Research Procedures Update

October 4, 2016

The following document provides an update of research-related activities and is divided into three sections: in-treatment study, follow-up study, and dissemination of findings related to effectiveness.

**In-Treatment Study**

Data being collected

We have a fairly comprehensive set of research procedures tied to in-treatment outcomes. Some data are currently being collected: (1) Group Climate Survey; and (2) Client Log of Daily Activities. These data provide information on client engagement in and perception of various treatment elements (and speak to fidelity of treatment implementation—something of focus in evidence-based models).

Data fully pilot tested

*Comprehensive baseline assessment*

We have pilot tested several administrations of the comprehensive baseline assessment of client functioning. Procedures and measures were modified iteratively based on discussions with Rob and Brandon and how clients interacted with the measures and procedures. In general, the baseline administration should take between 90 minutes and 150 minutes and can be delivered over the course of two or three days/testing sessions.

The comprehensive baseline assessment is critical to understanding significant dimensions of the center’s clinical population. In addition to being of interest in their own right, these client characteristics might be related to treatment response (e.g., individuals with comorbid conditions might respond less well to treatment or individuals with a music background might respond more favorably to treatment).

The comprehensive baseline assessment is anchored by the Addiction Severity Index (ASI), an instrument widely used in the field of substance use treatment for over 30 years. We looked into using other available instruments (e.g., the Global Appraisal of Individual Needs or GAIN) or a pre-packaged computer-administered version of the ASI, but cost was prohibitive in both instances. In lieu of these more expensive options, we programmed the ASI into Survey Monkey for ease of administration and to obviate the need for data entry. The ASI requires interviewer assistance, but the interviewer does not require special certifications.

Date currently being pilot tested

*Clinician-assisted measures*

We began pilot testing clinician-assisted measures during the week of September 19th. The current plan is to collect these data when the clinicians have individual sessions with clients. Measure selection and procedures were designed based on discussions with clinicians. In fact, two of the four measures being used were developed by clinicians based on assessments / questions they had been asking of clients or issues they thought were important. Additional modifications to these measures and/or procedures should take place during the month of October 2016.

Data in need of pilot testing

*Additional ‘session-related’ measures*

Following completion of an individual session with a clinician, the client will complete brief measures rating the session and the working alliance (with the clinician). These measures should take two minutes to complete. The Survey Monkey links are active.

*Day 4 assessment*

Should take approximately nine minutes to complete. The Survey Monkey links are active.

*Day 14 assessment*

Should take approximately 37 minutes to complete. The Survey Monkey links are active.

*Day 21 assessment*

Should take approximately 28 minutes to complete. The Survey Monkey links are active.

*Typical discharge assessment*

Should take approximately 39 minutes to complete. The Survey Monkey links are active.

Once all methods have been pilot tested and the research infrastructure is established, data collection can begin on every client newly admitted to the PHP treatment at Recovery Unplugged.

**Follow-Up Study**

Once the follow-up study is approved by the NSU Institutional Review Board, residents can be consented for study participation.

Paul expressed an interest in consenting individuals at the beginning of their treatment stay, while they are signing other important documents. The consent process can be carried out by a staff member at Recovery Unplugged and Christian’s contact information will be provided if the resident would like to ask additional questions about research-related activities.

Once residents are formally discharged from the PHP program at Recovery Unplugged, they will be contacted by Christian’s team and asked to complete follow-up assessments on four occasions.

Similar to the baseline assessment, the follow-up assessments will be anchored by the Addiction Severity Index, which will require phone-based interviewer assistance (by a member of Christian’s team). This interviewer-assisted portion of the interview will require up to 30 minutes and the participant can complete the remaining survey items on his or her own.

The proposed follow-up assessment schedule is as follows:

* 30 days post-discharge (~25 to 45 minutes)\*
* 3 months post-discharge (~35 to 55 minutes)
* 6 months post-discharge (~35 to 55 minutes)
* 12 months post-discharge (~35 to 55 minutes)

Although it would be possible to simplify this assessment schedule (e.g., by cutting it down to the 3, 6, and 12 month assessments), the 30 day assessment can be used to engage clients who relapsed in the first month following discharge, possibly increasing the likelihood that the relapse will be shorter in duration and less severe. In addition, the 30-day assessment can provide the participants with useful insights (e.g., about commitment to recovery, cravings, stress, coping, the use of music to cope) that might help galvanize a weaker post-treatment trajectory.

Sample size projections and time lines related to post-discharge data collection are discussed in the next section of this document.

Once the research-related procedures have been approved by the IRB, consenting residents for study participation can commence.

Christian’s team will complete a number of pilot tests of the 30 day follow-up using residents who were recently discharged from the PHP program but are still active in the aftercare program.

**Dissemination of Findings Related to Effectiveness**

As data about in-treatment and post-treatment outcomes begin flowing into the research system (some of these data streams are flowing already), Christian and his team can make these data public by presenting them at relevant conferences and by trying to publish these data in academic journals. This public dissemination of results can be used to support a *practice-based* model of recovery at Recovery Unplugged.

The process of dissemination of research findings in a series of studies like the ones proposed has the potential to be impacted profoundly by several issues: 1) initial participant recruitment; 2) the data collection time line; 3) participant tracking and retention; 4) the actual clinical outcomes; and 5) the time needed to conceptualize, prepare, and disseminate research results (at conferences and in academic journals). Below these issues are discussed in more detail. In addition, tables related to “Key Research-Related Dates” and “Tasks Related to Fielding In-Treatment and Follow-Up Studies” can be found at the end of this document.

Initial participant recruitment and data collection time line

*In-treatment data*

If we assume that the approximate number of residents admitted each month to the PHP program in Sunrise is 30 and approximately 92% of them will consent to the follow-up study, approximately 331 individuals will flow into the system over the first 12 months of participant recruitment. (Technically, the in-treatment data do not require participant consent, so the actual sample size could be 8% larger.)

If participant recruitment began in January of 2017, and data flow was consistent with the above specifications, 100 residents would have complete in-treatment data by May of 2017. These in-treatment data could be presented at a conference in the summer or fall of 2017. This conference submission would help Christian’s team generate and disseminate the first set of in-treatment outcomes.

By January of 2018, approximately 330 residents will have complete in-treatment data related to the first complete calendar year of data collection. At that point, Christian and his team can prepare and submit a full-length manuscript looking at in-treatment changes in all residents. Manuscript preparation can occur between January and June of 2018 and the manuscript can be submitted by July of 2018.

*Follow-up data*

Although the data collection time line for the in-treatment outcomes can be conceptualized as fairly straightforward, unfortunately, the same cannot be said for the post-treatment data. While the residents are in the PHP program they are a captive audience and will generally complete the measures. Once they are discharged, however, successful completion of follow-up interviews depends on our ability to track participants (many of whom will be mobile following treatment), and participant willingness to complete assessment measures.

We have a reliable (and industry-standard plan) for participant tracking, which should serve us well.

We have also pruned the follow-up measures dramatically to keep measure completion times between 35 minutes and an hour. (Completion times will vary somewhat depending on the resident’s level of post-discharge substance use.)

Christian’s team has sample size (and resource allocation) projections according to a time line that assumes residents will begin being consented for the follow-up study in January of 2017.

Assuming that (1) 30 new residents are admitted to Recovery Unplugged each month, (2) 92% of new admits will consent to research procedures, and (3) Christian’s team will be able to successfully track and retain 70% of the originally consented residents over the 12-month follow-up, data collection will occur for two calendar years (beginning in January of 2017 and ending in January of 2019).

Three month follow-up data will be collected on approximately 286 residents by April of 2018. These data can be presented at a relevant professional conference in the summer or fall of 2018.

Six month follow-up data will be collected on approximately 266 residents by July of 2018.

These data can be published in the first manuscript documenting post-discharge outcomes.

Primary factors that will impact these projected numbers include:

* Low admission flow into system
* A lower percentage of individuals consenting to the follow-up study
* A higher percentage of individuals remaining in their index treatment beyond 30 days (which will delay their availability for the follow-up study)
* An attrition rate from the follow-up study higher than the projected 30%

A note on the process of making these outcome data publically available

Christian is currently proposing two sets of conference submissions and three full-length manuscript submissions. Because we will be collecting a lot of meaningful data, there is always the potential for many more conference and manuscript submissions.

*Conference submissions*

The threshold for getting conference submissions accepted is often quite reasonable (although it may vary depending on the conference and research area). For example, in the past several years, out of approximately 20 conference submissions proposed by my research team, only two were rejected, suggesting a 90% acceptance rate.

The time line for conference submissions is fixed in advance. For example, for a conference that takes place in August of 2017, the submission deadline might be in November of 2016. The researchers will be notified of decisions in March of 2017. If their submission is accepted, it gives them several months to complete the submission and make necessary travel arrangements.

*Peer reviewed manuscript submissions*

The threshold for getting manuscripts accepted is often quite formidable. For example, the top journals in a field might reject over 90% of manuscripts submitted for consideration at their journal. Moreover the time line is more variable. Manuscripts typically take three to six months to complete. Once completed and submitted to a journal, it can take another seven weeks to hear about a *first decision*. A positive outcome might result in the researchers being given an opportunity to undertake a revision, which typically takes two months to complete. If at that point, the journal’s decision is to accept the manuscript with minor revisions, the final revision often takes a couple of weeks to complete. Today, journals will typically make accepted papers available to their online readers before publication in their regular (paper) editions. It is possible that the revised manuscript will be rejected from further consideration. At that point, the researcher is free to submit the manuscript at a different journal and start the process all over again.

If an original submission is rejected initially (i.e., the journal does not offer an opportunity for researchers to revise the manuscript), it can be rejected prior to peer review or after the first round of peer review. If the submission is rejected prior to peer review, the authors might be notified more quickly (e.g., within 14 days). If the submission is rejected after the first round of peer review, it might take two months to receive the bad news. At that point, however, the researchers are free to submit to manuscript to a different journal and activate the process again.

Key Research-Related Dates

October 4, 2016

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| Activity | Date |
| Train Recovery Unplugged personnel to assist with baseline administration (requires training in Addiction Severity Index, research procedures, and general familiarity with other survey measures) | Nov 15, 2016 |
| Completion of pilot testing for all in-treatment data collection procedures | Nov 30, 2016 |
| Secure IRB approval | Dec 16, 2016 |
| Commence participant recruitment and consent into follow-up study | January 1, 2017 |
| Commence data collection for in-treatment study | January 1, 2017 |
| Complete in-treatment data on approximately 100 residents | May of 2017 |
| Presentation of in-treatment outcomes at a relevant professional conference | Summer or fall of 2017 |
| Completion of in-treatment data collection for calendar year 2017 resulting in data on approximately 330 residents | January of 2018 |
| Preparation of manuscript on in-treatment outcomes\* | January through June of 2018 |
| Initial submission of manuscript on in-treatment outcomes\* | July of 2018 |
| Completion of 3 month follow-up resulting in data on approximately 286 residents (or 87% of original baseline sample) | April of 2018 |
| Presentation of 3 month follow-up outcomes at a relevant professional conference | Summer or fall of 2018 |
| Completion of 6 month follow-up resulting in data on approximately 266 residents (or 81% of original baseline sample) | July of 2018 |
| Preparation of manuscript on 6 month follow-up\* | August of 2018 through  February of 2019 |
| Initial submission of manuscript on 6 month follow-up\* | March of 2019 |
| Completion of 12 month follow-up resulting in data on approximately 230 residents (or 70% of original baseline sample) | January of 2019 |
| Preparation of manuscript on 12 month follow-up\* | January through June of 2019 |
| Submission of manuscript on 12 month follow-up\* | July of 2019 |

\*Manuscript preparation and submission depend in large part on the pattern of results that are observed and if the pattern is roughly consistent with hypotheses. If the results picture is markedly different than anticipated, time line of manuscript submission could be delayed considerably.

Tasks Related to Fielding In-Treatment and Follow-Up Studies

October 4, 2016

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| Task | Person | Due Date |
| Christian to expand research team to 5 or 6 members | Christian & Recovery Unplugged | Oct of 2016 through Jan 31, 2017 |
| Finalize decision on participant payment | Recovery Unplugged | Oct 16, 2016 |
| Finalize decision on saliva testing | Recovery Unplugged | Oct 16, 2016 |
| Creation of Survey Monkey links for follow-up assessments | Olivia / Morgan | Oct 16, 2016 |
| Initial IRB submission | Christian | Oct 20, 2016 |
| Secure IRB approval | Christian | Dec 16, 2016 |
| Finalize procedures for clinician-assisted measure completion for measured tied to individual sessions. | Christian & Clinicians | Oct 31, 2016 |
| Pilot test Day 4 assessment | Olivia / Morgan or Recovery Unplugged | Oct 31, 2016 |
| Pilot test Day 14 assessment | Olivia / Morgan or Recovery Unplugged | Oct 31, 2016 |
| Pilot test Day 21 assessment | Olivia / Morgan or Recovery Unplugged | Nov 15, 2016 |
| Pilot test Typical Discharge assessment | Olivia / Morgan or Recovery Unplugged | Nov 15, 2016 |
| Pilot test ‘additional session-related’ measures | Olivia / Morgan or Recovery Unplugged | Nov 15, 2016 |
| Provide training to Recovery Unplugged personnel on baseline assessment procedures and measures (especially the Addiction Severity Index). | Olivia / Morgan | Nov 15, 2016 |
| Finalize procedures for carrying out all in-treatment data collection. | Recovery Unplugged & Christian | Dec 15, 2016 |
| Begin collecting in-treatment data on all new PHP admissions | Recovery Unplugged & Christian | Jan 1, 2017 |
| Begin consenting residents for follow-up study | Recovery Unplugged & Christian | Jan 1, 2017 |
| Pilot testing 30 day follow-up assessment | Christian’s team | Jan 31, 2017 |