Quorum

1501 Fourth Avenue
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QuorumReview.com

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08/01/2017

Laura Dunlap
c/o Victoria Albright
RTI
3040 E. Cornwallis Rd.
Durham, NC 27709

Re: Centers for Disease Control and Prevention (CDC)
Protocol #: N/A
PI: Laura Dunlap
QR#: 32609/1

Dear Dunlap:

Quorum Review has reviewed and approved the following material on 08/01/17 for use during the course of the above referenced study:

- *Client Focus Group Guide*
- *Participant Form: Medication Assisted Treatment Evaluation Study (MATES) Client Permission Form*
- *Provider Focus Group Guide*
- *Questionnaire: Crime and Criminal Behavior Questions*
- *Questionnaire: Medication Assisted Treatment Evaluation Study (The MAT Study) Check-In Questionnaire (Version 1, 06-21-2017)*
- *Questionnaire: Medication Assisted Treatment Evaluation Study (The MAT Study) Client Questionnaire (Version 1, 06-23-2017)*
- *Questionnaire: Medication Assisted Treatment Evaluation Study (The MAT Study) Screener Form*
- *Questionnaire: Medication Assisted Treatment Evaluation Study (The MAT Study) Site Director Questionnaire*
- *Questionnaire: Medication Assisted Treatment Evaluation Study (The MAT Study) Visit Form*

Please note the following conditions of Quorum Review's approval of recruitment and participant study materials:

- The above material is approved for use on the Quorum approval date noted above or this site's IRB approval date, whichever is later.
- Any changes to the content or presentation of approved material, other than site specific contact information modifications or spelling corrections, must be reviewed and approved prior to use.

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- Material listed above as “Replacement Material” has been identified as a replacement for previously approved material. Approval documents for previous versions of this material no longer apply.
- Radio and television scripts to be recorded are approvable pending review and approval of a final audio/video recording. The final recording must be approved by Quorum prior to broadcast use.
- Radio scripts for live broadcast use must be read exactly as approved.
- The approval stamp on this material represents Quorum Review’s approval for the use of this version of the material within the context of the above identified protocol.
- This material may not be used for other studies without appropriate IRB approval, however, this version of the material may be used without the Quorum approved stamp as long as no other modifications are made.

Additionally, please note that recruitment activities might implicate the HIPAA Privacy Rule (U.S.) or PIPEDA (Canada). You may need to have a specific authorization to collect and use health information in conjunction with your recruitment activities. Please consult your legal counsel with any questions. If your site is in the U.S. and you decide you need a partial HIPAA waiver of authorization for your recruitment activities, you can contact Quorum or visit our website at www.quorumreview.com.

If you have any questions, please don’t hesitate to contact the Client Support Team at (206) 448-4082. Thank you for using Quorum Review.

CC:

RTI	Sarah Duhart Clark
Quorum Review File #	32609/1

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Notice of Approval

Dear Dunlap:

Quorum Expedited Review has reviewed and approved the above-referenced research. Enclosed please find a **Notice of Approval** and, if applicable, stamped consent form(s) in support of this approval.

Quorum Review has determined this research is expeditable under the following category(ies):

- 5,7

Your site's approval for this study expires on **8/1/2018**. Quorum Review will remind you to submit a Site Status Report form four weeks prior to the due date. Per FDA and other regulatory agency regulations research activity may not continue on or after the expiration date shown on the Notice of Approval without prior review and approval.

Please note that documents helpful to your site (including Participant Recruitment and Safety Reporting Guidance, Safety Report Forms, the California Bill of Rights (for CA sites) etc.) can be found on Quorum Review's website at www.quorumreview.com.Current and historical ***Board Rosters*** *can be found on the Quorum OnQ Portal at https://onq.quorumreview.com/Library/.*

If you have any questions, please don't hesitate to contact the Client Support Team at (206) 448-4082. Thank you for using Quorum Review.

Enclosure

CC:

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NOTICE OF APPROVAL

Approval Date: **8/1/2017**

Expiration begins on: **8/1/2018**

Study Title: Medication-Assisted Treatment for Opioid Use Disorders (MAT Study)
Protocol Number: N/A
Sponsor: Centers for Disease Control and Prevention (CDC)
Principal Investigator: Laura Dunlap

This approval includes:

The Protocol, dated 06/28/17; Grant Requisition/Reference No.: 0HCUHFC3-2016-00372
The Principal Investigator
Client Informed Consent/Assent Form, Version 1, dated 08/01/17;Provider Focus Group Participant Informed Consent, Version 1, dated 08/01/17; Client Focus Group Participant Informed Consent/Assent Form, Version 1, dated 08/01/17

The following report is necessary:

Site Status Report due by: 6/17/2018

CC:

RTI	Sarah Duhart Clark
Quorum Review File #	32609/1

See the next page for additional conditions of this approval.

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Quorum Review approvals are provided to Principal Investigators contingent upon the continuing approval of the underlying protocol and also subject to the following conditions:

Quorum Review regards the Principal Investigator as responsible for the conduct of research trials at his/her site and all associated research facilities. Specific responsibilities of the Principal Investigator include ensuring:

- ❑ supervision of all research activity at the site and facilities in accordance with Quorum Review policy, applicable laws, guidelines and the ethical principles outlined in the Belmont Report
- ❑ conduct of research according to the research protocol as approved by Quorum Review and any restrictions or conditions placed on the study by Quorum Review
- ❑ if the site is utilizing consent forms:
  - use of the most recently Quorum Review-approved, stamped informed consent form
  - provision of a Quorum Review-approved consent form in the participant's first language
  - subjects unable to read are enrolled only if a Quorum Review-approved consent form contains the witness statement and signature lines and all expected safeguards are followed
  - subjects requiring a legally authorized representative are enrolled only if a Quorum Review approved consent form contains a legally authorized representative statement and signature lines and all expected safeguards are followed
- ❑ prospective approval by Quorum Review of changes in research activity including protocol amendments and/or consent form revisions prior to implementation, changes in Principal Investigator, change in research site, and addition of research facilities to a previously approved site
- ❑ prompt reporting to Quorum Review of the completion of research
- ❑ prospective approval by Quorum Review of all advertisements / recruiting materials prior to use
- ❑ prompt reporting to Quorum Review of serious adverse events, major protocol deviations/violations, and other unanticipated problems involving risks to participants or others
- ❑ prompt reporting to Quorum Review of updated safety information and significant findings or information during the course of research which may relate to a participant's willingness to continue participation in the research
- ❑ timely submission of required progress reports
- ❑ all participants are aware that the research is investigational
- ❑ maintenance of adequate records in accordance with national, federal, state, provincial and local regulations
- ❑ maintenance of open communication with participants regarding participant requests for additional information or concerns about the research
- ❑ compliance with all requirements specified in the Quorum Handbook

Quorum Review IRB is an appropriately constituted research ethics board as required by regulation. This research was reviewed and approved by the Board in accordance with pertinent authorities, including but not limited to, the ICH Guidelines for Good Clinical Practice, U.S. Food and Drug Administration (21 CFR Parts 50 and 56), U.S. Department of Health and Human Services (45 CFR Part 46), the ethical principles outlined in the Belmont Report, the Canadian Food and Drug Regulations (Part C, Division 5), Part 4 of the Canadian Natural Health Products Regulations, and the Tri-Council Policy Statement (TCPS). This approval and the views of the Board have been documented in writing and certified by the Board Chair.