

Agreement Between
THE UNIVERSITY OF MARYLAND, COLLEGE PARK
and
THE NATIONAL INSTITUTES OF HEALTH
To Rely on an NIH IRB

Pursuant to 45 C.F.R. 46.114, the National Institutes of Health (NIH) and the University of Maryland, College Park are entering into this agreement for NIH to conduct Institutional Review Board (IRB) review of the research protocol or activities identified below, which are jointly conducted by NIH and the University of Maryland, College Park.

Name of Institution Providing IRB Review (Institution A):
National Institutes of Health
Federal Wide Assurance (FWA) # 00005897, expiration date 8/28/2018

IRB Registration # 00008803

Name of Institution Relying on the Designated IRB (Institution B):

FWA # 00005856, expiration: 6/11/2017

Institution B will rely on the designated NIH IRB for review and continuing oversight of its human subjects research described below. This agreement is limited to the following specific protocol(s) or research activity:

Name of Research Project/Activity: Sleep Disturbance and Relapse in Individuals with Alcohol
Dependence: An Exploratory Mixed Methods Study
Protocol Number(s): 14-CC-0486
Name of Principal Investigator (NIH): Gwennyth R. Wallen, PhD
Name of Investigator(s) (Institution B): Alyssa Brooks
Name of NIH Principal Investigator's Institute or Center: NIH Clinical Center

The review performed by the NIH IRB will meet the human subject protection requirements of Institution B's OHRP-approved FWA. The protocol(s) reviewed by the NIH IRB must include a description of the research to be conducted by Institution B. The extent to which Institution B may rely upon the review by the NIH IRB is limited to the specific activities described in the reviewed protocol. The NIH IRB will follow written procedures for reporting its findings and actions to appropriate officials at Institution B. Relevant minutes of IRB meetings will be made available to Institution B upon request. Institution B remains responsible for ensuring compliance with the IRB's determinations and with the terms of its OHRP-approved FWA.

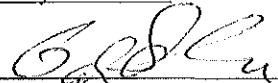
Both Institutions will maintain current copies of the IRB approved protocol. NIH will conduct its portion of this joint research in accord with the terms and conditions of its OHRP-approved FWA. Institution B will conduct its portion of this joint research in accord with the terms and conditions of its OHRP-approved FWA. This Agreement will be kept on file at both Institutions and will be available to OHRP upon request.

The NIH IRB retains responsibility for compliance with regulatory requirements under 45 C.F.R. Part 46 and 21 C.F.R. 56 (as applicable) related to the administration and operation of the IRB. These include, for example, following written procedures and maintaining records in accord with 45 C.F.R. parts 46.103 and 115, respectively. Institution B agrees that the NIH IRB may suspend or terminate approval of research that is not conducted in accordance with the NIH IRB's requirements or that is associated with unexpected serious harm to subjects pursuant to 45 C.F.R. 46.113. The NIH IRB will notify Institution B of any non-compliance, or suspensions, or terminations of this research in a timely manner.

Institution B will ensure that before implementing a change to an NIH IRB-approved protocol its investigator will obtain NIH IRB approval for the change (unless the change is designed to eliminate an apparent immediate hazard to subjects), pursuant to 45 C.F.R. 46.103. Institution B retains responsibility, pursuant to 45 C.F.R. Part 46, including subsections 103 and 113, to promptly report to the NIH IRB, appropriate institutional officials, and the HHS or NIH agency head any unanticipated risks to subjects or others, and any serious or continuing noncompliance with 45 C.F.R. Part 46 or the IRB's requirements or determinations. The NIH IRB may also make these reports, but doing so does not relieve Institution B of the obligation to report to institutional officials and HHS or NIH officials.

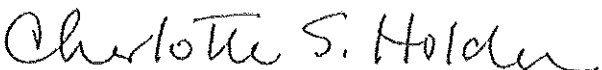
This Agreement is effective on the date that the last official signs and may be terminated by either party at any time. If the Agreement is terminated prior to the completion of the research, Institution B will need to obtain alternative IRB review.

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Date: June 9, 2014

Protocol Number: T-CC-0486

Protocol Title: Sleep Disturbance and Relapse in Individuals with Alcohol Dependence: An Exploratory Mixed Methods Study

Abbreviated Title: Sleep Disturbance and Relapse

Protocol Number: T-CC-0486

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Total requested accrual:

215 Patients

0 Healthy Volunteers

Project Uses Ionizing Radiation: ☒ No ☐ Yes (*attach RSC/RDRC documentation*)

IND/IDE ☒ No ☐ Yes (*attach FDA documentation*)

Durable Power of Attorney ☒ No ☐ Yes

PI Name: Wallen

Date: June 9, 2014

Protocol Number: T-CC-0486

Multi-institutional Project ☒ No ☐ Yes

Data and Safety Monitoring Board ☒ No ☐ Yes

Technology Transfer Agreement ☒ No ☐ Yes

Samples are being stored ☒ No ☐ Yes

Flesch-Kincaid reading level of consent form: 11.9

- A. **Précis:** Despite research establishing the relationship between sleep disturbances and alcohol use, there is no clear understanding or model for what occurs once individuals who seek inpatient alcoholism treatment are discharged from rehabilitation facilities and attempt to integrate back into their homes and communities. The purpose of this investigation will be to characterize sleep patterns, perceptions, and beliefs throughout the process of alcohol rehabilitation. The misuse of alcohol is a global public health concern that compromises both individual and societal wellbeing, resulting in an estimated 2.5 million deaths annually (WHO, 2013b). The National Institute on Alcohol Abuse and Alcoholism (NIAAA) distinguishes alcoholism by craving, loss of control, physical dependence, and tolerance (NIAAA, *Alcohol Use Disorders*). The relationship between alcohol use and sleep disturbances is complex and bidirectional, but sleep disturbances are common among alcoholics during phases of drinking, withdrawal, and abstinence (Gillin & Drummond, 2000; Brower, 2003; Teplin, Raz, Daiter, Varenbut, & Tyrrel, 2006). Outcome expectancies, behavioral capability, and self-efficacy beliefs are central constructs in the Social Cognitive Theory (Bandura, 1986) and will be measured directly in this study using both quantitative and qualitative methods. A mixed methods approach will be used to study the following aims: a) to assess individuals' perceptions of and experiences with sleep during alcohol rehabilitation, b) to describe sleep patterns, perceptions, and beliefs among alcohol-dependent individuals throughout the transition from a clinical research facility providing rehabilitation treatment back to the community, c) to assess whether sleep-related beliefs and/or behavior of individuals are predictive of sleep quality or relapse to drinking, and d) to assess whether sleep quality predicts relapse. Adult research participants admitted to the inpatient behavioral health unit and enrolled on to the NIAAA intramural study NCT 0010693: *Assessment and Treatment of People with Alcohol Drinking Problems* will be recruited for participation in this study (n=215). Sleep quality and duration will be quantitatively assessed approximately one week prior to discharge from the inpatient facility and again 4-6 weeks post-discharge. In addition to quantitative measures, qualitative semi-structured interviews will be conducted with a subset of 25 participants (to reach 25 completed cases) within a week of the scheduled discharge date and again four to six weeks post-discharge to assess perceptions of sleep during recovery. The proposed study will fill a gap in the literature by characterizing sleep throughout the rehabilitation process and ongoing maintenance of abstinence.

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Background: Alcohol dependency is often accompanied by various psychiatric and behavioral problems, including significant sleep disturbances (WHO, 2013a; WHO, 2013b; Benca, 1996). The relationship between alcohol use and sleep disturbances is complex and bidirectional, but the two often occur simultaneously (Gillin & Drummond, 2000; Brower, 2003; Teplin, Raz, Daiter, Varenbut, & Tyrrel, 2006). Alcohol can negatively affect many aspects of sleep including the proportion of rapid eye movement (REM) sleep, nightmare frequency, and snoring (Landolt & Gillin, 2001). Insomnia can persist for weeks or months following abstinence, suggesting that issues with sleep may originate prior to the development of alcoholism (Brower, 2003). Ford & Kamerow (1989) demonstrated that individuals who met criteria for alcohol abuse and dependence were more likely to report *ever* experiencing a period of two or more weeks of insomnia when compared to non-alcohol dependent individuals. Additionally, Weissman and colleagues (1997) demonstrated that those with insomnia in the past year (and no other psychiatric condition) were more than twice as likely to *develop* alcohol abuse problems over the subsequent year compared to those without either condition. Some evidence suggests that sleep problems as early as childhood may increase the risk for early-onset alcohol use (Wong, Brower, Fitzgerald, & Zucker, 2004).

Regardless of which precedes the other, sleep disturbances are common among those who are alcohol-dependent during phases of drinking, withdrawal, and abstinence (Gillin & Drummond, 2000) and abnormal sleep may persist for months or years during the process of recovery and abstinence (Landolt & Gillin, 2001). Sleep disturbances are particularly common among alcoholics in the early stages of recovery and are far more common among alcoholics with co-morbid depression (Gillin, Smith, Irwin, Kripke, & Schuckit, 1990). Up to 91% of alcohol-dependent individuals continue to suffer with sleep disturbances after one week of abstinence (Cohn, Foster, & Peters, 2003), which can sometimes persist for five weeks or more (Alling, Balldin, Bokström, Gottfrieds, Karlsson, & Långström, 1982). Compared to heavy drinking, both abstinence and moderate drinking can reduce insomnia symptoms among recovering alcoholics (Brower, Krentzman, & Robinson, 2011).

Sleep disturbances during various stages of alcohol recovery are often associated with relapse to drinking (Landolt & Gillin, 2001; Brower, 2001; Brower, Aldrich, Robinson, Zucker, & Greden, 2001). Among alcoholics who seek treatment, *baseline* sleep problems upon entering treatment have demonstrably predicted subsequent relapse to drinking (Brower, 2001; Brower, Aldrich, Robinson, Zucker, & Greden, 2001). Smith and colleagues (2013) demonstrated that longer sleep onset latency during inpatient rehabilitation predicted relapse one month after discharge from the treatment facility. Those who report insomnia within six months prior to achieving abstinence are more likely to relapse after five months of abstinence (Brower, 2003). Aside from the fact that sleep disturbances among alcoholics can predict relapse, sleep insufficiency even in the general population is associated with a variety of adverse health behaviors and lower health-related quality of life (Strine & Chapman, 2005).

Among alcohol-dependent individuals, re-initiation of drinking following achieving abstinence may be an attempt to self-medicate sleep problems (Vitiello, 1997). Mahfoud and colleagues reported that nearly half of a sample of individuals with active substance abuse used substances to self-medicate for sleep problems (Mahfoud, Talih, Stroom, & Budur, 2009). Those with sleep disturbances may choose to drink alcohol specifically because of its depressive effects (Fetting, 2012). Heavy alcohol consumption can induce fatigue and speed up the process of falling asleep (Vitiello, 1997), which may be particularly tempting for those who are struggling with difficulty sleeping and already accustomed to drinking heavily.

In theories of addiction, enabling factors that give people skills, resilience, and environmental control are important to both understand and elucidate as methods for overcoming dependence (Bandura, 1997). The Social Cognitive Theory (SCT), which posits that personal factors, the environment, and human behavior exert influence upon each other through *reciprocal determinism* (Bandura, 1986), will be used as the underlying theory for this study. In addition to individual behaviors and personal factors, a supportive environment can increase the likelihood of sustained behavior change. An individual's sleeping environment (and other environmental factors including facilitators and barriers to recovery), sleep-related cognitions, thoughts, and perceptions, and sleep-related behaviors should be carefully considered in maximizing the success of recovery efforts. Unhealthy sleep-related cognitions are established contributors to poor sleep (Harvey, 2002; Yang, Spielman, & Golvinsky, 2006). Cognitive arousal and inaccurate beliefs about sleep can lead to maladaptive sleep behaviors (Yang, Spielman, & Golvinsky, 2006). Behaviors such as late-night physical activity, daytime napping, and sleeping in on weekends can be harmful to overall sleep quality (Yang, Spielman, & Golvinsky, 2006). This behavior can be influenced by an individual's home sleeping *environment*: bedtime, lighting, temperature, pressure to attend to other obligations, bed-partner snoring, noise, pets in the bedroom and other factors. Lastly, regardless of what motivates an individual to drink (such as environmental triggers, the influence of another person, boredom, difficulty falling asleep, or stress), self-efficacy can determine whether the response is drinking or another, healthier adaptation (Bandura, 1999). Refer to Appendix H for the conceptual model driving the measures and analyses for this study.

Constructs from the SCT will be assessed in this study using both quantitative and qualitative methods. Qualitative interviews on a subset of participants will help to characterize individuals' environment for recovery and aid in understanding individualized facilitators and barriers to sleep and expectations about transitioning back into the community. Quantitative measures will assess self-efficacy, beliefs, and behaviors related to sleep throughout recovery as well as general sleep quality. These measures will be triangulated with qualitative data exploring parallel themes.

Preliminary data were collected from patients at the NIH Clinical Center between September 2011 and March of 2013 (n=164) and patients' sleep patterns during the inpatient phase of the study were characterized. The average length of inpatient stay was 31.6 days. The average age of patients was 45.6 years and the sample was mostly male (70.1%) and non-Hispanic (95.7%), and approximately half of the sample was Black/African American (47.6%). Nearly half (48.1%) of the sample had one or more anxiety disorders, 54.2% had one or more mood disorders, and 24.4% of the sample had experienced PTSD in their lifetime. Average sleep duration was 5.37

hours and sleep onset latency was 47.5 minutes at baseline (during the first week of inpatient treatment). Over 90% of patients reported sleep disturbances at baseline (day 2 of inpatient treatment), which decreased to 50.5% at day 28 for those who were in treatment 28 days or more. Of those who had valid data at both time points, sleep onset latency significantly decreased and sleep duration significantly increased from day 2 to day 28 (Wallen, Brooks, Whiting, et al., In Press). Despite slightly improved sleep during treatment, on average, individuals were still experiencing significant sleep disturbances at day 28 which makes the need for outpatient data collection a priority for researchers and clinicians alike.

Arnedt and colleagues (2007) recently called for more controlled studies characterizing the phenomenology of sleep during recovery. Very little is known regarding the quality of individuals' sleep upon returning to their home environment after inpatient alcoholism treatment. Addressing individuals' concerns surrounding sleep, particularly post-discharge, could be a step in the right direction toward tailored, holistic, and patient-centered care for alcohol-dependent individuals. Understanding alcoholics' experience with sleep throughout recovery, as well as their unique needs, will provide preliminary data for informing the structure, timing, and delivery of a future behavioral sleep intervention.

Study Objectives: This study has four objectives:

- 1) To assess individuals' perceptions of and experiences with sleep during alcohol rehabilitation.
- 2) To describe sleep patterns, perceptions, and beliefs among alcohol-dependent patients during the transition from an inpatient rehabilitation facility to the community.
- 3) To assess whether sleep-related beliefs, and/or behavior of individuals predict sleep quality or relapse.
- 4) To assess whether sleep quality predicts relapse.

The mixed-methods component for the first 25 completed cases will drive further hypotheses and analyses, but the following preliminary hypotheses will be examined with the full sample of 215 participants:

Hypothesis 1: Higher self-efficacy for sleep is associated with better sleep quality and lower relapse rates.

Hypothesis 2: Fewer dysfunctional beliefs about sleep are associated with better sleep quality and lower relapse rates.

Hypothesis 3: Higher endorsement of sleep-related safety behaviors is associated with poorer sleep quality and higher relapse rates.

Hypothesis 4: Better sleep quality is associated with lower relapse rates.

Study design and methods: All participants enrolled in this study will first be admitted under the screening and assessment protocol on the 1SE clinic (currently 05-AA-0121), which includes adults over 18 years of age seeking treatment for alcohol dependency. Upon being admitted to the treatment protocol, participants are evaluated and recruited for more focused research efforts (including the study described herein). All participants receive continued physical evaluations, inpatient treatment of alcohol withdrawal, psychosocial management, and an educational treatment program. Patients may receive up to six or more weeks of inpatient

treatment followed by 16 weeks of optional outpatient treatment for alcoholism, including weekly Alcoholics Anonymous (AA) meetings. Individuals will be eligible to participate in this portion of the study whether or not they elect to receive outpatient treatment through the NIAAA following discharge, but will be asked to come back to the Clinical Center 4-6 weeks post-discharge for a follow-up visit to complete a face-to-face semi-structured interview and surveys. If participants are unable to return for the follow-up visit, we will attempt to conduct the surveys and interview via phone.

Quantitative Sleep-Related Measures

Pittsburgh Sleep Quality Index (PSQI). The Pittsburgh Sleep Quality Index (PSQI) is a 19-item, self-rated questionnaire used to measure sleep quality and disturbances over a one-month (30 days) time interval. Nineteen individual items generate seven “component” scores: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medication, and daytime dysfunction. A global summation score of five or higher is indicative of poor sleep quality (Buysse, Reynolds, Monk, Berman, & Kupfer, 1989). The PSQI has been validated in populations with insomnia and other sleep disorders, with psychiatric patients, and in normal populations (Backhaus, Junghanns, Broocks, Riemann, & Hohagen, 2002; Doi, Minowa, Uchiyama, Okawa, Kim, Shibui, & Kamei, 2000). There exists some early evidence of validity in alcohol-dependent populations (Brooks, Krumlauf, Whiting, Clark, & Wallen, 2012; Wallen, Brooks, Whiting, et al., In Press). The PSQI has internal consistency and a reliability coefficient ranging from 0.80 to 0.83 for its seven components (Buysee, Reynolds, Monk, Berman, & Kupfer, 1989; Carpenter & Andrykowski, 1998). It takes approximately five minutes to complete.

Epworth Sleepiness Scale (ESS). The Epworth Sleepiness Scale (ESS) is an eight-item self-administered questionnaire that provides a measure of an individual’s general level of excessive daytime sleepiness over a one week time period (Johns, 1991). Individuals are asked to rate their usual chances of dozing off or falling asleep on a four-point scale in eight distinct situations or activities that most people engage in during their daily lives. Higher scores are indicative of higher levels of daytime sleepiness. An alpha coefficient between 0.70 to 0.88 has been documented and numerous studies support high validity and reliability (Spira, Beaudreau, Stone, et al., 2012; Johns, 1992). A score higher than ten is indicative of *excessive* daytime sleepiness (Johns, 1993). Completing the ESS generally takes two to three minutes.

Dysfunctional Beliefs and Attitudes about Sleep (brief version; DBAS-16). The DBAS-16 is a 16-item questionnaire that assesses sleep-related cognitions including faulty beliefs and appraisals, unrealistic expectations, and perceptual and attention bias. The DBAS-16 has adequate internal consistency (Cronbach alpha = 0.77 for clinical and 0.79 for research samples) and temporal stability ($r = 0.83$). Factor structure is similar to the original 30-item version of the questionnaire and includes perceived consequences of insomnia, worry/helplessness about insomnia, sleep expectations, and medication. Domains include expectations about sleep requirements and issues with being worried or feeling helpless about insomnia (Morin, Vallieres, & Ivers, 2007). The scoring of the DBAS-16 is the average score of all items.

Self-Efficacy for Sleep Scale (SE-S). The SE-S includes nine items used to measure the level of confidence a person has in performing behaviors that might be helpful in initiating sleep. Each item is scored on a five-point Likert scale from 1 representing “not confident” to 5 representing “very confident.” The total score ranges from nine to 45, with higher scores indicative of greater confidence. Concurrent validity of the scale was established by comparison with PSQI, sleep diaries, and objective measures of sleep (Edinger, Wohlgemuth, Radtke, Coffman, & Carney, 2007). The scale has excellent internal reliability (Cronbach's alpha of 0.71-0.86; Edinger, Wohlgemuth, Radtke, Coffman, & Carney, 2007; Rutledge, La Guardia, & Bluestein, 2013). Test-retest reliability has also been established (Fichten, Libman, Creti, Amsel, Sabourin, Brender, & Bailes, 2001).

Sleep-Related Behaviours Questionnaire (SRBQ). The SRBQ assesses the use of safety behaviors that individuals may use to promote sleep and cope with tiredness. It is a 32-item scale with a possible score range of 0 to 128. Each item is scored on a five-point Likert scale ranging from 0 (almost never) to 4 (almost always). The scale has discriminated between normal sleepers and those with insomnia in previous research and correlates with the PSQI ($r = 0.78$, $p < .01$). Each item on the questionnaire also positively correlates with the Insomnia Severity Index (ISI), indicating that implementation of the techniques in the scale are associated with insomnia severity (Ree & Harvey, 2004).

Quantitative Alcohol-Related Measures

Addiction Severity Index (ASI). The ASI is an instrument used extensively in the Addiction Medicine field to comprehensively identify problems in multiple dimensions including medical, employment, drug and alcohol use, legal, family, social and psychiatric (McLellan, Luborsky, Woody, & O'Brien, 1980). It is a 200-item interview that takes approximately 60 minutes to complete. Average concordance for severity of treatment problems has been estimated at 0.89 and concurrent and discriminant validity has been demonstrated (McLellan, Luborsky, Cacciola, Griffith, Evans, Barr, & O'Brien, 1985). To gauge an individual's environment, we will specifically be examining the family and social sub-component of the scale, which ranges from zero to eight and indicates severity of problems in that domain. Scoring of the family/social section includes detailed assessments of living arrangements, marital status, number of close relationships, problems getting along with friends and family, and abusive relationships.

Penn Alcohol Craving Scale (PACS). The PACS is a clinical tool for practitioners to measure alcohol cravings. It is a five-item self-administered instrument that measures frequency, intensity, and duration of thoughts about drinking along with ability to resist drinking. The final item asks the responder to provide an average rating of his or her craving over the course of the past week. The PACS has excellent internal consistency (Cronbach's alpha = 0.92). Construct, predictive, and discriminant validity has been established. This assessment takes between two and five minutes to complete (Flannery, Volpicelli, & Pettinati, 1999).

Subjective measure of alcohol relapse: Timeline Follow-Back (TLFB). The TLFB collects drinking information using personal historical events recounted over a fixed time period (Sobell & Sobell, 1992). It is a standard assessment for measuring alcohol drinking patterns and quantification in treatment programs. The number of items corresponds to the number of days of interest,

typically 90, which usually takes about 30 minutes to complete. The TLFB has demonstrated high test-retest reliability across multiple populations of drinkers. Content, criterion, and construct validity have been demonstrated in both clinical and general population samples (Sobell & Sobell, 2000). It is extensively used in research and practice (Mason, Quello, Goodell, Shadan, Kyle, & Begovic, 2014; Connors & Maisto, 2003; Del Boca & Darkers, 2003). Relapse will be examined first as *any* level of self-reported drinking and also as a categorical quantification of *level* of drinking based on the distribution of the data.

Quantitative Mental Health/Diagnostic Measures

Childhood Trauma Questionnaire (CTQ). The CTQ questionnaire assesses adverse experiences, including stressful experiences like physical and emotional abuse, neglect or other trauma, experienced in childhood. It is a 28-item questionnaire that takes five to ten minutes to complete. Factor analysis supports the use of the CTQ as a screening instrument for maltreatment in clinical groups. The scale demonstrates good evidence of criterion-related validity (Bernstein, Stein, Newcomb, et al., 2003).

Comprehensive Psychopathological Rating Scale (CPRS). The CPRS-S-A consists of 19 self-assessed variables that correspond to CPRS-based subscales for affective and anxiety syndromes (Åsberg, Montgomery, Perris, Schalling, & Sedvall, 1978). These subscales are the Montgomery Åsberg Depression Rating Scale (MADRS; Montgomery & Åsberg, 1979) and the Brief Scale for Anxiety (BSA; Tyrer, Owen, & Cicchetti, 1984). This self-report measure takes 5-10 minutes to complete.

With the exception of the semi-structured interviews and the SE-S, DBAS-16, and SRBQ, all proposed measures are either a) currently being collected as part of the existing screening protocol (05-AA-0121) or b) have been pilot-tested in the population as part of a recent study amendment which examined the prevalence of sleep disturbances among inpatients on the unit between 2011 and 2013. As previously mentioned, the purpose of the sleep assessments including the PSQI and ESS is not to clinically diagnose someone with insomnia but to establish subjective sleep quality and determine the extent to which sleep disturbances exist.

Objective measures of alcohol relapse. Currently, there is no clear standard set of blood and body fluid tests that clearly indicate relapse to alcohol use. However, guidelines are emerging (Litten & Fertig, 2003) and include a hepatic blood panel which tests for liver damage, Gammaglutamyl-transpeptidase (GGT) which detects alcohol-induced liver disease and is indicative of heavy drinking, and carbohydrate-deficient transferrin (CDT) which is a biomarker for heavy alcohol consumption. While biomarkers are generally less sensitive than well-standardized and properly administered self-report measures, they provide a unique source of information on drinking status and are often used as corroborators to self-reported measures (Allen & Litten, 2003). As part of the screening protocol (currently 05-AA-0121), participants are asked to provide blood samples at their follow-up visits. We propose including these biomarkers as a secondary measure of alcohol relapse in our analyses only if participants are returning as part of the screening protocol for an outpatient visit between four and six weeks following discharge and already providing a blood sample. For those subjects who do not have blood drawn as part of the screening protocol we will not obtain blood samples. Thus, participation in

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this sleep and alcohol relapse study does not include any blood draws. When participants return for the outpatient follow-up visit approximately four to six weeks after discharge, they will also be asked to provide a breath sample to assess *current* drinking via Breath Alcohol Content (BAC). These biomarkers will be analyzed as secondary outcome measures for the purposes of corroborating self-reported drinking.

Qualitative Measures

Sleep and sleep hygiene behaviors are unique and individualized aspects of health. Currently, we do not have a clear understanding of sleep trajectories for recovering alcoholics and how sleep *behaviors* may affect relapse, but it is well established that insomnia and other sleep disturbances can increase risk of relapse among alcoholics (Brower, 2011; Roth, 2009; Drummond, Gillian, Smith, & DeModena, 1998). The qualitative component of this study will allow us to explore this pattern in-depth and inform a future sleep intervention through individual semi-structured interviews. Interview prompts are attached to this protocol in Appendix G. The interviews will be conducted within one week prior to participants' scheduled discharge date and again four to six weeks post-discharge when they return for a follow-up visit (or via phone). Questions will be focused on sleep patterns prior to becoming an inpatient, during the inpatient stay, and in anticipation of becoming an outpatient. A secondary goal of the qualitative phase will be to inform the development of a sleep hygiene intervention. Interviews will be audio recorded (with the interviewee's consent) and will last between 20-60 minutes depending on the participant's responses.

Study timeline overview. Specific measures already collected as part of the screening and assessment protocol during the inpatient phase will be used to characterize patients who participate in this study (denoted in Table 1*). Certain measures already collected as part of the screening and assessment protocol during the inpatient phase will be used to characterize patients who participate in this study. Approximately one week prior to patients' scheduled discharge, a study team member will approach patients to begin the first segment of data collection for the study. Participants will be asked to complete subjective measures regarding daytime sleepiness, self-efficacy for sleep, and sleep-related beliefs and behaviors at this time in addition to a semi-structured interview. Four to six weeks following discharge, participants will return to the Clinical Center to complete sleep measures similar to those administered when they were inpatients as well as another semi-structured interview in the outpatient clinic. If participants are unable to return for the follow-up visit, we will attempt to conduct the surveys and interview via phone.

Table 1: Study timeline

		Inpatient			Outpatient (follow-up)
		Baseline (Day 2)	Other	Within 7 days of discharge	(4-6 weeks following discharge)
Sleep ep	PSQI	x*		x (day 28)*	x
	ESS			x	x

	DBAS-16			x	x
	SE-S			x	x
	SRBQ			x	x
	DSM-V Sleep disorder checklist			x	
Alcohol measures	ASI		Day 8*		
	PACS		Day 19*		x
	Objective measures				x**
	TLFB		Day 13*		x
	CTQ	x*			
	CPRS		Day 16*		
	Demographics (gender, age, race, ethnicity)	x*			
	Semi-structured interview			x	x

*The second PSQI will be administered on day 28, unless the patient is discharged prior to day 28 in which case the PSQI will be administered the day prior to discharge. To be eligible for participation in this component of the study, patients must be inpatients for a minimum of 21 days. If a patient stays longer than five weeks, the PSQI will be repeated closer to discharge (instead of on day 28).

**A breath sample will be the only objective measure in this study. A blood draw will not be required as a part of this study. If participants return as part of the screening protocol (currently 05-AA-0121), we will use the data from that blood draw as a secondary outcome measure (specifically CDT, GGT, and the hepatic panel as outlined on page 10).

C. Inclusion and Exclusion Criteria:

Participants will be eligible for this study if they are:

- 18 years of age or older,
- enrolled on the screening, assessment and treatment protocol (currently 05-AA-0121),
- have been an inpatient for 21 days or more preceding discharge,
- not enrolled onto a pharmacologic intervention study,
- able to understand the study, and
- willing to return to the Clinical Center 4-6 weeks after being discharged from inpatient treatment for a follow-up visit.

Participants will be ineligible for this study if they are:

- Less than 18 years of age,
- unable to understand the purpose of the study,
- unable to provide informed consent,
- unable to follow the study design, or
- unable or unwilling to return to the Clinical Center 4-6 weeks after being discharged from inpatient treatment for a follow-up visit.

Statistical Analysis: Each audio-recorded interview will be transcribed. An internal reliability check will be performed on each transcript by having a member of the research team listen to

the audio files to ensure they were transcribed verbatim. A codebook will be developed based on themes from the interviews. Each code will be accompanied by an operational definition that will allow for clarity and consistency in the coding process. For example, some codes may include dysfunctional beliefs about sleep, information on sleeping environment, and/or sleep-related behaviors and cognitions. Evidence of each code or theme will be assessed using quotes from the interviews. A team of coders will independently review all transcripts.

After data is transcribed and cross-checked with a second coder, NVivo (version 9.0) will be utilized for further qualitative analysis. Using NVivo 9.0, inter-rater reliability percentages will be calculated. Kappa coefficients, which take into account any agreement occurring by chance and are therefore a more conservative measure of agreement, will be calculated as an indicator of inter-rater reliability. Discordant coding will be discussed until consensus among the coding team is achieved.

Once the iterative process of consensus building is complete, a representative from the clinical team and an NIH intramural qualitative expert will validate the themes and coding. Qualitative data will be analyzed as it is made available. Once 25 participants have completed *both* semi-structured interviews (baseline and follow-up), no further interviews will be conducted.

Statistical analyses of quantitative results will be conducted with the Statistical Package for Social Sciences (SPSS) software. All quantitative data will be double-data entered, cross-checked, and reconciled where necessary. The first step in quantitative data analysis will be running baseline "diagnostics" to check for outliers and normal distribution of all continuous variables. If the assumptions of normality are not violated, we will proceed with parametric testing. If the assumptions of normality are violated, non-parametric tests will be utilized. For quantitative analyses, statistical significance will be considered at $p < 0.05$.

Descriptive data will include frequencies for categorical variables and range, mean, and standard deviation for continuous variables. The ASI, PACS, CTQ, CPRS, and basic demographics including age, gender, race, and ethnicity will be used to characterize the sample. Patterns of missing data will be examined thoroughly to assess whether any questions were systematically skipped by all participants or any sub-group of participants. If more than 5% of the quantitative data is missing at random, multiple imputation will be employed to retain as many samples as possible for subsequent data analysis.

Initial analyses will be descriptive and exploratory in nature to assess the prevalence of sleep disturbances pre- and post-discharge. Relationships between variables will be examined with bivariate correlation coefficients (for two continuous variables), Chi-squares (for two categorical variables), and basic t-tests (for one categorical and one continuous variable). PSQI (baseline, exit, and post-discharge) and ESS data will be presented from each time point.

Sleep quality (PSQI) will be measured at all three time points. Poor sleep quality at any time point is the main outcome of interest. Relationship between PSQI and demographic, sleep related beliefs/behavior, and relapse will be checked by appropriate parametric or non-parametric tests such as Pearson correlation, t test, ANOVA, Spearman rho correlation, Mann-

Whitney U test, or Kruskal Wallis tests. Significant variables from bivariate tests will be entered in a multiple linear regression to test whether sleep related belief and behavior predict sleep quality. Although not the main purpose of the study, linear mixed modeling will be used to test whether there is change over time in sleep quality.

Relapse at 4-6 weeks after discharge will be calculated and all variables which have significant relationships ($p > 0.20$) with relapse determined through bivariate tests will be included in the multiple logistic regression model to test whether sleep quality or sleep related beliefs/behavior predict relapse.

Power analysis for quantitative analyses: The total proposed sample size for this study is 215 participants. This number takes into account a 30% attrition rate for a sample of 150 needed for the anticipated power level. For the qualitative analyses, the recommendation for the sample size ($n=25$ completed cases) is based on the concept of saturation, which describes the number at which no new themes are being generated. The qualitative phase is not meant to infer, generalize, or generate statements about the population as a whole. It is expected that 36 patients will be screened to achieve 25 completers.

The total sample size ($n=215$) for phase II of this study will test the hypotheses associated with the analysis plan. With relapse as the outcome, assuming a reference relapse rate of 80% and considering a 30% attrition rate from a sample size of 150, alpha level of 0.05 and power level of 0.8 will allow us to test an odds ratio of 2.05 or larger in a logistic regression model. With sleep as the outcome, considering a 30% attrition rate, with six potential predictors, an alpha level of 0.05, and power level of 0.8, we will be able to detect an effect size of 0.14 or larger with 150 completed cases.

Merging data: As described by Creswell and colleagues (2011), merging data, or presenting results simultaneously is the approach that will be taken to present findings. More specifically, qualitative responses which reflect sleep quality, perceptions, experiences, and beliefs will be triangulated with quantitative measures of sleep quality (the PSQI and ESS) over time. For example, one way to combine methods is to report first the quantitative statistical results and then show qualitative quotes or themes which may support, refute, or help to explain the quantitative results. This allows merging quantitative and qualitative results together after analysis and during interpretation (Bishop & Holmes, 2013). In this study, for example: if self-efficacy for sleep is indeed associated with better sleep quality, qualitative responses could help to elucidate why or how individuals have self-efficacy: what strategies for sleep are they employing? "By combining and increasing the number of research strategies used within a particular project, we are able to broaden the dimensions and hence the scope of our project. By using more than one method within a research program, we are able to obtain a more complete picture of human behavior and experience" (Morse, 2003, p. 189). Collecting both types of data concurrently and comparing emerging themes from qualitative data with quantitative analyses will allow a more thorough understanding of the relationships between SCT constructs, sleep quality, and relapse. These findings can be used to guide future individualized behavioral sleep interventions in the population.

Human Subjects Protection Plan**The responsibilities of investigators/names of investigators who will obtain informed consent.**

Gwenyth R. Wallen, PhD has extensive experience with monitoring sleep evaluations and will serve as a senior nursing research mentor for the NIAAA inpatient unit nursing staff. She is currently the Chief of Nursing and Translational Science (NIH Clinical Center) and has been a member of the NICHD Institutional Review Board since 2001. Dr. Wallen will obtain consent.

Alyssa T. Brooks, BS is a pre-doctoral fellow in the CC Nursing Department and a doctoral candidate at the University of Maryland School of Public Health. She has been with the NIH Clinical Center for the past four years, supporting several intramural protocols from a research portfolio of health behavior and chronic care management in diverse and vulnerable populations. She has experience working with research participants in university and clinical settings, including protocol implementation and data management. Ms. Brooks will obtain consent, conduct interviews, collect data, and conduct data analysis.

Vijay A. Ramchandani, PhD is the Chief of the Section on Human Psychopharmacology in the Laboratory of Clinical and Translational Studies (LCTS). He is a clinical pharmacologist with several years of experience conducting alcohol administration studies. Dr. Ramchandani will not obtain consent.

CDR Michael Krumlauf, RN, BSN has worked with the Clinical Center Nursing Department as an Associate Investigator and Nurse Consultant for over five years. He obtained his BSN from the University of New Hampshire in 1998 and has worked at the NIH since 1999 with experience working with research participants and conducting research in many capacities including: performing direct patient care, protocol implementation and data management, research participant education, obtaining consent, clinical research nursing, and protocol screening and management of care. He has been an associate investigator on multiple Clinical Center and intramural NCI protocols. CDR Krumlauf will obtain consent.

Barbara A. Whiting, RN, MSN received her MSN in 1972 from Boston University. She has worked in nursing for 40 years with experience as a university faculty member, assistant director of nursing, clinician in acute care and after care settings. She has worked at the NIH for the past 21 years as a Clinical Research Nurse and Clinical Educator and is a resource person for the nursing staff on the NIAAA inpatient unit. She will not be obtaining consent.

Rosa Clark, RN is the nurse manager for the 1SE Patient Care Unit and the 1H Alcohol clinic. She currently serves on the Addictions IRB. Ms. Clark has served as a resource for the nursing staff on the NIAAA inpatient and outpatient units. She will not obtain consent.

Li Yang, MS is a biostatistician at the National Institutes of Health, Clinical Center. She has served as the lead statistician on multiple protocols at the NIH, advising study hypotheses, research design, statistical methods selection, and results interpretation. She received an MS in Epidemiology and Biostatistics from George Mason University in 2008 and is proficient in

multiple statistical analytic software packages. She will not obtain consent.

Melanie Schwandt, PhD is a Staff Scientist in the Laboratory of Clinical and Translational Studies. She will assist the PI with data management and analysis. She has more than 10 years of experience constructing, managing, and analyzing large datasets that combine behavioral and physiological outcomes, and over five years experience in pre-clinical research involving alcohol-related phenotypes. She will not obtain consent for the study.

David T. George, MD is the Associate Clinical Director for NIAAA and is Chief of the Section on Clinical Assessment and Treatment Evaluation, Laboratory of Clinical and Translational Studies, NIAAA. He is a board certified psychiatrist and internist with over 20 years of experience treating participants with alcoholism. He has conducted numerous clinical research studies. Dr. George will not obtain consent.

Nancy Diazgranados, MD received her Doctoral Degree in Medicine and Surgery from the Pontificia Universidad in Bogoto Colombia in 2001. She completed her Psychiatry residency at Albert Einstein Medical Center and a Master in Science Degree in Pharmacology at Thomas Jefferson University in 2007. In 2008 she became a Diplomate of the American Board of Psychiatry and Neurology. She continued her training as a Post-Doctoral Clinical Research Fellow at the Intramural Program at the National Institute of Mental Health. There, she worked at the Experimental Therapeutics and Pathophysiology Branch in the Mood and Anxiety Disorders Program. In 2010 she joined the University of Texas Health Science Center at San Antonio as a tenure track assistant professor within the Division of Mood and Anxiety Disorders. In 2012 she joined a private practice and relocated to Maryland. In September 2013 she joined the National Institute on Alcohol Abuse and Alcoholism as a Staff Clinician. Dr. Diaz Granados will not obtain consent.

Lorenzo Leggio, MD, PhD, MSc is the Chief of the Section on Clinical Psychoneuroendocrinology and Neuropsychopharmacology. Dr. Leggio's clinical research has been primarily focused on the treatment of alcoholism, with a special emphasis on the role of feeding-related as well as GABAergic pathways; and on the medical consequences of alcoholism, with a special emphasis on alcoholic liver diseases. In June 2012, Dr. Leggio joined the NIAAA and NIDA Intramural Research Programs, where he is a Tenure-Track Clinical Investigator and Section Chief. Additionally, he is also an Adjunct Associate Professor at the Center for Alcohol and Addiction Studies, Department of Behavioral and Social Sciences, Brown University (Providence, RI). Dr. Leggio will not obtain consent.

The Principal Investigator or a designated Associate Investigator (Alyssa Todaro Brooks or Michael Krumlauf) will obtain written informed consent. All investigators who obtain informed consent have completed NIMH consent training. Participants will receive an oral explanation of the purpose and potential risks of participation in this protocol and an opportunity to ask questions prior to signing the consent document. A copy of the signed consent form will be offered to participants. The consent form contains all required elements.

Rationale for subject selection: This study will be open to both males and females of all racial and ethnic groups, without targeting any specific group. We anticipate the target enrollment of participants to reflect the racial/ethnic distribution of residents in the greater Washington DC area.

Recruitment plan: Following IRB approval, all eligible participants admitted to the Clinical Center alcohol rehabilitation unit (1SE) will be approached for participation in this study. The PI or a designee will explain the study objectives, time commitment, expectations, and processes for assessments.

Rationale for involvement of vulnerable populations: Not applicable.

Justification for exclusion of vulnerable populations: Vulnerable populations (including individuals who are pregnant, HIV-positive, cognitively impaired, children, prisoners, and mentally ill) will not be enrolled in this study as they are ineligible for admission under the screening and assessment protocol (currently 05-AA-0121).

Evaluation of Risks/Discomforts and Benefits ratio: This study falls under the minimal risk category. This study will provide information on the quality of individuals' sleep upon returning to their home environment after inpatient alcoholism treatment. Understanding alcoholics' experience with sleep throughout recovery, as well as their unique needs, will provide preliminary data for informing the structure, timing, and delivery of a future behavioral sleep intervention.

- a. **Benefits:** There are no direct benefits to individuals who participate in this research study. We hope to learn more about alcoholism, sleep disturbances, and the recovery process through this study.
- b. **Risks:** There are no known risks to completing the survey assessments or interviews.
- c. **Alternative treatments and procedures:** The alternative to participating in this study is not to participate.
- d. **Procedures for protecting/minimizing risk:** Confidentiality and information technology standards are in place at the intramural programs of the NIH campus to protect electronic repositories of patient data. It is reasonably expected that these safeguards will protect participants' medical and personal health information, ensuring their privacy.

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- e. **Provisions for ensuring that necessary medical or professional intervention is available in the case of adverse events to the subjects:** The MAI will be made aware of any adverse events to subjects directly related to this protocol.

M. Protection of Participants' Privacy and Confidentiality: Participants will complete surveys and interviews behind closed doors for privacy. Data will be de-identified where possible through the use of non-identifiable codes. Any personally-identifiable information that participants mention during the interview (specifically their names) will be removed from transcripts and excluded from all data sets and any publications. The key to the code will be kept securely and separate from data and samples. Subject information will be maintained in secured databases and computers in locked files and a locked office. Paper records will be maintained in locked files and a locked office. Access to samples and data will be limited to authorized study personnel.

N. Study Agents/Interventions: Not applicable.

O. Reporting Procedures: It is not anticipated that patients participating in this study will experience side effects, toxicities and adverse events associated with completion of study procedures. Adverse events reported under this protocol will be limited to those events which are possibly, probably or definitely related to the research described in this protocol. The clinical care team overseeing the primary screening protocol will report any adverse events that are related to the screening protocol.

An adverse event is defined as any untoward medical occurrences that 1) result in death, 2) are life-threatening, 3) require hospitalization, 4) cause persistent or significant disability / incapacity, 5) result in congenital anomalies or birth defects, 6) are other conditions which in the judgment of the investigators represent significant hazards. All events will be reported to the IRB in accordance with NIH Human Research Protection Program Standard Operating Procedure #16 (Reporting Requirements for Unanticipated Problems, Adverse Events and Protocol Deviations). The principal investigator will provide continuous, close monitoring of data and side effects, toxicities and adverse events to identify trends. The principal investigators will be responsible for revising the protocol as needed to maintain safety. All expected adverse events will be reported in aggregate at the time of continuing review, unless otherwise granted waiver by the IRB. If it is determined from the review of the aggregate data that an event is occurring at a greater frequency or level of severity than previously expected, it constitutes an unanticipated problem (UP), and the problem will be reported to the IRB expeditiously.

P. Data Safety and Monitoring Plan: This is a natural history protocol without experimental interventions. Data and safety will be monitored by the Principal Investigator, Gwenyth R. Wallen, PhD and Medical Advisory Investigator, David T. George, MD.

The PI will submit protocol amendments, as appropriate, to the IRB for review and approval of monitor recommendations. Data quality assurance is performed by the Clinical Center Quality Coordinator.

Q. Clinical Monitoring Plan: Clinical monitoring will be conducted in accordance with the Clinical Center (CC) Monitoring Policy. In brief, protocols will be submitted to the CC Quality Assurance Coordinator who will determine the frequency and complexity of monitoring based on the IRB assigned risk and patient populations. Monitoring will be performed by the CC Quality Assurance Coordinator.

R. Data/Records Management: The PI will be responsible for assuring that all investigators follow the plan for protecting the confidentiality of information and data provided by research participants. Data will be de-identified where possible through the use of non-identifiable codes. The key to the code will be kept securely and separate from data and samples. Subject information will be maintained in secured databases and computers in locked files and a locked office. Paper records will be maintained in locked files and a locked office. Access to samples and data will be limited to authorized study personnel. The PI will be responsible for overseeing entry of the data (quantitative and interview transcripts) into a password protected electronic system and ensuring data accuracy, consistency and timeliness. Data will be stored in locked cabinets and a password-protected database until it is no longer of scientific value.

Study closure will be handled according to SOP 11A: Study Closure. At the time of study closure, the PI will submit an *Intramural Clinical Protocol Study Closure Application*. Research records will be maintained by the PI in accordance with record retention policies of the CC. Research records shall be made available for inspection and copying by authorized representatives of OHRP at reasonable times and in a reasonable manner. Premature study closure is not anticipated, but if necessary the PI will work with the IRB to inform currently-enrolled subjects about the closure.

S. Compensation: Participants will be compensated for research-related discomfort and inconveniences in accord with NIH guidelines. If participants are unable to finish the study, they will be paid only for those parts completed. Payment will be made via check or direct deposit based on Clinical Research Volunteer Program (CRVP) guidelines. If participants complete the second (outpatient/follow-up) interview and surveys by phone, they will still receive the \$30.00 for that portion of the study.

- Inpatient qualitative interview and surveys: \$30.00
- Outpatient qualitative interview and surveys: \$30.00

Total possible compensation: \$60.00

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T. Appendices

Appendix A: Pittsburgh Sleep Quality Index (PSQI)
Appendix B: Epworth Sleepiness Scale (ESS)
Appendix C: Sleep-related Behaviour Questionnaire (SRBQ)
Appendix D: Self-efficacy for Sleep Scale (SE-S)
Appendix E: Dysfunctional Beliefs and Attitudes about Sleep Scale (DBAS-16)
Appendix F: Penn Alcohol Craving Scale (PACS)
Appendix G: Interview scripts
Appendix H: Conceptual Model based on the Social Cognitive Theory
Appendix I: DSM-V Sleep disorder checklist

Appendix A: Pittsburgh Sleep Quality Index (PSQI)

Subject's Initials ID# _____ Date _____ Time _____

PITTSBURGH SLEEP QUALITY INDEX

INSTRUCTIONS:

The following questions relate to your usual sleep habits during the past month only. Your answers should indicate the most accurate reply for the majority of days and nights in the past month. Please answer all questions.

1. During the past month, what time have you usually gone to bed at night?

BED TIME _____

2. During the past month, how long (in minutes) has it usually taken you to fall asleep each night?

NUMBER OF MINUTES _____

3. During the past month, what time have you usually gotten up in the morning?

GETTING UP TIME _____

4. During the past month, how many hours of actual sleep did you get at night? (This may be different than the number of hours you spent in bed.)

HOURS OF SLEEP PER NIGHT _____

For each of the remaining questions, check the one best response. Please answer all questions.

5. During the past month, how often have you had trouble sleeping because you . . .

- a) Cannot get to sleep within 30 minutes

Not during the	Less than	Once or twice	Three or more
past month_____	once a week_____	a week_____	times a week_____

- b) Wake up in the middle of the night or early morning

Not during the	Less than	Once or twice	Three or more
past month_____	once a week_____	a week_____	times a week_____

- c) Have to get up to use the bathroom

Not during the	Less than	Once or twice	Three or more
past month_____	once a week_____	a week_____	times a week_____

- d) Cannot breathe comfortably

Not during the	Less than	Once or twice	Three or more
past month_____	once a week_____	a week_____	times a week_____

- e) Cough or snore loudly

Not during the	Less than	Once or twice	Three or more
past month_____	once a week_____	a week_____	times a week_____

- f) Feel too cold

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Not during the	Less than	Once or twice	Three or more
past month_____	once a week_____	a week_____	times a week_____

g) Feel too hot

Not during the	Less than	Once or twice	Three or more
past month_____	once a week_____	a week_____	times a week_____

h) Had bad dreams

Not during the	Less than	Once or twice	Three or more
past month_____	once a week_____	a week_____	times a week_____

i) Have pain

Not during the	Less than	Once or twice	Three or more
past month_____	once a week_____	a week_____	times a week_____

j) Other reason(s), please describe_____

How often during the past month have you had trouble sleeping because of this?

Not during the	Less than	Once or twice	Three or more
past month_____	once a week_____	a week_____	times a week_____

6. During the past month, how would you rate your sleep quality overall?

Very good _____

Fairly good _____

Fairly bad _____

Very bad _____

7. During the past month, how often have you taken medicine to help you sleep (prescribed or "over the counter")?

Not during the	Less than	Once or twice	Three or more
past month_____	once a week_____	a week_____	times a week_____

8. During the past month, how often have you had trouble staying awake while driving, eating meals, or engaging in social activity?

Not during the	Less than	Once or twice	Three or more
past month_____	once a week_____	a week_____	times a week_____

9. During the past month, how much of a problem has it been for you to keep up enough enthusiasm to get things done?

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No problem at all _____

Only a very slight problem _____

Somewhat of a problem _____

A very big problem _____

10. Do you have a bed partner or roommate?

No bed partner or room mate _____

Partner/roommate in other room _____

Partner in same room, but not same bed _____

Partner in same bed _____

If you have a room mate or bed partner, ask him/her how often in the past month you have had . . .

a) Loud snoring

Not during the	Less than	Once or twice	Three or more
past month_____	once a week_____	a week_____	times a week_____

b) Long pauses between breaths while asleep

Not during the	Less than	Once or twice	Three or more
past month_____	once a week_____	a week_____	times a week_____

c) Legs twitching or jerking while you sleep

Not during the	Less than	Once or twice	Three or more
past month_____	once a week_____	a week_____	times a week_____

d) Episodes of disorientation or confusion during sleep

Not during the	Less than	Once or twice	Three or more
past month_____	once a week_____	a week_____	times a week_____

e) Other restlessness while you sleep; please describe_____

Not during the	Less than	Once or twice	Three or more
past month_____	once a week_____	a week_____	times a week_____

Buyse DJ, Reynolds CF, Monk TH, Berman SR, Kupfer DJ: *Psychiatry Research*, 28:193-213, 1989.

Appendix B: Epworth Sleepiness Scale (ESS)

Protocol Number: T-CC-0486

Epworth Sleepiness Scale

Name: _____

Today's date: _____

Your age (Yrs): _____

Your sex (Male = M, Female = F): _____

How likely are you to doze off or fall asleep in the following situations, in contrast to feeling just tired?

This refers to your usual way of life in recent times.

Even if you haven't done some of these things recently try to work out how they would have affected you.

Use the following scale to choose the **most appropriate number** for each situation:

0 = would **never** doze

1 = **slight chance** of dozing

2 = **moderate chance** of dozing

3 = **high chance** of dozing

It is important that you answer each question as best you can.

Situation**Chance of Dozing (0-3)**

Sitting and reading _____

Watching TV _____

Sitting, inactive in a public place (e.g. a theatre or a meeting) _____

As a passenger in a car for an hour without a break _____

Lying down to rest in the afternoon when circumstances permit _____

Sitting and talking to someone _____

Sitting quietly after a lunch without alcohol _____

In a car, while stopped for a few minutes in the traffic _____

THANK YOU FOR YOUR COOPERATION

M.W. Johns 1990-97

Appendix C: Sleep-related Behaviour Questionnaire (SRBQ)**Sleep-Related Behaviour Questionnaire**

Instructions		Almost never	Rarely	Sometimes	Often	Almost always					
Please carefully read each of the statements below and circle the number that best describes how often you do the following things in order to cope with tiredness or improve your sleep (ie, 0 = almost never, 4 = almost always).											
<i>To cope with tiredness or improve sleep....</i>											
1.	I spend time considering ways to improve sleep	0	1	2	3	4					
2.	I stay in the background in social situations	0	1	2	3	4					
3.	I try to stop all thinking when trying to get to sleep	0	1	2	3	4					
4.	I do something active close to bed-time to tire myself out	0	1	2	3	4					
5.	I miss or cancel appointments (daytime or evening)	0	1	2	3	4					
6.	During the day, I block thoughts about sleep out of my mind	0	1	2	3	4					
7.	I reduce my expectations of what I can achieve	0	1	2	3	4					
8.	I figure out how I will catch up my sleep later on	0	1	2	3	4					
9.	I work less hard to conserve energy	0	1	2	3	4					
10.	I try to keep all disturbing thoughts and images out of my mind while in bed	0	1	2	3	4					
11.	I avoid talking about my sleep	0	1	2	3	4					
12.	I look at the clock on waking to calculate how many hours of sleep I got	0	1	2	3	4					
13.	I plan to get an early night	0	1	2	3	4					
14.	I give up trying to work	0	1	2	3	4					
15.	I take a sleeping pill or pills	0	1	2	3	4					
16.	I catch up on sleep by napping	0	1	2	3	4					
17.	I wear earplugs to block out all sounds that might wake me up/prevent me falling asleep	0	1	2	3	4					
18.	I worry about the consequences of poor sleep while lying in bed	0	1	2	3	4					
19.	I take on fewer social commitments	0	1	2	3	4					

20. I put tasks off until tomorrow	0	1	2	3	4
21. I avoid difficult conversations with people	0	1	2	3	4
22. During the day, I conserve energy any way I can	0	1	2	3	4
23. I avoid sleeping away from home	0	1	2	3	4
24. I look at the clock to see how long it's taking to get to sleep	0	1	2	3	4
25. I am less active during the day	0	1	2	3	4
26. I keep busy to stop thinking about my sleep	0	1	2	3	4
27. I limit myself to mundane chores or tasks during the day/evening	0	1	2	3	4
28. I worry about other things (e.g. work) to distract from concerns about sleep	0	1	2	3	4
29. I take herbal remedies to aid sleep	0	1	2	3	4
30. While in bed, I try to block out thinking about any problems	0	1	2	3	4
31. I stick to a routine during the day so that I don't have to think as much	0	1	2	3	4
32. I give myself lots of time to fall asleep by going to bed early	0	1	2	3	4

Appendix D: Self-efficacy for Sleep Scale (SE-S)

Self-Efficacy for Sleep Scale

Name _____ Date _____

For the following 9 items, please rate (by circling a number from 1 to 5) your ability to carry out each behavior. If you feel able to accomplish a behavior some of the time but not always, you should indicate a lower level of confidence.

Indicate how confident you are that you can:

- | | | | | | |
|--|---------------|---|---|----------------|---|
| 1. Lie in bed, feeling physically relaxed. | 1 | 2 | 3 | 4 | 5 |
| | Not confident | | | Very confident | |
| 2. Lie in bed, feeling mentally relaxed. | 1 | 2 | 3 | 4 | 5 |
| | Not confident | | | Very confident | |
| 3. Lie in bed with your thoughts "turned off." | 1 | 2 | 3 | 4 | 5 |
| | Not confident | | | Very confident | |
| 4. Fall asleep at night in under 30 minutes. | 1 | 2 | 3 | 4 | 5 |
| | Not confident | | | Very confident | |
| 5. Wake up at night fewer than 3 nights. | 1 | 2 | 3 | 4 | 5 |
| | Not confident | | | Very confident | |
| 6. Go back to sleep within 15 minutes of waking in the night. | 1 | 2 | 3 | 4 | 5 |
| | Not confident | | | Very confident | |
| 7. Feel refreshed upon waking in the morning. | 1 | 2 | 3 | 4 | 5 |
| | Not confident | | | Very confident | |
| 8. Wake after a poor night's sleep without feeling upset about it. | | | | | |

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1	2	3	4	5
Not confident			Very confident	
9. Not allow a poor night's sleep to interfere with daily activities.				
1	2	3	4	5
Not confident			Very confident	

Appendix E: Dysfunctional Beliefs and Attitudes about Sleep (DBAS)

Dysfunctional Beliefs and Attitudes about Sleep (DBAS)

Name: _____ Date: _____

Several statements reflecting people's beliefs and attitudes about sleep are listed below. Please indicate to what extent you personally agree or disagree with each statement. There is no right or wrong answer. For each statement, circle the number that corresponds to your own personal belief. Zero (0) indicates **disagreement** and ten (10) indicates **agreement**. Please respond to all items even though some may not apply directly to your own situation.

1. I need 8 hours of sleep to feel refreshed and function well during the day.

0 1 2 3 4 5 6 7 8 9 10

2. When I don't get the proper amount of sleep on a given night, I need to catch up on the next day by napping or on the next night by sleeping longer.

0 1 2 3 4 5 6 7 8 9 10

3. I am concerned that chronic insomnia may have serious consequences on my physical health.

0 1 2 3 4 5 6 7 8 9 10

4. I am worried that I may lose control over my abilities to sleep.

0 1 2 3 4 5 6 7 8 9 10

5. After a poor night's sleep, I know that it will interfere with my daily activities on the next day.

0 1 2 3 4 5 6 7 8 9 10

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6. In order to be alert and function well during the day, I believe I would be better off taking a sleeping pill rather than having a poor night's sleep.

0 1 2 3 4 5 6 7 8 9 10

7. When I feel irritable, depressed, or anxious during the day, it is mostly because I did not sleep well the night before.

0 1 2 3 4 5 6 7 8 9 10

8. When I sleep poorly on one night, I know it will disturb my sleep schedule for the whole week.

0 1 2 3 4 5 6 7 8 9 10

9. Without an adequate night's sleep, I can hardly function the next day.

0 1 2 3 4 5 6 7 8 9 10

10. I can't ever predict whether I'll have a good or poor night's sleep.

0 1 2 3 4 5 6 7 8 9 10

11. I have little ability to manage the negative consequences of disturbed sleep.

0 1 2 3 4 5 6 7 8 9 10

12. When I feel tired, have no energy, or just seem not to function well during the day, it is generally because I did not sleep well the night before.

0 1 2 3 4 5 6 7 8 9 10

13. I believe insomnia is essentially the result of a chemical imbalance.

0 1 2 3 4 5 6 7 8 9 10

14. I feel insomnia is ruining my ability to enjoy life and prevents me from doing what I want.

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0 1 2 3 4 5 6 7 8 9 10

15. Medication is probably the only solution to sleepiness.

0 1 2 3 4 5 6 7 8 9 10

16. I avoid or cancel obligations (social, family) after a poor night's sleep.

0 1 2 3 4 5 6 7 8 9 10

©Morin, C. 1993

Appendix F: Penn Alcohol Craving Scale (PACS)**PENN ALCOHOL CRAVING SCALE**

Circle the most appropriate number for each item. If this is the first time you are filling out this form, the questions apply to the last week that you drank any alcohol. If you received serax or another medication for detoxification, exclude that time period. If you are currently participating in the medication trial, these questions cover the time period from the day of your last visit to the day before your current visit.

1. How often have you thought about drinking or about how good a drink would make you feel during this period?

Never, that is, 0 times during this period of time. = 0

Rarely, that is, 1 to 2 times during this period of time. = 1

Occasionally, that is, 3 to 4 during this period of time. = 2

Sometimes, that is, 5 to 10 times during this period or 1 to 2 times per day. = 3

Often, that is, 11 to 20 times during this period or 2 to 3 times a day. = 4

Most of the time, that is, 20 to 40 during this period or 3 to 6 times a day. = 5

Nearly all of the time, that is, more than 40 times during this period or more than 6 times a day. = 6

2. At its most severe point, how strong was your craving during this period?

None at all. = 0

Slight, that is a very mild urge. = 1

Mild urge. = 2

Moderate urge. = 3

Strong urge, but easily controlled. = 4

Strong urge and difficult to control. = 5

Strong urge and would have drunk alcohol if it were available. = 6

3. How much time have you spent thinking about drinking or about how good a drink would make you feel during this period?

None at all = 0

Less than 20 minutes = 1

21-45 minutes = 2

46-90 minutes = 3

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90 minutes - 3 hours = 4
Between 3 to 6 hours = 5
More than 6 hours = 6

4. How difficult would it have been to resist taking a drink during this period of time if you had known a bottle were in your house?

Not difficult at all = 0
Very mildly difficult = 1
Mildly difficult = 2
Moderately difficult = 3
Very difficult = 4
Extremely difficult = 5
Would not be able to resist = 6

5. Keeping in mind your responses to the previous questions, please rate your *overall average* alcohol craving for the stated period of time.

Never thought about drinking and never had the urge to drink = 0
Rarely thought about drinking and rarely had the urge to drink = 1
Occasionally thought about drinking and occasionally had the urge to drink = 2
Sometimes thought about drinking and sometimes had the urge to drink = 3
Often thought about drinking and often had the urge to drink = 4
Thought about drinking most of the time and had the urge to drink most of the time = 5
Thought about drinking nearly all of the time and had the urge to drink nearly all of the time = 6

Appendix G: Interview scripts

Interview #1 (conducted within a week of scheduled discharge)

Thank you for participating in this study. My name is _____ and I'll be facilitating the interview today. _____ is with me to observe and take some notes. We are audio-recording this session because we don't want to miss any of your comments.

We're conducting these interviews because we're trying to understand more about your recovery, transition into the community, and sleep patterns. Some questions are very general and others are more specific to your transition. I want you to talk out what you are thinking more than what you might normally be used to - so basically, to "think out loud." I do have a set of questions written out, but mainly, I just want to hear what you have to say. There are no "right" or "wrong" answers. If you are uncomfortable with any question, we can skip it. However, the more information you are able to provide me with, the more I'll be able to understand your experience and how each person's recovery process differs. You can choose to end the interview at any time and this will not affect your treatment here at NIH.

What should I know about you as a person?

Describe the process of how you adjusted to being an inpatient in the Clinical Center.

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Talk me through what your experience has been throughout the process of rehabilitation here at NIH.

Think about the first few days after you leave here and go home. Walk me through what you think it will be like.

Describe in as much detail as you can any expectations you have about transitioning back into your home environment.

Probe: What barriers or facilitators to recovery do you expect?

How did you sleep last night? Describe in as much detail as you can.

Talk me through what your experience has been with sleep throughout the process of rehabilitation here at NIH.

Describe how it has been to adjust to sleeping in this hospital. What about it is the same or different from your home environment?

Probe: positives and negatives of both environments...

Describe what you think your sleep will be like when you leave the NIH.

Describe what you will do if you have trouble sleeping when you get home.

When you feel like you have had a really "good night's sleep," what does that generally mean to you? Describe this in as much detail as you can.

Probe: how many hours, how you felt in the morning, ease of falling asleep...

How do you think alcohol affects sleep?

Is there anything you'd like to add that we haven't discussed already?

We appreciate your responses - thank you for time.

Interview #2 (conducted approximately one month post-discharge)

Thank you for participating in this study. My name is _____ and I'll be facilitating the interview today. _____ is with me to observe and take some notes. We are audio-recording this session because we don't want to miss any of your comments.

We're conducting these interviews because we're trying to understand more about your recovery, transition into the community, and sleep patterns. Some questions are very general and others are more specific to your transition. I want you to talk out what you are thinking more than what you might normally be used to - so basically, to "think out loud." I do have a set of questions written out, but mainly, I just want to hear what you have to say. There are no "right" or "wrong" answers. If you are uncomfortable with any question, we can skip it. However, the more information you are able to provide me with, the more I'll be able to understand your experience

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and how each person's recovery process differs. You can choose to end the interview at any time and this will not affect your treatment here at NIH.

It's been about a month since you left the Clinical Center. Talk me through what the transition has been like as you returned to your home environment.

Probe: Different environment, support system...

Probe: Describe any barriers or facilitators to recovery you have experienced.

How did you sleep last night? Describe in as much detail as you can.

Compared to what it was like in the hospital, what has your sleep been like since leaving the NIH?

Probe: More/less sleep, more/less tired, dreams...

Describe what your process has been if you have experienced any trouble sleeping.

Probe: television, reading, medication, alcohol...

When you feel like you have had a really "good night's sleep," what does that generally mean to you?

Describe this in as much detail as you can.

Probe: how many hours, how you felt in the morning, ease of falling asleep...

How do you think alcohol affects sleep?

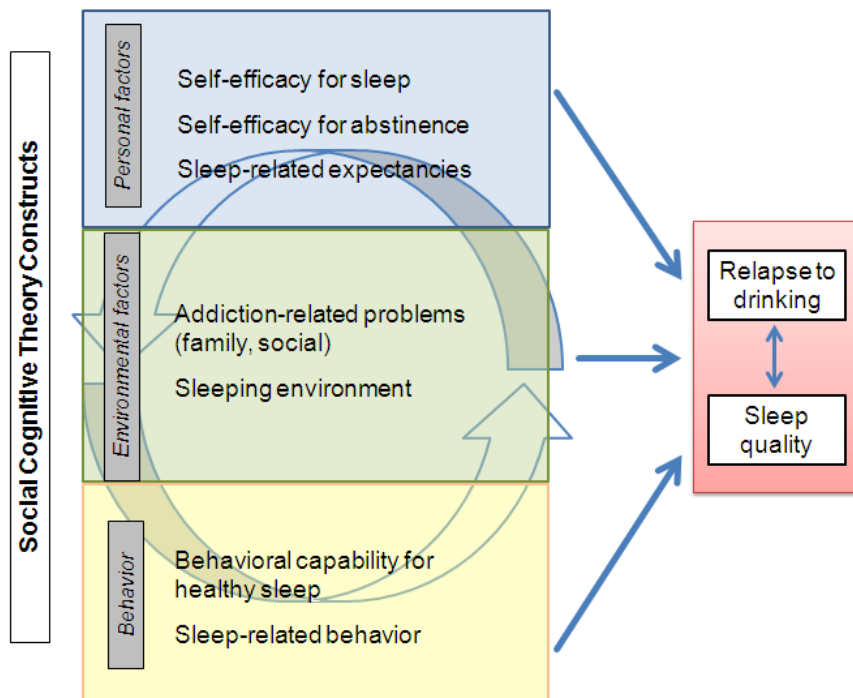
Would you be open to an intervention to help you sleep? What would an ideal sleep intervention look like to you?

Probe: Inpatient or outpatient, group-based or one-on-one, setting, timing...

Is there anything you'd like to add that we haven't discussed already?

We appreciate your responses - thank you for time.

Model
Social
Theory



Appendix H:
Conceptual
based on the
Cognitive

Appendix I: DSM-V Sleep disorder checklist**Have you ever been diagnosed with any the following?**

Insomnia disorder	Yes ☐	No ☐
Hypersomnolence disorder	Yes ☐	No ☐
Narcolepsy	Yes ☐	No ☐
Sleep apnea	Yes ☐	No ☐
Sleep-related hypoventilation	Yes ☐	No ☐
Circadian rhythm sleep-wake disorders	Yes ☐	No ☐
Non-rapid eye movement sleep arousal disorders	Yes ☐	No ☐
Nightmare disorder	Yes ☐	No ☐
Rapid eye movement sleep behavior disorder	Yes ☐	No ☐
Restless legs syndrome	Yes ☐	No ☐
Substance/medication-induced sleep disorder	Yes ☐	No ☐

List generated from the Diagnostic and Statistical Manual of Mental Disorders (5th ed; DSM-5): American Psychiatric Association. (2013). *Diagnostic and statistical manual of mental disorders* (5th ed.). Arlington, VA: American Psychiatric Publishing.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Addictions IRB
Room 02A-401
251 Bayview Blvd, Suite 200
Baltimore, MD 21224
443-740-2393
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DATE: June 30, 2014
TO: Gwentyth R. Wallen
Principal Investigator, CC
FROM: Ivan Montoya, MD
Chair, ADDICTIONS IRB
ADDICTIONS IRB Office
SUBJECT: Expedited IRB Review of Protocol# 14-CC-0143, Sleep Disturbance and Relapse in Individuals with Alcohol Dependence: An Exploratory Mixed Methods Study
Final Approval

Your Amendment 06/09/2014 (1) application was reviewed and approved by the ADDICTIONS IRB through an expedited review procedure on June 30, 2014.

Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more specified categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110.

In accord with 45 CFR 46.110 and 21 CFR 56.110, your Amendment 06/09/2014 (1) application falls under the following research category for expedited review:

A minor change in previously approved research during the period (of one year or less) for which approval is authorized.

Your IRB approved expedited Amendment 06/09/2014 (1) application will be forwarded to the Office of Protocol Services for final processing. You will receive notification when the Office of Protocol Services completes the processing of this application.

The protocol expiration date is May 12, 2015.

IMPORTANT INFORMATION ABOUT YOUR PROTOCOL:

Please use the final approved version of the protocol and consent as a guide for documents submitted for the next review.

ANY change in research activity MUST receive IRB review and approval prior to implementation. Request for review of changes should be submitted as an amendment.

Adverse or unexpected/unanticipated events or new information that may alter the risk or benefit determination or subjects willingness to continue in the study must be reported in accordance with NIH policy. Additional reporting (for example, to the sponsor or FDA) may also be required.

As Principal Investigator you are responsible for informing the Associate Investigators of the status of this project.

Please contact the ADDICTIONS IRB Office if you have any questions and/or concerns.

Bridge, Heather (NIH/OD) [E]

From: Montoya, Ivan (NIH/NIDA) [E]
Sent: Monday, June 30, 2014 11:58 AM
To: Gupman, Anne E. (NIH/NIDA/IRP) [E]; Bridge, Heather (NIH/OD) [E]; Brooks, Alyssa (NIH/CC/NURS) [F]
Cc: Wallen, Gwenyth (NIH/CC/NURS) [E]
Subject: RE: Reliance by UMD upon Addictions IRB

The amendment is now approved. The reliance is approved.

Ivan

From: Gupman, Anne E. (NIH/NIDA/IRP) [E]
Sent: Monday, June 30, 2014 10:59 AM
To: Montoya, Ivan (NIH/NIDA) [E]; Bridge, Heather (NIH/OD) [E]; Brooks, Alyssa (NIH/CC/NURS) [F]
Cc: Wallen, Gwenyth (NIH/CC/NURS) [E]
Subject: RE: Reliance by UMD upon Addictions IRB

The Initial review just got approved Friday so I can send the Amendment to Ivan today...

From: Montoya, Ivan (NIH/NIDA) [E]
Sent: Monday, June 30, 2014 10:57 AM
To: Bridge, Heather (NIH/OD) [E]; Brooks, Alyssa (NIH/CC/NURS) [F]
Cc: Wallen, Gwenyth (NIH/CC/NURS) [E]; Gupman, Anne E. (NIH/NIDA/IRP) [E]
Subject: RE: Reliance by UMD upon Addictions IRB

Hi Heather,

According to the attached email, we decided to wait for the amendment before approving the concurrence. So, I won't be able to approve it until we have the approved amendment. I cc'd Anne, so she'll be in the loop and alert me to approve the reliance as soon as the amendment is approved.

Thank you,

Ivan

From: Bridge, Heather (NIH/OD) [E]
Sent: Monday, June 30, 2014 10:48 AM
To: Brooks, Alyssa (NIH/CC/NURS) [F]; Montoya, Ivan (NIH/NIDA) [E]
Cc: Wallen, Gwenyth (NIH/CC/NURS) [E]
Subject: FW: Reliance by UMD upon Addictions IRB
Importance: High

Hi Alyssa and Ivan

We are waiting on the approved amendment describing Alyssa's role on the protocol for her dissertation project. We are also waiting on Ivan's concurrence. Any movement with regards to these items for the reliance agreement?
Best,

Heather Bridge
Office of Human Subjects Research Protections