

## Change Request

### Cooperative Re-Engagement Controlled Trial (CoRECT), OMB No. 0920-1133

February 9, 2017

#### Overview

The CoRECT study is a randomized controlled trial being conducted by the Massachusetts State Department of Public Health, the Connecticut State Department of Health, and the Philadelphia Department of Public Health. Each site will enroll approximately 300 study participants. The CoRECT study seeks to 1) establish a data-sharing partnership between each health department and collaborating HIV care clinical providers, 2) accelerate the identification of HIV-infected persons who are out of care, 3) successfully re-engage these individuals in HIV medical care, and 4) evaluate three site-specific models of enhanced data linkage and re-engagement in care. Each jurisdiction is implementing an active health department field services intervention that has been tailored to its operating environment.

Minor changes are proposed to two forms in use at the Philadelphia site. Philadelphia elicited feedback from the medical providers who would be completing the Barriers to Care and Standard of Care surveys. After receiving their input, Philadelphia made a few changes to improve the surveys' ease of use. The proposed changes will not result in any additional burden to the respondents or grantees in the CoRECT study.

- Attachment 7: Barriers to Care Survey (Philadelphia). This is a one-time domain assessment that Disease Intervention Specialists (DIS) use to determine barriers and challenges that prevent participants from seeking HIV care. This Change Request seeks to add two domain categories, allowing the DIS conducting the survey more comprehensive options to discuss when identifying the participant's barriers to remaining in or linking to HIV care.
- Attachment 10: Standard of Care Survey (Philadelphia). This is a self-administered survey of project clinical providers conducted at multiple time points throughout the study period. The proposed changes will decrease the length of the survey by omitting four questions that had been asked in prior data tools for the CoRECT study, thus removing the questions prevents redundancy. Five questions will be added to assess the study's participating healthcare provider's capacity to conduct the activities for the CoRECT study.

#### Detailed Discussion of Nonmaterial/non-substantive changes to Attachment 10

- 1) The change in the wording of the questions on the "Standard of Care Survey" will result in clearer, more specific questions for the HIV providers.
- 2) Five questions were added to Philadelphia's Standard of Care survey to collect information on the HIV provider's capacity to identify their patient population who have disengaged HIV care.
- 3) Four questions were removed from the Standard of Care survey to prevent duplication.
- 4) The format for Attachment 10 was modified to improve usability and fit in a document. The form will be administered electronically.

Current Question/Item	Requested Change
<p>4) What administrative support staff are employed at your facility? (Please check all that apply.)</p> <ul style="list-style-type: none"> <li>-Other (please specify)</li> <li>-Office Manager</li> <li>-Medical Billing Staff</li> <li>-Scheduling Staff</li> <li>-None of these</li> </ul>	<p>4) Please indicate how many administrative support staff you have at your facility.</p> <p>Number of staff Total amount of FTE to the nearest tenth</p> <ul style="list-style-type: none"> <li>-Office Manager</li> <li>-Medical Billing Staff</li> <li>-Scheduling Staff</li> </ul>
<p>Added Question</p>	<p>6) If any new positions have been added to your practice please indicate them below. If there have been no new positions added please enter "no changes" in the box below.</p>
<p>Added questions</p>	<p>12) Please indicate what changes have occurred at your practice since the last time you took this survey.</p>
<p>13) In the last year, what methods has your practice used to re-link HIV patients back to care? (Please check all that apply.)</p> <ul style="list-style-type: none"> <li>-Other (please specify)</li> <li>-Called the patient after a missed medical office visit</li> <li>-Made a field visit to the patient after a missed medical office visit</li> <li>-Sent letters to the patient after a missed medical visit</li> <li>-Sent the patient a text message</li> <li>-Sent the patient a message via -your health system's secure patient portal</li> </ul>	<p>13) In the last six months, what methods has your practice used to re-link HIV patients back to care? (Please check all that apply.)</p> <ul style="list-style-type: none"> <li>-Called the patient after a missed medical office visit</li> <li>-Made a field visit to the patient after a missed medical office visit</li> <li>-Sent letters to the patient after a missed medical visit</li> <li>-Sent the patient a text message</li> <li>-Sent the patient a message via your health system's secure patient portal</li> <li>Other _____</li> </ul>
<p>16) Briefly describe your facility's protocol for re-linking HIV patients who have been lost to care?</p>	<p>15) Briefly describe your facility's protocol for re-linking HIV patients to care. If it is too long to describe below, please send it separately.</p> <p>If nothing has changed since your last survey please indicate no change in the box below.</p>
<p>19) How often is your facility's protocol for re-linkage practices modified?</p> <ul style="list-style-type: none"> <li>-Other (please specify)</li> <li>-Never</li> <li>-Every 3-6 mos</li> <li>-Every 6-12 mos</li> <li>-Every 1-2 yrs</li> </ul>	<p>17) How often is your facility's protocol for re-linkage to care reviewed?</p> <ul style="list-style-type: none"> <li>- twice a year</li> <li>-once a year</li> <li>-every 1-2 years</li> <li>-never</li> <li>-Other</li> </ul>
<p>22) What other computerized systems do you use to collect data on your patients? (Please check all that apply.)</p>	<p>18) Are any of your computer or data systems currently undergoing replacement, upgrades or Development?</p>
<p>Added Question</p>	<p>19) Are any of your computer or data systems scheduled to undergo replacement, upgrades or development?</p>
<p>Added Question</p>	<p>20) If your facility has incurred any new costs as a result of participating in the CoRECT project please describe them below.</p>
<p>Added Question</p>	<p>21) Do you have any concerns about participating in CoRECT that you'd like to share with us?</p>
<p>Question Removed</p>	<p>14) Which staff at your facility contact HIV patients when you are attempting to re-link them to care?</p>
<p>Question Removed</p>	<p>12) How frequently do patients report the following issues as a barrier to <b>staying in treatment</b> for their HIV?</p>
<p>Question Removed</p>	<p>11) How frequently do patients report the following issues as a barrier to <b>initially linking</b> to treatment for their HIV?</p>

## Detailed Discussion of Nonmaterial/non-Substantive changes to Attachment 7

- 1) There was a change to the number of barrier domains that will be utilized to identify the patients barriers to remaining linked to care. In an effort to capture more possible barriers to care “Other” was added to each domain to allow the DIS to describe barriers not previously identified in this assessment. In addition to adding the “other” option to each domain, three other domains were added: Patient education, Utilities, and Communication with service system. Adding these domains will allow the DIS additional areas to identify barriers to care.
- 2) There were four other categories added to the assessment which will allow the DIS to prioritize the barrier identified and indicate who identified the barrier. The assessment was modified to provide the DIS with ability to prioritize the barrier identified as “Primary” or “Secondary”. Because the “Patient Barrier Assessment” will be administered in a qualitative format the DIS will indicate who identified the barrier. The DIS will indicate the status of the barrier identified by selecting whether the barrier identified was resolved, not resolved or pending.
- 3) The “Intervention Phase” was added to the “Patient Barrier Assessment” to enable the DIS to indicate the phase the study participants are engaging in the ARTAS intervention. The intervention phase categories are Care Engagement, Transition to Care or Both.

Current Question/Domains	Requested Change
<b>1) Attitudes/ Perceptions about HIV and Health</b> My CD4 count and viral load are good There is no cure for HIV so I don't need to go to the dr.	<b><u>A)Attitude / Perception about HIV and Health</u></b> 4) CD4 count and viral load are good 5) Didn't think I am HIV positive 3) Since there is no cure for HIV, why should I go to my doctor
<b>2)Challenges with Medical Facility</b> + Added question	<b>B) Challenges with Medical Facility</b> 16) + Other _____
<b>3)Challenge with Medical Provider</b> I didn't like the way that I was treated at the clinic in the past + Added question	<b>P) Challenge with Medical Provider</b> My doctor is not addressing my needs 50) +Other _____
<b>4) Time Management and Organization</b> + Added question	<b>H) Time Management and Organization</b> 34) +Other _____
<b>5)Health Insurance and access to Medical Care</b> + Added question	<b>G) Health Insurance and access to Medical Care</b> 29 + Other _____
<b>6)Childcare</b> + Added question	<b>I) Childcare</b> 36)+Other _____
<b>7) Housing</b> + Added question	<b>N) Housing</b> 45) + Other
<b>8) Transportation</b>	<b>J) Transportation</b>

+ Added question	38) +Other
<b>9) Financial Challenges</b> I can't Pat my bills	<b>T) Financial Challenges</b> 57) Intermittent public assistance 58) +Other _____
<b>10) Food Security</b> I don't have any food +Added question	<b>S) Food Security</b> 55) I don't have enough food 56) +Other _____
<b>11) Unemployment</b> +Added question	<b>F) Unemployment</b> 24) +Other _____
<b>12) Incarceration</b> +Added question	<b>O) Incarceration</b> 48) +Other _____
<b>13) Religious Objection</b> +Added question	<b>M) Religious Objection</b> 44) +Other _____
<b>14) Disclosure/Privacy</b> +Added question	<b>L) Disclosure/Privacy</b> 42) +Other _____
<b>15) Stigma</b> +Added question	<b>E) Stigma</b> 22) +Other _____
<b>16) Medication Adherence</b> +Added question	<b>D) Medication Adherence</b> 20) +Other _____
<b>17) Mental Health</b> +Added question	<b>C) Mental Health</b> 18) +Other _____
<b>18) Substance Use</b> +Added question	<b>K. Substance Use</b> 40) +Other _____
+Added Domains/Barriers	<b>Q) Patient Education</b> 51) +Lack of understanding of HIV disease 52) +Other _____  <b>U) Utilities</b> 59) Can't Pay my utilities 60) +Other _____  <b>V) Communication with service systems</b> 61) +No TTY 62) +Language Barrier 63) +Other _____

<p>Patients Assessment Categories</p>	<p><b>Patient Barrier Assessment</b>  <b>Barrier Priority</b>  <input type="checkbox"/> Primary  <input type="checkbox"/> Secondary  <b>Barrier identified by:</b>  <input type="checkbox"/> Pt <input type="checkbox"/> DIS  <input type="checkbox"/> Both  <b>Barrier Status</b>  <input type="checkbox"/> Resolved  <input type="checkbox"/> Not Resolved  <input type="checkbox"/> Pending  <b>Intervention Phase</b>  <input type="checkbox"/> Care Engagement  <input type="checkbox"/> Transition to Care  <input type="checkbox"/> Both</p>
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