

## **Author's response to reviews**

**Title:** Human Subjects Protection Issues in QUERI Implementation Research

### **Authors:**

Edmund Chaney ([chaney@u.washington.edu](mailto:chaney@u.washington.edu))

Laura G. Rabuck ([Laura.Rabuck@va.gov](mailto:Laura.Rabuck@va.gov))

Jane Uman ([Jane.Uman@va.gov](mailto:Jane.Uman@va.gov))

Debbie Mittman ([Debbie.Mittman@va.gov](mailto:Debbie.Mittman@va.gov))

Carol Simons ([Carol.Simons@va.gov](mailto:Carol.Simons@va.gov))

Barbara Simon ([Barbara.Simon@va.gov](mailto:Barbara.Simon@va.gov))

Mona Ritchie ([RitchieMonaJ@uams.edu](mailto:RitchieMonaJ@uams.edu))

Marisue Cody ([Marisue.Cody@va.gov](mailto:Marisue.Cody@va.gov))

Lisa V Rubenstein ([lisar@rand.org](mailto:lisar@rand.org))

**Version:** 3 **Date:** 27 July 2007

**Author's response to reviews:** see over

Edmund Chaney, Ph.D.  
VA Puget Sound Health Care System  
Seattle Division 116MHC  
1660 S Columbian Way  
Seattle, WA 98108  
206-764-2815  
FAX 206-764-2872  
edmund.chaney@med.va.gov  
chaney@u.washington.edu

July 27, 2007

Martin Eccles  
Ian Graham  
Series Editors  
*Implementation Science*

**Re: MS ID 2717689201122955**  
**Title: Human Subjects Protection Issues in QUERI Implementation Research**  
**Journal: Implementation Science**  
**Authors: Edmund Chaney, Laura G. Rabuck, Jane Uman, Debbie Mittman, Carol Simons, Barbara Simon, Mona Ritchie, Marisue Cody and Lisa V. Rubenstein**

Dear Dr. Eccles and Graham:

Thank you for the opportunity to resubmit our revised manuscript. We have corrected and revised all the issues raised in the last review dated June 23, 2007. Below, we have included the reviewers' comments to facilitate description of our responses, noted in italics. The revised manuscript includes 5,519 words, 4 tables, 35 references, and 7 additional files.

Thanks again for your feedback on our manuscript. Please contact us if there are any further revisions.

Sincerely,

Edmund Chaney, Ph.D.  
Corresponding Author

### **Referee 3: (Martin Eccles and Ian Graham)**

1. Abstract, Methods third sentence, could you change the word “proven” to “proved” at this point and on the few occasions it occurs throughout the manuscript.

*“Proven” has been changed to “proved” when it occurs in the article as requested.*

2. At the beginning of the Method section (page 7) you introduce a number of study acronyms. These are defined in the accompanying Table 2 as a footnote to the table. We would prefer them to be defined in the text. Later in the same paragraph on page 7 the tense of the writing slips. All of what you have written is in the past tense. Hence the sentence should read “The sites we worked with were either...”

*The study acronyms have been defined in the text at the beginning of the Methods section and the definitions have been removed as a footnote to Table 2. The tense of the writing in the sentence has been changed to “The sites we worked with were either...”*

3. Half way down first paragraph on page 8 suggest delete [which can be ... on the file].

*The phrase “which can be...” has been deleted as requested.*

4. Page 9, section a contains the first reference to Additional files. “Additional” should be capitalized throughout the manuscript.

*“Additional” has been capitalized at the first reference to Additional file and throughout the manuscript.*

5. Page 13, the journal style doesn’t include underlining (even if this was present in the quote).

*Underlining has been removed.*

6. Page 24, you mention the “three basic ethical principles identified by...” but don't say what they are - since this the paper is about ethics it might be good to list them for the less knowledgeable readers.

*The three basic principles have been added. See sentence below.*

*Through lack of unambiguous guidelines and local liability concerns, IRBs are at risk of applying both variable and inappropriate or unnecessary standards that may impede the conduct of evidence-based quality improvement implementation research because they are not consistent with the spirit of the Belmont Report, a summary of the three basic ethical principles (Respect for persons, Beneficence, and Justice) identified by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.*

7. Table 2. The explanation of the acronyms will now appear in the text and some can be deleted from here. We would also like you to include the other footnote in the TIDES/Goals cell of the table.

*The other footnote has been moved to the TIDES/Goals cell of the table. See below.*

*Study feasibility and safety of evidenced-based quality improvement for depression care. Steps included: 1) Adapt depression collaborative care models to VA settings through Evidence-Based Quality Improvement for Depression (EBQID); 2) Support and evaluate depression collaborative care implementation; and 3) Prepare for dissemination of depression improvement methods and materials throughout the VHA*

8. Table 3, Multiple Health Care systems, third row middle column; the text doesn't quite make sense. It looks as if there is a word too many ("and") or a word missing ("store").

*This has been corrected. See below.*

*Centralize records retention at a single administrative site*

9. Table 4. The presence of such extensive footnotes will cause formatting problems. It would be easiest if you could extend the borders of the table to include the footnotes.

*This has been corrected. See Table 4 below*

**Table 4. TIDES / RETIDES IRB Initial Application Information**

<b>TIDES Study</b>				
<i>Site*</i>	<i>IRB type</i>	<i>IRB required changes?</i>	<i>Approval Type†</i>	<i>Time Elapsed‡</i>
A	VA in-house	No	Exempt	32
B	VA in-house	No	Exempt	67
C	University	Yes <sup>1</sup>	Expedited	75
D	University	No	Expedited	9
E	VA in-house	Yes <sup>2</sup>	Expedited	5
F	University	Yes <sup>3</sup>	Full	7
G§	VA in-house	No	Full	82
H¶	University	Yes <sup>4</sup>	Expedited	38
I	University	No	Expedited	5
				Average=35.55
<b>ReTIDES Study</b>				
F	University	Yes <sup>5</sup>	Full	22
I	University	N/A	Non-human research	5
J	University	No	Exempt	3

K	University	No	Exempt	20
H¶	University	Yes <sup>6</sup>	Expedited	30
L	VA in-house	Yes <sup>7</sup>	Expedited	14
A	VA in-house	No	Exempt	6
M	VA in-house	No	Exempt	14
				Average = 14.25

\* Site identification codes are uniform, showing both new sites for ReTIDES and some TIDES sites not (yet) participating in ReTIDES

† We experienced no variance between review type preferred and actual approval type granted.

‡ In days, starting with submission date, ending with approval date (weekends, holidays included)

§ From IRB G Investigator Guide & Instructions booklet: “No research is exempt from review and there are no “expedited” reviews”.

¶ This was the only site that required an electronic submission

1 Concerns included: consent form alterations, include contact info in mailing, survey data storage, patient information protocol, number of interviews, adding written consent at local level

2 Concerns included: changes to allow better informed consent decision-making, protocol on frequency of subject contact, advance phone call consent, telephone interview protocol, recording interview protocol, time estimated for interviews, why are patients being interviewed, and obtaining consent

3 Concerns included: consent obtained to access patient data registry, justification for exemption of worksheet data forms, how does VA encrypt medical records, number discrepancy, terminology issues, protocol regarding the movement of paper data, oral consent procedure, clarification of anonymous/confidential, changes to worksheets, who has data access, confirm study codes are not SSN, how is questionnaire used, typographic errors

4 Concerns included: typographic errors, further justification for no consent

5 Concerns included: coercion as possible risk, determining coordinating center, providing a consent form if requested by subject, how participation is / isn't related to job description, including text about participating not affecting job security

6 Concerns were administrative, related to the electronic submission process

7 Concerns were administrative

10. Additional File 2, could you define (preferably writing in full on each occasion) the meaning of TBA and TBN.

*“To Be Announced” and “To Be Named” have been written out in full on each occasion as requested.*

11. Additional File 4. The first pages suggests that there should be a further six pages. If this is the case then there is a technical problem as the pdf consists of only a single page. If however, it is intended to be illustrative only then the lead in text of the manuscript and the Additional File itself need amending.

*In addition to the first page of Additional File 4, there should have been seven additional pages. This has been corrected and Additional File 4 now contains a total of eight pages.*