)	2 (100) [INF]	14 (70)	
12. The treatment I would receive is based on my medical needs.	4 (100) [INF]	17 (94)	20 (95) [0.0]	1 (100)	8 (100) [INF]	13 (93)	2 (100) [INF]	19 (95)	
17. My doctor would adjust the treatment I receive (e.g. medication dosage) to ensure that I receive the best possible care.	4 (100) [INF]	13 (72)	16 (76) [0.0]	1 (100)	5 (63) [0.30]	12 (86)	2 (100) [INF]	17 (75)	
19. My doctor could access the information obtained during the course of this clinical trial.	4 (100) [INF]	7 (39)	10 (48) [0.0]	1 (100)	5 (63) [2.13]	6 (43)	1 (50) [1.0]	10 (50)	
23. This trial is conducted mostly to gather knowledge about my condition.	1 (25) [0.25]	7 (39)	8 (38) [INF]	0 (0)	2 (25) [0.46]	6 (43)	1 (50) [1.8]	7 (35)	
26. The treatment/Intervention I would receive may be changed in response to the way my medical condition changes.	4 (100) [INF]	6 (33)	9 (43) [0.0]	1 (100)	4 (50) [1.73]	6 (43)	1 (50) [1.2]	9 (45)	
5. The researchers in this study know that one of the treatments or interventions in this study will have better results than others.	4 (100) [INF]	14 (78)	17 (81) [0.0]	1 (100)	7 (88) [1.85]	11 (79)	2 (100) [INF]	16 (80)	
7. The treatment/intervention I would receive in this study will be adapted according to my needs, like the treatment of any other doctor.	3 (75) [0.64]	14 (82)	16 (80) [0.0]	1 (100)	5 (63) [0.15]	12 (92)	2 (100) [INF]	15 (79)	
9. Medical researchers are only allowed to do things that will benefit all patients.	3 (75) [0.40]	16 (89)	18 (38) [0.0]	1 (100)	6 (75) [0.25]	13 (93)	2 (100) [INF]	17 (85)	

TABLE 2.1.3 THERAPEUTIC MISCONCEPTION (3)									
	Prior Clinical Experience?		Prior Medical Ethics Course?		Other Ethics Course?		Clinical vs Research?		
	Yes	No	Yes	No	Yes	No	Yes	No	
	n= correct n (%) [OR]								
1. The main reason that people will be recruited for this study is so they can benefit from the special treatment in this research project.	5 (63) [0.47]	11 (76)	8 (89) [4.67]	8 (62)	10 (83) [3.12]	6 (60)	15 (71) [0.0]	1 (100)	
12. The treatment I would receive is based on my medical needs.	7 (88) [0.0]	14 (100)	9 (100) [INF]	12 (92)	12 (100) [INF]	9 (90)	20 (95) [0.0]	1 (100)	
17. My doctor would adjust the treatment I receive (e.g. medication dosage) to ensure that I receive the best possible care.	7 (88) [2.68]	10 (71)	5 (55) [0.11]	12 (92)	10 (83) [2.07]	7 (70)	16 (76) [0.0]	1 (100)	
19. My doctor could access the information obtained during the course of this clinical trial.	3 (38) [1.07]	8 (57)	4 (44) [0.70]	7 (54)	5 (42) [0.49]	6 (60)	10 (48) [0.0]	1 (100)	
23. This trial is conducted mostly to gather knowledge about my condition.	3 (38) [1.07]	5 (36)	3 (33) [0.81]	5 (38)	4 (33) [0.76]	4 (40)	7 (33) [0.0]	1 (100)	
26. The treatment/intervention I would receive may be changed in response to the way my medical condition changes.	3 (38) [0.61]	7 (50)	4 (44) [0.93]	6 (46)	6 (50) [1.23]	4 (40)	9 (43) [0.0]	1 (100)	
5. The researchers in this study know that one of the treatments or interventions in this study will have better results than others.	7 (88) [1.86]	11 (79)	7 (78) [0.65]	11 (85)	10 (83) [1.23]	8 (80)	17 (81) [0.0]	1 (100)	
7. The treatment/intervention I would receive in this study will be adapted according to my needs, like the treatment of any other doctor.	7 (88) [2.03]	10 (77)	7 (78) [0.71]	10 (83)	10 (83) [1.4]	7 (78)	16 (80) [0.0]	1 (100)	
9. Medical researchers are only allowed to do things that will benefit all patients.	8 (100) [INF]	11 (79)	8 (89) [1.43]	11 (85)	10 (83) [0.57]	9 (90)	18 (86) [0.0]	1 (100)	

TABLE 2.2.1 THERAPEUTIC MISESTIMATION (1)								
	Gender		Age		BUSM Year		Anticipated Specialty	
	Male	Female	≤24	≥25	I & II	III & IV	1° care	Other
	n = correct n (%) [OR]							
4. The treatment that I would receive in this clinical trial would cure my illness.	11 (100) [INF]	10 (91)	13 (93) [0.0]	8 (100)	19 (95) [0.0]	2 (100)	7 (100) [INF]	13 (93)
21. My participation in this clinical trial will prolong my life.	11 (100) [1.0]	11 (100)	14 (100) [1.0]	8 (100)	20 (100) [1.0]	2 (100)	7 (100) [1.0]	14 (100)
10. My participation in this study will improve my quality of life.	10 (91)	10 (91)	13 (93) [1.81]	7 (88)	18 (90) [0.0]	2 (100)	6 (86) [0.48]	13 (93)
16. My participation in this clinical trial would boost my immune system.	10 (91) [1.0]	10 (91)	14 (100) [INF]	6 (75)	18 (90) [0.0]	2 (100)	6 (86) [0.48]	13 (93)
22. I'm more likely to benefit than the average person.	9 (82) [0.47]	10 (91)	12 (86) [0.87]	7 (88)	18 (90) [7.70]	1 (50)	6 (86) [1.0]	12 (86)
13. Taking part in this study would cure my illness.	11 (100) [INF]	10 (91)	13 (93) [0.0]	8 (100)	19 (95) [0.0]	2 (100)	7 (100) [INF]	13 (93)

TABLE 2.2.2 THERAPEUTIC MISESTIMATION (2)

	Graduate Degree?		Prior Research Experience?		Future Research Career?		Past RCT Participant?	
	Yes	No	Yes	No	Yes	No	Yes	No
	n= correct n (%) [OR]							
4. The treatment that I would receive in this clinical trial would cure my illness.	4 (100) [INF]	17 (94)	20 (95) [0.0]	1 (100)	7 (88) [0.0]	14 (100)	2 (100) [INF]	19 (95)
21. My participation in this clinical trial will prolong my life.	4 (100) [1.0]	18 (100)	20 (100) [1.0]	1 (100)	8 (100) [1.0]	14 (100)	2 (100) [1.0]	20 (100)
10. My participation in this study will improve my quality of life.	3 (75) [0.20]	17 (94)	19 (90) [0.0]	1 (100)	7 (88) [0.55]	13 (93)	2 (100) [INF]	12 (86)
16. My participation in this clinical trial would boost my immune system.	4 (100) [INF]	16 (89)	19 (90) [0.0]	1 (100)	8 (100) [INF]	12 (85)	1 (50) [0.07]	19 (95)
22. I'm more likely to benefit than the average person.	4 (100) [INF]	15 (83)	18 (90) [0.0]	1 (100)	8 (100) [INF]	11 (79)	2 (100) [INF]	17 (85)
13. Taking part in this study would cure my illness.	4 (100) [INF]	17 (94)	20 (95) [0.0]	1 (100)	7 (88) [0.0]	14 (100)	2 (100) [INF]	19 (95)

TABLE 2.2.3 THERAPEUTIC MISESTIMATION (3)									
	Prior Clinical Experience?		Prior Medical Ethics Course?		Other Ethics Course?		Clinical vs Research?		
	Yes	No	Yes	No	Yes	No	Yes	No	
	n = correct n (%) [OR]								
4. The treatment that I would receive in this clinical trial would cure my illness.	8 (100) [INF]	13 (93)	9 (100) [INF]	12 (92)	12 (100) [INF]	9 (90)	20 (95) [0.0]	1 (100)	
21. My participation in this clinical trial will prolong my life.	8 (100) [1.0]	14 (100)	9 (100) [1.0]	13 (100)	12 (100) [1.0]	10 (100)	21 (100) [1.0]	1 (100)	
10. My participation in this study will improve my quality of life.	8 (100) [INF]	12 (86)	9 (100) [INF]	11 (85)	11 (92) [0.0]	9 (100)	19 (90) [0.0]	1 (100)	
16. My participation in this clinical trial would boost my immune system.	8 (100) [INF]	12 (86)	8 (89) [0.68]	12 (92)	11 (92) [1.2]	9 (90)	19 (90) [0.0]	1 (100)	
22. I'm more likely to benefit than the average person.	6 (75) [0.23]	13 (93)	9 (100) [INF]	10 (77)	12 (100) [INF]	7 (70)	18 (86) [0.0]	1 (100)	
13. Taking part in this study would cure my illness.	8 (100) [INF]	13 (93)	9 (100) [INF]	12 (92)	12 (100) [INF]	9 (90)	20 (95) [0.0]	1 (100)	

TABLE 2.3.1 THERAPEUTIC OPTIMISM (1)		Anticipated Specialty						
n= True (%) [OR]	Gender		Age		BUSM Year		Specialty	
	Male	Female	≤24	≥25	I & II	III & IV	1° care	Other
14. I am very optimistic about my chances for successful treatment.	0 (0) [0.0]	3 (27) p=0.21	3 (21) [INF]	0 (0) p=0.37	3 (15) [INF]	0 (0)	1 (14) [1.0]	2 (14)
8. There are many ways my participation in this study would help me.	4 (36) [1.0]	4 (36)	4 (29) [0.41]	4 (50) p=0.32	8 (40) [INF]	0 (0)	3 (43) [1.33]	5 (36)
24. My past medical experiences have prepared me well for participation in this study.	9 (81) [3.52]	6 (55) p=0.26	9 (64) [0.61]	6 (75)	13 (65) [0.0]	2 (100)	5 (71) [1.37]	9 (64)
15. I look forward to participating in this study with hope and enthusiasm.	9 (81) [2.46]	7 (64)	9 (64) [0.27]	7 (88) p=0.48	14 (70) [0.0]	2 (100)	6 (86) [0.43]	10 (71)
18. I look forward to being in this study.	9 (82) [3.52]	6 (55) p=0.40	9 (64) [0.61]	6 (75)	13 (65) [0.0]	2 (100)	6 (86) [3.13]	9 (64)

TABLE 2.3.2 THERAPEUTIC OPTIMISM (2)

	n=	True (%)	[OR]	Graduate Degree?		Prior Research Experience?		Future Research Career?		Past RCT Participant?				
				Yes	No	Yes	No	Yes	No	Yes	No			
14. I am very optimistic about my chances for successful treatment.	0	3	(17)	0	0	3	(16)	2	(25)	1	(7)	0	3	(15)
				[0.0]			[INF]		[4.0]		p=0.15		[0.0]	
8. There are many ways my participation in this study would help me.	3	5	(28)	3	1	7	(33)	8	(25)	6	(43)	1	7	(35)
				[7.01]			[0.0]		[2.17]		p=0.31		[1.80]	
24. My past medical experiences have prepared me well for participation in this study.	4	11	(61)	14	1	14	(67)	6	(75)	9	(64)	1	14	(70)
				[INF]			[0.0]		[1.64]		p=0.43		[0.45]	
15. I look forward to participating in this study with hope and enthusiasm.	4	12	(72)	15	1	15	(71)	5	(71)	10	(71)	2	14	(70)
				[INF]			[0.0]		[1.0]		p=0.29		[INF]	
18. I look forward to being in this study.	4	11	(61)	14	1	14	(67)	5	(63)	10	(71)	2	13	(65)
				[INF]			[0.0]		[0.68]		p=0.40		[INF]	

TABLE 2.3.3 THERAPEUTIC OPTIMISM (3)

	Prior Clinical Experience?		Prior Medical Ethics Course?		Other Ethics Course?		Clinical vs Research?	
	Yes	No	Yes	No	Yes	No	Yes	No
	n= True (%) [OR]							
14. I am very optimistic about my chances for successful treatment.	1 (13) [0.86]	2 (14)	2 (22) [3.20]	1 (8)	2 (17) [1.75]	1 (10)	3 (14) [INF]	0 (0)
8. There are many ways my participation in this study would help me.	2 (25) [0.46]	6 (43)	4 (44) [1.75]	4 (31)	5 (42) [1.63]	3 (30)	8 (38) [INF]	0 (0)
24. My past medical experiences have prepared me well for participation in this study.	6 (75) [1.63]	9 (64)	5 (56) [0.39]	10 (77)	9 (75) [1.94]	6 (60)	15 (71) [INF]	0 (0)
15. I look forward to participating in this study with hope and enthusiasm.	4 (50) [0.18]	12 (86) p=0.18	7 (77) [1.53]	9 (69)	9 (75) [1.27]	7 (70)	15 (71) [0.0]	1 (100)
18. I look forward to being in this study.	4 (50) [0.29]	11 (79) p=0.36	6 (67) [0.89]	9 (69)	8 (67) [0.86]	7 (70)	15 (71) [INF]	0 (0)

TABLE 3.1 ATTITUDES TO CLINICAL RESEARCH ETHICS EDUCATION (1)									
	mean (SD) [range]	Gender		Age		BUSM Year		Anticipated Specialty	
		Total	Male	Female	≤24	≥25	I & II	III & IV	1° care
1. Ethics Interest in:									
Clinical Medicine	7.78 (1.1) [5, 9]	7.7(1.0) [6,9]	7.6 (1.3) [5,9]	8.0 (9.6) [6,9]	7.1 (1.2) [5,9]	7.8 (1.2) [5,9]	7.0 (0.0) [7,7]	7.6 (0.99) [6,9]	7.9 (0.99) [6,9]
Clinical Research	6.95 (1.3) [5,9]	6.9 (1.14) [5,9]	7.0 (1.4) [5,9]	7.4* (1.22) [5,9]	6.1 (0.83) [5,7]	6.0 (1.4) [5,9]	7.0 (1.23) [5,7]	6.9 (1.34) [5,9]	7.1 (1.2) [5,9]
2. The goal of ethics education:									
Clinical care and decisions	8.00 (1.5) [2,9]	8.3 (0.78) [7,9]	7.7 (2.0) [2,9]	7.9 (1.8) [2,9]	8.3 (0.71) [7,9]	7.95 (1.6) [2,9]	8.5 (0.71) [8,9]	8.1 (0.69) [2,9]	7.9 (1.9) [7,9]
Ethics in clinical research	7.86 (1.7) [2,9]	8.4 (0.92) [6,9]	7.4 (2.1) [2,9]	7.7 (2.0) [2,9]	8.1 (0.99) [6,9]	7.8 (1.7) [2,9]	9.0* (0.0) [9,9]	8.3 (0.91) [2,9]	7.0 (2.6) [6,9]
Knowledge of Clinical Care	6.95 (2.3) [2,9]	6.3 (2.7) [2,9]	7.6 (1.7) [3,9]	7.64 (1.6) [3,9]	5.8 (3.0) [2,9]	7.25 (2.1) [2,9]	4.0 (2.8) [2,6]	7.0 (2.4) [2,9]	7.2 (2.2) [2,9]
Knowledge of Clinical Research	6.55 (2.3) [2,9]	6.5 (2.2) [2,9]	6.5 (2.5) [2,9]	6.8 (2.3) [2,9]	6.1 (2.4) [2,8]	6.6 (2.4) [2,9]	6.5 (0.71) [6,7]	6.0 (3.0) [2,9]	7.1 (1.7) [3,9]
3. Professional Attitudes									
Formally teach clinical medicine ethics	7.95 (1.1) [6,9]	7.9 (1.4) [6,9]	8.0 (0.89) [7,9]	8.1 (1.1) [6,9]	7.8 (1.2) [6,9]	7.85 (1.1) [6,9]	9.0** (0.0) [9,9]	8.1 (1.0) [7,9]	7.9 (1.3) [6,9]
Formally teach clinical ethics	8.14 (1.2) [5,9]	8.4 (1.2) [5,9]	7.9 (1.1) [6,9]	8.2 (1.1) [5,9]	8.0 (1.3) [6,9]	8.0 (1.2) [5,9]	9.0* (0.0) [9,9]	8.3 (0.49) [8,9]	8.2 (1.3) [5,9]
Formally teach clinical research ethics	7.32 (1.3) [4,9]	7.4 (1.7) [4,9]	7.3 (0.78) [6,8]	7.5 (1.0) [5,9]	7.0 (1.8) [4,9]	7.4 (1.1) [5,9]	6.5 (3.5) [4,9]	7.6 (0.53) [7,8]	7.3 (1.6) [4,9]
6. Ethics training helps physicians									
Ethics training helps physicians	7.59 (1.2) [5,9]	7.7 (1.1) [5,9]	7.5 (1.3) [5,9]	7.9 (0.95) [5,9]	7.1 (1.5) [5,9]	7.7* (1.2) [7,7]	7.0 (0.0) [7,7]	8.1 (0.38) [8,9]	7.5 (1.2) [5,9]
7. Ethics training helps researchers									
Ethics training helps researchers	7.59 (1.1) [5,9]	7.5 (1.1) [5,9]	7.6 (1.1) [5,9]	7.6 (1.1) [5,9]	7.5 (1.2) [5,9]	7.7* (1.1) [5,9]	7.0 (0.0) [7,7]	8.1* (0.8) [8,9]	7.3 (1.3) [7,9]
8. Ethics can be learned									
Ethics can be learned	7.27 (1.5) [4,9]	7.3 (1.2) [6,9]	7.3 (1.7) [4,9]	7.9* (1.1) [6,9]	6.1 (1.4) [4,8]	7.4** (1.5) [4,9]	6.0 (0.0) [6]	7.7 (0.95) [6,9]	7.3 (1.4) [5,9]

*p<0.05, **p<0.01, ***p<0.001

TABLE 3.2 ATTITUDES TO CLINICAL RESEARCH ETHICS EDUCATION (2)

	mean (SD) [range]	Gender		Age		BUSM Year		Anticipated Specialty	
		Total	Male	Female	≤24	≥25	I & II	III & IV	1° care
9. Need for more ethics training	6.41 (1.8) [2,9]	5.5 (1.8) [2,9]	7.3* (1.4) [5,9]	7.0* (1.7) [5,9]	5.4 (1.6) [2,7]	6.7 (1.5) [5,9]	3.5 (2.1) [2,5]	6.9 (1.6) [5,9]	6.2 (2.0) [2,9]
10. I would like more ethics trainings in:									
Informed consent	5.36 (2.3) [1,9]	4.5 (2.3) [1,8]	6.3 (2.1) [2,9]	5.9 (2.2) [2,9]	4.5 (2.4) 1,8]	5.8*** (2.0) [2,9]	1.0 (0.0) [1,1]	6.0 (2.1) [2,8]	5.1 (2.5) [1,9]
Risk/Benefit Ratio	6.82 (1.9) [1,9]	6.5 (2.2) [1,8]	7.2 (1.7) [4,9]	7.6** (1.2) [5,9]	5.5 (2.3) [1,8]	7.1 (1.5) [4,9]	4.5 (4.9) [1,8]	7.3 (1.1) [5,8]	6.8 (2.2) [1,9]
Participant recruitment	5.86 (2.4) [1,9]	4.5 (2.5) [1,8]	7.2** (1.5) [4,9]	6.8*** (1.9) [2,9]	4.3 (2.4) [2,7]	6.3** (2.0) [2,9]	1.5 (0.70) [1,2]	6.4 (2.2) [2,8]	5.7 (2.6) [1,9]
IRB Processes	6.41 (2.2) [1,9]	5.5 (2.5) [1,9]	7.3 (1.4) [5,9]	7.5*** (1.1) [6,9]	4.5 (2.3) [1,7]	6.7 (1.9) [2,9]	4.0 (4.2) [1,7]	6.6 (2.4) [2,9]	6.4 (2.2) [1,9]
Research design	6.23 (2.7) [1,9]	5.0 (2.6) [1,8]	7.5* (2.2) [2,9]	6.4 (2.7) [2,9]	5.9 (2.9) [1,8]	6.4 (2.5) [2,9]	4.5 (4.9) [1,8]	5.9 (2.9) [2,9]	6.3 (2.7) [1,9]
Investigator vs. Clinician	6.91 (2.1) [1,9]	5.9 (2.3) [1,9]	7.9* (10.3) [2,9]	7.4 (1.4) [5,9]	6.0 (2.8) [1,9]	7.15 (1.7) [3,9]	4.5 (4.9) [1,8]	6.9 (2.1) [3,9]	7.0 (2.2) [1,9]
11. Ethics education should take place:									
Didactic training	6.64 (1.7) [2,8]	6.5 (1.6) [3,8]	6.8 (1.9) [2,8]	6.4 (2.0) [2,8]	7.0 (1.2) [5,8]	6.7 (1.8) [2,8]	6.0 (0.0) [6,6]	6.4 (2.3) [2,8]	6.9 (1.5) [3,8]
Journal clubs/seminars	7.27 (1.8) [2,9]	7.3 (1.9) [2,9]	7.3 (1.8) [4,9]	7.4 (2.1) [2,9]	7.1 (1.5) [5,9]	7.2 (1.9) [2,9]	8.0 (0.0) [8,8]	7.3 (1.6) [4,9]	7.4 (1.9) [2,9]
Post didactic training	6.95 (1.8) [2,9]	7.2 (1.3) [4,9]	6.7 (2.1) [2,9]	7.1 (2.0) [2,9]	6.6 (1.3) [5,8]	6.85 (1.8) [2,9]	8.0** (0.0) [8,8]	6.8 (2.3) [2,9]	7.1 (1.5) [4,9]
12. Education in clinical research and research ethics is important	7.95 (1.0) [6,9]	8.1 (1.0) [6,9]	7.8 (1.1) [6,9]	8.1 (0.92) [6,9]	7.8 (1.3) [6,9]	7.9 (1.0) [6,9]	9.0*** (0.0) [9,9]	7.3 (0.76) [6,8]	8.4*** (0.85) [6,9]
13. There should be increased focus on clinical research and research ethics in medical school	6.72 (1.6) [2,9]	6.5 (1.9) [2,9]	7.0 (1.3) [5,9]	6.6 (1.9) [2,9]	6.9 (1.1) [6,9]	6.6 (1.6) [2,9]	8.0 (1.4) [7,9]	6.6 (0.97) [5,8]	6.9 (2.0) [2,9]

*p<0.05, **p<0.01, ***p<0.001

TABLE 3.3 ATTITUDES TO CLINICAL RESEARCH ETHICS EDUCATION (3)										
	mean (SD) [range]	Graduate Degree?		Prior Research Experience?		Future Research Career?		Past RCT Participant?		
		Yes	No	Yes	No	Yes	No	Yes	No	
1. Ethics Interest in:										
Clinical Medicine	8.3 (0.95) [7.9]	7.6 (1.1) [5.9]	7.6 (1.1) [5.9]	7.6 (1.1) [5.9]	9.0 (0.0) [9]	8.1 (0.83) [7.9]	7.4 (1.2) [5.9]	6.5 (0.71) [6.7]	7.8 (1.1) [5.9]	
Clinical Research	6.8 (0.50) [6.7]	7.0 (1.4) [5.9]	6.9 (1.3) [5.9]	7.00 (0.0) [7]	7.6 (1.1) [6.9]	6.6* (1.2) [5.9]	6.5 (0.71) [6.7]	7.0 (1.3) [5.9]		
2. The goal of ethics education:										
Clinical care and decisions	8.8 (0.50) [8.9]	7.8 (1.6) [2.9]	7.9 (1.5) [2.9]	9.0 (0.0) [9]	7.8 (2.4) [2.9]	8.1 (0.77) [7.9]	8.5 (0.71) [8.9]	7.9 (1.6) [2.9]		
Ethics in clinical research	7.8 (1.3) [6.9]	7.9 (1.8) [2.9]	7.9 (1.7) [2.9]	8.0 (0.0) [8]	8.5 (0.76) [7.9]	7.5 (2.0) [2.9]	8.5 (0.71) [8.9]	7.8 (1.7) [2.9]		
Knowledge of Clinical Care	6.3 (3.1) [2.9]	7.1 (2.2) [2.9]	6.9 (2.4) [2.9]	8.0 (0.0) [8]	8.3* (1.0) [6.9]	6.2 (2.5) [2.9]	7.0 (1.4) [6.8]	6.9 (2.4) [2.9]		
Knowledge of Clinical Research	5.5 (2.4) [2.7]	6.8 (2.3) [2.9]	6.5 (2.3) [2.9]	7.0 (0.0) [7]	7.6 (1.5) [5.9]	5.9 (2.5) [2.9]	7.0 (1.4) [6.8]	6.5 (2.4) [2.9]		
3. Professional Attitudes										
Formally teach clinical medicine ethics	8.0 (1.4) [6.9]	7.9 (1.1) [6.9]	7.9 (1.1) [6.9]	9.0 (0.0) [9]	8.1 (1.1) [6.9]	7.9 (1.2) [6.9]	8.0 (1.4) [7.9]	7.9 (1.1) [6.9]		
Formally teach clinical research ethics	8.8 (0.50) [8.9]	8.0 (1.2) [5.9]	8.1 (1.2) [5.9]	9.0 (0.0) [9]	8.3 (1.2) [6.9]	8.1 (1.2) [5.9]	8.5 (0.71) [8.9]	8.1 (1.2) [5.9]		
4. Ethics training helps physicians										
Ethics training helps physicians	8.3 (0.96) [7.9]	7.4 (1.2) [5.9]	7.5 (1.2) [5.9]	9.0 (0.0) [9]	7.6 (1.2) [5.9]	7.6 (1.2) [5.9]	7.5 (0.71) [7.8]	7.6 (1.2) [5.9]		
5. Ethics training helps researchers										
Ethics training helps researchers	8.3 (0.96) [7.9]	7.4 (1.1) [5.9]	7.5 (1.1) [5.9]	9.0 (0.0) [9]	7.5 (1.2) [5.9]	7.6 (1.1) [5.9]	7.5 (0.71) [7.8]	7.6 (1.1) [5.9]		
6. Ethics can be learned										
Ethics can be learned	6.8 (0.95) [6.8]	7.4 (1.5) [4.9]	7.3 (1.5) [4.9]	7.0 (0.0) [7]	7.6 [^] (1.7) [5.9]	7.1 (1.3) [4.9]	6.0 (0.0) [6.6]	7.4 ^{***} (1.5) [4.9]		

*p<0.05, **p<0.01, ***p<0.001

TABLE 3.4 ATTITUDES TO CLINICAL RESEARCH ETHICS EDUCATION (4)										
	Graduate Degree?		Prior Research Experience?		Future Research Career?		Past RCT Participant?			
	Yes	No	Yes	No	Yes	No	Yes	No		
mean (SD) [range]										
9. Need for more ethics training	5.5 (1.0) [5,7]	6.6 (1.9) [2,9]	6.5 (1.8) [2,9]	5.0 (0.0) [5]	7.3 (1.6) [5,9]	5.9 (1.8) [2,9]	6.0 (1.4) [5,7]	6.5 (1.8) [2,9]		
10. I would like more ethics trainings in:										
Informed consent	5.0 (2.9) [1,8]	5.4 (2.3) [1,9]	5.4 (2.4) [1,9]	5.0 (0.0) [5]	5.8 (2.3) [1,8]	5.1 (2.4) [1,9]	3.0 (2.8) [1,5]	5.6 (2.2) [1,9]		
Risk/Benefit Ratio	6.0 (3.4) [1,8]	7.0 (1.6) [4,9]	6.8 (2.0) [1,9]	8.0 (0.0) [8]	6.8 (2.6) [1,9]	6.9 (1.6) [4,9]	3.0 (2.8) [1,5]	7.2 (1.4) [4,9]		
Participant recruitment	3.5 (2.4) [1,6]	6.4 (2.1) [2,9]	5.9 (2.4) [1,9]	5.0 (0.0) [5]	6.6 (2.4) [1,8]	5.4 (2.4) [2,9]	3.0 (2.8) [1,5]	6.1 (2.2) [2,9]		
IRB Processes	4.0 (2.9) [1,7]	6.9 (1.6) [3,9]	6.4 (2.2) [1,9]	7.0 (0.0) [7]	7.0 (2.6) [1,9]	6.1 (1.9) [2,9]	3.0 (2.8) [1,5]	6.75 (1.8) [2,9]		
Research design	4.0 (2.9) [1,7]	6.7 (2.4) [2,9]	6.2 (2.7) [1,9]	6.0 (0.0) [6]	6.9 (2.9) [1,9]	5.9 (2.6) [2,9]	3.0 (2.8) [1,5]	6.6 (2.5) [2,9]		
Investigator vs. Clinician	4.8 (3.5) [1,9]	7.4 (1.4) [5,9]	6.9 (2.1) [1,9]	6.0 (0.0) [6]	7.4 (2.7) [1,9]	6.6 (1.6) [3,9]	3.0 (2.8) [1,5]	7.3 (1.6) [3,9]		
11. Ethics education should take place:										
Didactic training	7.5 (1.0) [6,8]	6.4 (1.8) [2,8]	6.6 (1.7) [2,8]	8.0 (0.0) [8]	7.5* (0.92) [6,8]	6.1 (1.9) [2,8]	7.0 (1.4) [6,8]	6.6 (1.8) [2,8]		
Journal clubs/seminars	8.0 (0.82) [7,9]	7.1 (2.0) [2,9]	7.2 (1.9) 2,9]	8.0 (0.0) [8]	8.1 (1.4) [5,9]	6.8 (1.9) [2,9]	7.5 (0.71) [7,8]	7.3 (1.9) [2,9]		
Post didactic training	7.0 (0.82) [6,8]	6.9 (1.9) [2,9]	7.0 (1.8) [2,9]	7.0 (0.0) [7]	7.3 (1.4) [5,9]	6.8 (2.0) [2,9]	7.0 (1.4) [6,8]	7.0 (1.8) [2,9]		
12. Education in clinical research and research ethics is important	8.3 (0.95) [7,9]	7.9 (1.1) [6,9]	8.0 (1.1) [6,9]	8.0 (0.0) [8]	8.6**(0.52) [8,9]	7.6 (1.1) [6,9]	7.5 (2.1) [6,9]	8.0 (0.97) [6,9]		
13. There should be increased focus on clinical research and research ethics in medical school	7.3 (1.7) [5,9]	6.6 (1.6) [2,9]	6.8 (1.6) [2,9]	5.0 (0.0) [5]	8.1*** (1.0) [6,9]	5.9 (1.4) [2,7]	7.5 (2.1) [6,9]	6.7 (1.6) [2,9]		

*p<0.05, **p<0.01, ***p<0.001

TABLE 3.5 ATTITUDES TO CLINICAL RESEARCH ETHICS EDUCATION (5)										
	Prior Clinical Experience?		Prior Medical Ethics Course?		Other Ethics Course?		Clinical vs Research?			
	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No
1. Ethics Interest in:										
Clinical Medicine	7.9 (0.83) [7,9]	7.6 (1.3) [5,9]	7.8 (1.1) [6,9]	7.6 (1.2) [5,9]	7.8 (1.2) [5,9]	7.5 (1.1) [6,9]	7.67 (1.2) [5,9]	8.0 (0.0) [8]		
Clinical Research	7.0 (1.4) [5,9]	6.93 (1.2) [5,9]	7.0 (1.0) [6,9]	6.9 (1.4) [5,9]	6.9 (1.2) [5,9]	7.0 (1.4) [5,9]	7.0 (1.3) [5,9]	6.0 (0.0) [6]		
2. The goal of ethics education:										
Clinical care and decisions	7.6 (2.3) [2,9]	8.2 (0.80) [7,9]	8.2 (0.83) [7,9]	7.8 (1.9) [2,9]	7.8 (1.9) [2,9]	8.2 (0.79) [7,9]	7.9 (1.5) [2,9]	9.0 (0.0) [9]		
Ethics in clinical research	8.0 (1.4) [6,9]	7.8 (1.8) [2,9]	7.9 (1.2) [6,9]	7.8 (2.0) [2,9]	7.9 (1.1) [6,9]	7.8 (2.3) [2,9]	7.8 (1.7) [2,9]	9.0 (0.0) [9]		
Knowledge of Clinical Care	6.6 (2.7) [2,9]	7.1 (2.1) [2,9]	7.7 (0.86) [6,9]	6.5 (2.9) [2,9]	7.5 (1.7) [3,9]	6.3 (2.8) [2,9]	6.9 (2.4) [2,9]	8.0 (0.0) [8]		
Knowledge of Clinical Research	6.9 (2.1) [3,9]	6.4 (2.4) [2,9]	7.0 (1.4) [5,9]	6.2 (2.7) [2,9]	6.75 (1.8) [3,9]	6.3 (2.8) [2,9]	6.5 (2.3) [2,9]	8.0 (0.0) [8]		
3. Professional Attitudes										
	8.5 (0.92) [7,9]	7.6 (1.2) [6,9]	7.8 (1.3) [6,9]	8.1 (1.0) [6,9]	8.2 (1.1) [6,9]	7.7 (1.2) [6,9]	8.0 (1.1) [6,9]	7.0 (0.0) [7]		
4. Formally teach clinical medicine ethics	8.5 (0.71) [7,9]	7.9 (1.3) [5,9]	8.0 (1.5) [5,9]	8.3 (0.93) [6,9]	8.2 (1.2) [6,9]	8.1 (1.2) [5,9]	8.2 (1.1) [5,9]	6.0 (0.0) [6]		
5. Formally teach clinical research ethics	7.0 (1.4) [4,9]	7.5 (1.3) [5,9]	7.3 (1.3) [5,9]	7.3 (1.4) [4,9]	7.3 (1.1) [6,9]	7.4 (1.6) [4,9]	7.4 (1.3) [4,9]	6.0 (0.0) [6]		
6. Ethics training helps physicians										
	7.9 (0.64) [7,9]	7.4 (1.4) [5,9]	7.3 (1.4) [5,9]	7.8 (1.0) [5,9]	7.6 (1.4) [5,9]	7.6 (0.97) [5,8]	7.7 (1.1) [5,9]	5.0* (0.0) [5]		
7. Ethics training helps researchers	7.6 (0.92) [6,9]	7.6 (1.2) [5,9]	7.1 (1.5) [5,9]	7.9 (0.64) [7,9]	7.8 (1.2) [5,9]	7.4 (0.97) [5,8]	7.7 (0.95) [5,9]	5.0** (0.0) [5]		
8. Ethics can be learned	7.5 (1.1) [6,9]	7.1 (1.7) [4,9]	7.4 (1.5) [5,9]	7.2 (1.5) [4,9]	6.8 (1.5) [4,9]	7.8 (1.3) [6,9]	7.4 (1.4) [4,9]	5.0 (0.0) [5]		

*p<0.05, **p<0.01, ***p<0.001

TABLE 3.6 ATTITUDES TO CLINICAL RESEARCH ETHICS EDUCATION (6)										
	Prior Clinical Experience?		Prior Medical Ethics Course?		Other Ethics Course?		Clinical vs Research?			
	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No
9. Need for more ethics training	6.6 (2.6) [2,9]	6.3 (1.3) [5,9]	6.8 (1.6) [5,9]	6.2 (1.9) [2,9]	6.5 (1.5) [5,9]	6.3 (2.2) [2,9]	6.4 (1.8) [2,9]	6.0 (0.0) [6]		
10. I would like more ethics trainings in:										
Informed consent	8.5 (0.71) [1,9]	4.7 (2.5) [1,8]	6.0 (1.7) [4,9]	4.9 (2.7) [1,8]	5.8 (2.1) [1,9]	4.8 (2.6) [1,8]	5.3 (2.4) [1,9]	6.0 (0.0) [6]		
Risk/Benefit Ratio	7.6 (1.3) [5,9]	6.4 (2.1) [1,8]	7.2 (1.5) [5,9]	6.5 (2.2) [1,9]	6.6 (2.3) [1,9]	7.1 (1.4) [5,8]	6.9 (1.9) [1,9]	5.0 (0.0) [5]		
Participant recruitment	6.3 (2.7) [2,9]	5.6 (2.3) [1,8]	6.9 (1.6) [4,9]	5.2 (2.6) [1,8]	6.3 (2.1) [1,9]	5.3 (2.7) [2,8]	5.8 (2.4) [1,9]	7.0 (0.0) [7]		
IRB Processes	7.3 (1.0) [6,9]	5.9 (2.5) [1,9]	6.8 (1.7) [3,9]	6.2 (2.4) [1,9]	6.2 (2.2) [1,9]	6.7 (2.1) [2,9]	6.4 (2.2) [1,9]	7.0 (0.0) [7]		
Research design	7.5 (2.3) [2,9]	5.5 (2.7) [1,9]	6.8 (2.2) [3,9]	5.8 (3.0) [1,9]	7.3 (2.2) [1,9]	4.9 (2.7) [2,9]	6.1 (2.7) [1,9]	8.0* (0.0) [8]		
Investigator vs. Clinician	7.9 (1.4) [5,9]	6.4 (2.3) [1,9]	7.3 (1.3) [6,9]	6.6 (2.5) [1,9]	7.3 (2.3) [1,9]	6.4 (1.8) [3,9]	6.9 (2.1) [1,9]	8.0 (0.0) [8]		
11. Ethics education should take place:										
Didactic training	6.9 (1.2) [5,8]	6.5 (2.0) [2,8]	6.4 (1.6) [3,8]	6.8 (1.9) [2,8]	6.9 (1.2) [5,8]	6.3 (2.2) [2,8]	6.6 (1.7) [2,8]	8.0 (0.0) [8]		
Journal clubs/seminars	7.0 (2.6) [2,9]	7.4 (1.3) [5,9]	7.6 (1.3) [5,9]	7.1 (2.1) [2,9]	7.3 (1.7) [4,9]	7.2 (2.1) [2,9]	7.4 (1.8) [2,9]	5.0 (0.0) [5]		
Post didactic training	7.9** (0.99) [6,9]	6.4 (1.9) [2,9]	7.2 (1.7) [4,9]	6.8 (1.8) [2,9]	7.3 (1.4) [5,9]	6.6 (2.1) [2,9]	7.0 (1.7) [2,9]	5.0 (0.0) [5]		
12. Education in clinical research and research ethics is important.	8.1 (0.83) [7,9]	7.9 (1.2) [6,9]	8.1 (0.93) [6,9]	7.8 (1.1) [6,9]	8.0 (0.95) [6,9]	7.9 (1.2) [6,9]	8.0 (1.1) [6,9]	8.0 (0.0) [8]		
13. There should be increased focus on clinical research and research ethics in medical school.	6.4 (2.0) [2,8]	6.9 (1.4) [5,9]	6.7 (1.3) [5,9]	6.8 (1.9) [2,9]	6.9 (1.4) [5,9]	6.5 (2.0) [2,9]	6.8 (1.7) [2,9]	6.0 (0.0) [6]		

*p<0.05, **p<0.01, ***p<0.001

LIST of JOURNAL ABBREVIATIONS

Acad Med	Academic Medicine
Acad Psychiatry	Academic Psychiatry
Am J Psychiatry	American Journal of Psychiatry
BMJ	British Medical Journal
Clin Trials	Clinical Trials
Int J Law Psychiatry	International Journal of Law and Psychiatry
IRB	IRB: Ethics and Human Research
J. Biol. Chem.	Journal of Biological Chemistry
J Can Chiropr Assoc	Journal of the Canadian Chiropractic Association
J Empir Res Hum Res Ethics	Journal of Empirical Research on Human Research Subjects
Med Anthropology	Medical Anthropology
Med Care	Medical Care
Med Teach	Medical Teacher
Trans Am Clin Climatol Assoc	Transactions of the American Clinical and Climatological Association

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VITA

