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# Affect and Craving: Examining the Differential Influences of Positive and Negative

Affect on Inclinations to Approach and Avoid Alcohol Use

by

Jacob A. Levine

A thesis submitted in partial fulfillment of the requirements for the degree of Master of Arts Department of Psychology College of Arts and Sciences University of South Florida

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Keywords: Ambivalence Model of Craving, Alcohol Use Disorder, Cue Reactivity, Eye Tracking.

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#### Abstract

Most research examining the role of affect in the etiology of alcohol craving has been limited to associations between negative affect and the desire to consume alcohol. This narrow focus has not only ignored the potential influence of positive affect on the desire to use alcohol, but has led to a failure to consider both desires to avoid using alcohol and motivational conflicts often thought to be present in alcohol use disorders (AUDs). Additionally, research investigating the influence of affect on attentional bias in favor of alcohol cues in individuals who have an AUD has been limited. Using 60 individuals recruited from the community who met criteria for AUD, the current study sought to investigate the influence of both positive and negative affect on craving (approach and avoidance) and attentional biases using an experimental paradigm to manipulate affect and utilizing eye-tracking methodology. The negative affect induction was successful, however, our positive affect induction failed. Affect induction did not influence approach or avoidance ratings for alcohol or attentional bias; further, approach and avoidance did not predict any attentional bias indices. Future research would benefit from investigating treatment samples using larger sample sizes and the inclusion of potential moderators to help investigate associations among affect, attentional biases, and craving.



#### Introduction

With an estimated 6.6% of the U.S. population 12 years or older diagnosed (i.e., 17.3 million; SAMHSA, 2014), alcohol use disorders (AUDs) continue to be a major public health concern. Greater understanding of the factors maintaining problematic patterns of alcohol use is a necessary step to improving treatments. With high rates of comorbidity between AUDs and mood and anxiety disorders (e.g., Grant et al., 2015), research has often focused on the links between affect and problematic alcohol use (Dvorak, Pearson, Sargent, Stevenson, & Mfon, 2016; Kassel & Veilleux, 2010; Khantzian, 1997; Stasiewicz et al., 2013). Further, with the reintroduction of craving as a diagnostic symptom in the DSM-5 (American Psychiatric Association, 2013), there has been a renewed interest in examining of the role of craving in substance use disorders, including the impact of affective states on such relationships. Although there are strong links between alcohol use and affective state, research on the effect of affective state on reactivity to cues (i.e., craving) has been limited despite strong theoretical links (Baker, Morse, & Sherman, 1986; Baker, Piper, McCarthy, Majeskie, & Fiore, 2004; Kavanagh, Andrade, & May, 2005; Robinson & Berridge, 1993; Stasiewicz & Maisto, 1993; Tiffany, 1990). For example, studies have focused primarily on the impact of negative affect on cue-reactivity or craving with minimal attention paid to positive affect. Further, they often fail to incorporate the ambivalence associated with craving itself (see Stritzke, McEvoy, Wheat, Dyer, & French, 2007; Tiffany, 2010 for review) and have relied heavily on correlational methods and self-report measures that may not be accurately capturing the craving experience (Sayette et al., 2000). The proposed study seeks to address some of these limitations by directly manipulating both positive



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and negative affect and examining the effect of such manipulations on both desires to use and not use alcohol using multiple methods of assessment.

## **Ambivalence Model of Craving: Approach and Avoidance Inclinations**

Although craving is thought to be important in the development, maintenance, and reinstatement of AUDs (Marlatt & Witkiewitz, 2005; Tiffany & Conklin, 2000), findings have been inconsistent and the role of craving in problematic alcohol use has been heavily debated (Drummond, 2001). Despite extensive research over the last 60 years, researchers have yet to agree on a definition of the term craving in regard to alcohol use (Kavanagh et al., 2013; Tiffany & Wray, 2012). Broadly defined, craving has been described as "an intense desire for alcohol or drugs." Unfortunately, this view fails to adequately account for the wide range of conceptualizations found in the addictions literature (Lowman, Hunt, Litten, & Drummond, 2000; Rosenberg, 2009; Sayette et al., 2000). Nevertheless, craving is commonly regarded as a subjective state associated with alcohol use more broadly (Pickens & Johanson, 1992), and the conscious experience of desiring the craved substance more specifically (Drummond, 2001; Tiffany & Wray, 2012).

The lack of a consistent definition is evidenced by the varied operationalizing of craving in prominent theoretical frameworks of addiction, including conditioned-reinforcement (e.g., Koob, 2000; Li, 2000), incentive sensitization (Robinson & Berridge, 1993, 2000), cognitive social learning theory (Marlatt & Gordon, 1985; Niaura, 2000), and cognitive processing models (Tiffany, 1990, 1999). Similarly, there is a lack of general consensus regarding how to best measure craving, or even how to best create psychometrically sound items (Kavanagh et al., 2013; Lowman et al., 2000; Rosenberg, 2009; Sayette et al., 2000). Furthermore, many assessments of craving are confounded by other factors known to contribute to drinking such as



expectancies, self-efficacy, and mood (Kavanagh et al., 2013). Finally, most theoretical models of craving fail to capture the competing motivations and "ambivalence" often present in drinking situations (i.e., "I want to" and "I don't want to") and do not adequately account for craving as a function of recovery (Breiner, Stritzke, & Lang, 1999; Sayette et al., 2000; Stritzke et al., 2007; Tiffany, 1990) Consistent with the idea that those with AUDs experience competing desires is research demonstrating that alcohol cues activate both appetitive and aversive reactions (e.g., Franken, de Haan, van der Meer, Haffmans, & Hendriks, 1999; Sinha, Fuse, Aubin, & O'Malley, 2000; Smith-Hoerter, Stasiewicz, & Bradizza, 2004). Failing to consider both appetitive and aversive inclinations likely contributes to the inconsistencies in the alcohol craving literature, such that drinking may change despite continued desires to use. Thus, it is possible that our understanding of the craving-drinking relationship could be improved by applying a model of craving that assesses both the desire to use and the desire to not use alcohol.

The Ambivalence Model of Craving (AMC; Breiner et al., 1999; Stritzke et al., 2007) conceptualizes craving as both desires to use (approach) and desires not to use (avoid) alcohol. Consistent with motivational models of addiction, the AMC considers approach and avoidance inclinations to result from a combination of historical (e.g., biochemical reactivity, personality, environment, and past reinforcement) and current (e.g., positive and negative incentives and availability of alternative valued activities) factors that influence outcome expectancies. Thus, people who expect positive outcomes will be more inclined to approach alcohol and people who expect negative outcomes will be more inclined to avoid alcohol. These approach and avoidance inclinations can occur simultaneously and independent of one another, such that a person could be high on both approach and avoidance at the same time, resulting in one of four quadrants (Breiner et al., 1999): low approach and low avoidance (indifference), low approach and high



avoidance (avoidance), high approach and high avoidance (ambivalence), and high approach and low avoidance (approach).

Although the AMC is a relatively recent development in the field of alcohol craving, a growing body of research has emerged to validate and further extend the theory. Methods of assessing approach and avoidance (e.g., the AAAQ and cue-reactivity) have shown consistently robust validity and reliability among diverse clinical samples in a variety of treatment settings and non-clinical samples across a wide range of drinking profiles (Curtin, Barnett, Colby, Rohsenow, & Monti, 2005; Levine, Noyes, Christensen, & Schlauch, 2016; McEvoy, Stritzke, French, Lang, & Ketterman, 2004; Schlauch, Breiner, Stasiewicz, Christensen, & Lang, 2013; Stritzke, Breiner, Curtin, & Lang, 2004). Further , latent profile analysis of alcohol cue-elicited craving has confirmed these classes across social drinkers, problem drinkers, and abstinent former problem drinkers and has found both ambivalence and high ambivalence groups in a sample seeking inpatient treatment for substance use disorders (Levine et al., 2016; Schlauch, Rice, Connors, & Lang, 2015), with problematic drinking most likely to be seen by those with a predominately approach or ambivalent craving profile (Schlauch, Rice, et al., 2015; Stritzke et al., 2007).

Approach and avoidance have both been significantly associated with problem recognition (e.g., Klein, Stasiewicz, Koutsky, Bradizza, & Coffey, 2007; Schlauch et al., 2012); moreover, approach has been uniquely associated with drinking quantity and frequency and avoidance has been uniquely associated with taking steps to change alcohol use and an increased number of treatment sessions attended (Schlauch, Breiner, et al., 2013; Schlauch, Levitt, et al., 2013; Schlauch et al., 2012). The interaction of approach and avoidance are also predictive of drinking outcomes across time, including number of drinks, number of drinking days, and



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number of heavy drinking days (Schlauch, Crane, Connors, Maisto, & Dearing, 2016; Schlauch, Levitt, et al., 2013). Furthermore, specific craving profiles including both approach and avoidance inclinations are predictive of treatment outcomes: avoidant profiles (low approach and high avoidance) significantly predict a reduction of heavy drinking days over the course of six months and a marginally significant decrease in number of drinks consumed; approach profiles (high approach and low avoidance) significantly predict an increase in drinking days; and ambivalent profiles (high approach and high avoidance) significantly predict a lower number of drinks consumed and less heavy drinking days, as compared to approach profiles (Schlauch, Levitt, et al., 2013). Positive treatment outcomes for problematic alcohol use are associated with changing craving profiles (i.e., decreases in approach and/or increases in avoidance move the craving profile from the approach or ambivalence quadrant to the avoidance quadrant), and relapse to problematic use is suggested to be associated with post-treatment declines in avoidance (Stritzke et al., 2007).

The AMC's consideration of avoidance inclinations co-occurring along with independent approach inclinations (i.e., motivational conflicts) allows for the capture of additional information that is vital to the process of craving, and essential to understanding the development, maintenance, and treatment of addictions (Stritzke et al., 2007). However, much is still unknown about the factors that directly impact approach and avoidance, including how both positive and negative affect differentially influence approach and avoidance inclinations.

#### Affect and Craving

Although strong empirical evidence exists supporting a relationship between substance use and affect, with substance use often intended as an affect regulation tool, the exact relationship is unclear (Kassel & Veilleux, 2010; Sher & Grekin, 2007). Given this strong



empirical support suggesting associations between affect and substance use, many theories of addiction include accounts of the link between inclinations favoring substance use (approach) and affect (Baker et al., 1986; Baker et al., 2004; Kavanagh et al., 2005; Robinson & Berridge, 1993, 2000; Stasiewicz & Maisto, 1993; Tiffany, 1990). Similar to craving, these theories differ in their predictions of the relationship between affect and craving and include both positive and negative affect as a precipitant, consequence, and/or defining feature of craving.

Negative affect has received significant empirical support as a predictor of craving. In experimental studies, induction of negative affect has consistently triggered cue-elicited craving (i.e., approach inclinations) in those diagnosed with alcohol use disorders (e.g., Cooney, Litt, Morse, Bauer, & Gaupp, 1997; Fox, Bergquist, Hong, & Sinha, 2007) and cigarette smokers (e.g., Bujarski et al., 2015; Conklin & Perkins, 2005; Maude-Griffin & Tiffany, 1996; Perkins & Grobe, 1992; Shiyko, Naab, Shiffman, & Li, 2014; Tiffany & Drobes, 1990). Further, negative affect is predicted as a consequence of craving when access to the desired substance is delayed or blocked (i.e., frustrative non-reward; Kavanagh et al., 2005; Stasiewicz & Maisto, 1993; Tiffany, 1990), including increased guilt and/or anxiety in those attempting to control their use (i.e., negative affect; Kavanagh et al., 2005). Negative affect is a prevalent emotional response to most or all experiences of craving (Baker et al., 2004; Kavanagh et al., 2005; Nosen et al., 2012), and is predicted to be positively related to approach inclinations (desire to use) and negatively related to avoidance inclinations (desire not to use). For instance, it is speculated that the negative association between negative affect and avoidance may be stronger among individuals with low self-efficacy to abstain from consuming alcohol and weaker among individuals attempting to regulate their alcohol use (Schlauch, Gwynn-Shapiro, Stasiewicz, Molnar, & Lang, 2013b).



Similarly, positive affect is also viewed as both a precursor (Baker et al., 1986) and a corollary of craving (Kavanagh et al., 2005), as well as an appetitive-motivational response to alcohol cues similar to craving itself (Robinson & Berridge, 1993; Stewart, de Wit, & Eikelboom, 1984). Additionally, it has been suggested that positive affect is more likely to elicit craving in the earlier stages of addiction (Tiffany, 2010). Positive affect is also theorized to share features common to the experience of pleasurable or rewarding aspects of substance use. As such, positive affect is believed to maintain approach inclinations toward substance use, possibly through the activation or sensitization of neural reward systems (Baker et al., 1986; Robinson & Berridge, 1993; Stewart et al., 1984) or enhancement of an appetitive-motivational process (Kavanagh et al., 2005). In contrast, it is also possible that positive affect may strengthen self-regulatory processes (e.g., Tice, Baumeister, Shmueli, & Muraven, 2007), resulting in increases in self-efficacy and negative expectancies as well as inhibiting approach inclinations and promoting avoidance inclinations.

Unlike negative affect, positive affect has received little empirical support as a predictor of approach inclinations (Tiffany, 2010) with positive affect predicting craving only in situations in which the consequences of use are minimal and consumption is imminent (Kavanagh et al., 2005). When presented in conjunction with substance-related stimuli, positive affective stimuli induced levels of craving similar to negative affect and significantly stronger than neutral affect (Maude-Griffin & Tiffany, 1996; Tiffany & Drobes, 1990; Veilleux, Conrad, & Kassel, 2013). In an alcohol dependent non-treatment seeking sample, Mason, Light, Escher, and Drobes (2008) found a significant relationship between experimentally induced positive affect and higher ratings of craving strength in response to beverage cues (i.e., "How strong is your craving to drink alcohol"). There were no significant associations found between positive affect and



intentions to use, positive expectancies, or lack of control; however, several limitations of the study were noted. Although craving strength increased after the induction of positive affect, the manipulations did not result in changes to participants' affective valence. Further, as acknowledged by the authors, the images used to induce positive affect may have elicited craving due to previous associations with alcohol consumption (e.g., sports) and the images used to induce negative affect may not have elicited craving due to a lack of previous associations with alcohol consumption (e.g., snakes). Finally, this study failed to account for competing desires often present in the experience of craving. This may be particularly important as "craving strength" may indeed be the net product of both approach and avoidance inclinations.

One of few studies to consider both approach and avoidance inclinations, Schlauch and colleagues (2013) used correlational methods to examine the association between positive and negative affect and approach and avoidance inclinations in a sample of patients from an inpatient detoxification unit for substance abuse. In this study, participants reported positive and negative affect at baseline using the Positive and Negative Affect Schedule (Watson, Clark, & Tellegen, 1988) and then completed a cue reactivity task using images from the Normative Appetitive Picture System (Stritzke et al., 2004), providing separate ratings of desire to consume (approach) and desire not to consume (avoid) alcoholic and non-alcoholic beverages displayed in slides. The study found that participants with higher levels of negative affect reported higher approach ratings for alcohol; participants with higher levels of positive affect reported lower approach ratings and higher avoidance ratings.

Consequently, disparate to negative affect, the role of positive affect in the development of craving is unclear and appears to depend on factors such as substance availability, perceived consequences of use, and abstinence self-efficacy. Individuals in clinical settings with higher



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levels of positive affect have shown increased avoidance inclinations, possibly representing a sense of purpose and optimism in changing their problematic substance use. Indeed, following a self-control depletion task, positive affect has been associated with greater restraint to refrain from smoking (Shmueli & Prochaska, 2012) and some studies have found a negative association between positive affect and craving (i.e., approaching) substance use (e.g., Bujarski et al., 2015; Schlauch, Gwynn-Shapiro, et al., 2013b). Thus, studies focusing on the association between affect and craving should examine both approach and avoidance inclinations as well as positive and negative affective states so as not to miss any clinically relevant information that may be lost by examining these constructs unidimensionally.

Additionally it has been argued that not all affective states are experienced consciously (Berridge & Winkielman, 2003), complicating matters even further. Although this viewpoint is contentious, Berridge and Winkielman argue that some core affective processes are implicit (i.e., automatic or unconscious), for example liking or wanting, while others such as subjective pleasure are explicit (i.e., effortful or conscious). The incentive-sensitization model (Robinson & Berridge, 1993, 2000) posits that the development of craving and addiction are largely implicit processes in which the affected individual becomes more sensitive to substance use related cues. The development of craving is thought to occur as a result of neuroadaptations in the dopamine system, causing the salience of substance related cues to increase in response to the rewarding effect of increased dopamine neurotransmission. Consistent with the AMC, neuroadaptation can increase both appetitive (i.e., approach) and aversive (i.e., avoidance) motivations (Berridge & Winkielman, 2003). This implicit preference in favor of approaching or avoiding visual substance cues (i.e., attentional bias) can be observed using eye tracking methodology to



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measure automatic eye movements in those with AUDs (Robinson & Berridge, 2008; Wiers & Stacy, 2006)

## **Attentional Bias and Craving**

In the past decade there has been a considerable amount of research focused on the disentanglement of implicit (i.e., automatic) processes involved in motivational predilections and explicit (i.e., controlled) processes germane to conscious decision making (Stacy & Wiers, 2010). Implicit cognition is thought to play an important role in motivation and decision making to use, although much remains unknown about how these processes contribute to the etiology, maintenance, and relapse to problematic substance use (Stacy & Wiers, 2010). Biases in the cognitive processing (i.e., attentional bias) of addiction related stimuli have been relatively overlooked and are likely an important aspect of substance cue reactivity (Field & Cox, 2008). Attentional bias in addictions is the tendency of frequent and problematic alcohol users to show automatic preferences in attention toward alcohol stimuli, and has been positively associated with both craving and substance use (Field & Cox, 2008; Rooke, Hine, & Thorsteinsson, 2008). Consistent with Robinson and Berridge (1993), substance related cues may grab the attention of more experienced users becoming more attractive and desired and increasing the likelihood of use. Additionally, it has been suggested that automatically detected substance cues may influence use behavior separately from explicit or conscious experiences such as craving (Tiffany, 1990). Further, it has been posited that attentional biases subjectively experienced by substance users may interact with other subjective experiences (e.g., craving) to influence substance use (Franken, 2003; Kavanagh et al., 2005).

There is strong support for attentional biases in favor of alcohol among individuals with AUDs, including positive associations between attentional bias and quantity and frequency of



alcohol use (Bruce & Jones, 2004; Field, Mogg, Zetteler, & Bradley, 2004; Townshend & Duka, 2001), as well as between attentional biases and subjective measurements of craving (Field, Munafo, & Franken, 2009). Research methods of testing for attentional biases are often categorized as direct or indirect. Indirect methods measure response times using tests involving alcohol stimuli, such as the addiction Stroop task (Cox, Fadardi, & Pothos, 2006) and the visual dot probe task (Ehrman et al., 2002). Direct methods capture explicit physiological responses, such as tracking eye movements in response to alcohol stimuli. A recent meta-analysis found significantly stronger associations between direct measures of attentional bias and subjective craving than the associations of indirect measures with craving (Field et al., 2009). One likely explanation for the difference is that response times measured using indirect methods are influenced by cognitive processes other than craving and do not measure attentional bias as accurately as direct methods (Field et al., 2009).

In addition to associations with craving and AUDs, attentional bias research has also found support for avoidance inclinations toward alcohol. Recently detoxified patients who received treatment for alcohol problems, as compared to social drinkers, showed a higher bias for alcohol cues measured after 50ms but a lower bias after 500ms, suggesting that effortful avoidance of alcohol stimuli takes over after initial orienting (Noel et al., 2006). Abstinent former problem drinkers both in and out of treatment have shown an attentional bias away from alcohol related stimuli (Christensen, 2009; Stormark, Field, Hugdahl, & Horowitz, 1997; Townshend & Duka, 2007), possibly indicating that as problematic use changes so does automatic processing. Furthermore, tasks measuring reaction time have shown higher alcohol avoidance motivation to be a predictor of less frequent binge drinking, however, approach motivations were not a significant predictor (Ostafin, Palfai, & Wechsler, 2003). The results of



attentional bias research indicate that avoidance is an important factor that should be considered when evaluating alcohol related cognitions (Kreusch, Quertemont, Vilenne, & Hansenne, 2014).

To date few studies have explored what effect, if any, both positive and negative affect have on attentional biases for alcohol. Most of these studies have focused solely on the association between negative affect and attentional bias, finding that negative mood increases bias for alcohol cues among those whose drinking is coping motivated, but not those whose drinking is enhancement motivated. (e.g., Birch et al., 2008; Field & Quigley, 2009). Studies examining positive affect have found that individuals with enhancement motivations show a preference for alcohol cues while those drinking to cope do not (Birch et al., 2008; Grant, Stewart, & Birch, 2007). It is important to note, however, that these studies have been conducted with samples of undergraduate college students and these findings may not generalize to clinical samples that meet criteria for an AUD. Little is known about the effect of both positive and negative affect on attentional biases in individuals with problematic alcohol use.

#### **Proposed Study**

This study sought to replicate and extend previous findings examining the association between positive and negative affect and approach and avoidance inclinations in a sample of patients from an inpatient detoxification unit for substance abuse using correlational methods (Schlauch, Gwynn-Shapiro, et al., 2013b). Using experimental methods the current study investigated the association between affect and alcohol craving, specifically how positive and negative affect differentially influence inclinations to approach alcohol and inclinations to avoid alcohol. Secondary aims included exploration of the association between affect and attentional bias in a clinical sample and using craving information captured by self-reported questionnaires and cue reactivity to predict attentional biases as measured by tracking eye movements. We did



do this by recruiting a sample of participants from the community with an alcohol use disorder and experimentally inducing positive and negative affect in order to see how affective manipulations affected approach and avoidance inclinations. Approach and avoidance were measured using multiple methods, including via questionnaire and cue reactivity. Attentional bias was measured by tracking eye movements during a decision making task. Based on the previous review of the literature, the proposed study had three aims:

Aim 1. To examine the effect of affect on cue-induced approach and avoidance inclinations. <u>Hypothesis 1a</u>: We predicted a main effect of affect manipulation on approach inclinations, such that those in the negative affect condition would report higher approach inclinations when compared to those in the positive condition. <u>Hypothesis 1b</u>. We predicted a main effect of affect manipulation on avoidance inclinations, such that those in the positive affect condition would report higher avoidance inclinations when compared to those in the negative condition.

Aim 2. To examine the effect of affect on measures of attentional bias. <u>Hypothesis 2</u>: We predicted a main effect of affect manipulation on attentional bias, such that those in the negative affect condition would show more attentional biases in favor of alcohol cues when compared to those in the positive condition.

Aim 3. To examine the relationship between approach and avoidance inclinations and measures of attentional bias. <u>Hypothesis 3a.</u> We predicted that approach inclinations would be a significant predictor of initial dwell location (i.e., which image was viewed first) and initial saccade latency (i.e., how long it took to focus on the first image viewed) toward alcohol cues. <u>Hypothesis 3b.</u> We predicted that avoidance would significantly moderate the association between approach and initial dwell duration (i.e., how long the initial image viewed was focused



on before looking away) and total dwell time (i.e., how much time was spent viewing each image during a trial, such that those low on avoidance would have higher initial dwell duration and total dwell time than those with high avoidance.



## Method

#### **Participants**

Participants (N=60) were recruited from the community using both newspaper and Craigslist advertisements. Inclusion criteria were: (a) must be between the ages of 18-65 years b) have a current diagnosis of an alcohol use disorder (initial screening with the AUDIT  $\geq 8$ , confirmed with the M.I.N.I. during the intake interview) Exclusion criteria were: (a) acute psychosis or severe cognitive impairment (assessed via Psychotic Module of the MINI; as indicated by a score of less than 23 on the MINI Mental State Exam), (b) those at high risk for suicide as indicated by a score of 8 or greater on the Suicide Behaviors Questionnaire (SBQ), (c) current drug use diagnosis other than nicotine or marijuana abuse, (d)lack of sufficient familiarity with the English language to comprehend the recruitment and consent procedures, (e) current or previous treatment for AUDs within the past 6 months, including medications to that may modify alcohol use (e.g., disulfiram, naltrexone). The average age of participants was 47.302 years old (SD = 12.103 years, with 65% of them male. Approximately 12% identified their ethnicity as Hispanic, and over half of participants identified their race as African American (51.7%; Caucasian 40%; Asian 1.7%; Native Hawaiian or Pacific Islander 1.7%; Multi-racial 1.7%; other 3.4%). Average years of education was 13.422 (SD = 2.704), 51.7% were employed, and 61.7% had incomes of less than \$20,000 (20% made \$20-40k; 6.7% \$40-60k; 10% \$60-80k; 1.7% \$80-100k). Participants reported drinking 35.87 (SD = 43.25) drinks on average per week and a mean AUDIT score of 20.68 (SD = 7.61). See table 1 for means, standard deviations, and correlation matrix for additional alcohol related variables.



## Materials

**Equipment.** A laptop computer with an external 23" Dell monitor and headphones will be used to display instruction slides and substance cues for the cue reactivity and the alcohol decision making tasks, as well to play music. A SensoMotoric Instruments (SMI) RED250MOBILE Eye Tracker will be used to track eye movements during the alcohol decision making task. The SMI RED250MOBILE is a binocular system with a sampling rate of 250 Hz, which captures a sufficient amount of detail to allow for the analysis of rapid saccadic eye movements.

**Cues.** Thirty images representing alcoholic beverages (n=15; 5 beer, 5 hard liquor, 5 wine), non-alcoholic beverages (n=10), and food (n=5) will be presented to participants during the cue reactivity and decision making tasks; the same set of images will be used in both tasks. Images will vary by setting (e.g., bar, restaurant, home, neutral background) and activity state (e.g., beverage sitting untouched on a table, held in hand, or actively consumed). When possible brand names and identifying symbols, as well as images with affective content, will be excluded to avoid contamination. The beverage images that will be used are part of the Normative Appetitive Picture System (NAPS; Stritzke et al., 2004), which has been validated for measuring both approach and avoidance in multiple independent samples (e.g., Curtin et al., 2005; Schlauch, Breiner, et al., 2013; Stritzke et al., 2004). Additionally, 108 images will be used to manipulate affect (54 positive affect and 54 negative affect) from the International Affective Picture System (IAPS; Lang, Bradley, & Cuthbert, 2008); positive and negative images will be matched on normed levels of arousal.



#### Measures

**Cue reactivity ratings.** For each cue ratings of approach and avoidance will be given via self-report. Participants will rate approach and avoidance by answering the following questions: 1) "How much do you want to consume the item right now?" and 2) "How much do you want to avoid consuming the item right now?" Both questions will be answered using a 9-point likert type scale, ranging from 0 ("not at all") to 8 ("very much"). Participants will be instructed to rate approach and avoidance scales as independent and asked to rate the images quickly according to their initial reactions. Similar procedures have been used to collect approach and avoidance ratings successfully in both clinical and non-clinical samples (Curtin et al., 2005; Schlauch, Breiner, et al., 2013; Schlauch, Gwynn-Shapiro, et al., 2013b; Stritzke et al., 2004). Cue reactivity ratings will be used to investigate aims 1 and 3.

Approach and Avoidance of Alcohol Questionnaire. The Approach and Avoidance of Alcohol Questionnaire (AAAQ; McEvoy et al., 2004) is a 14-item craving measure based on the AMC that assesses approach and avoidance inclinations toward consuming alcohol. The AAAQ has been independently validated in independent samples to measure approach and avoidance in both clinical and non-clinical samples (Klein & Anker, 2012; Klein et al., 2007; McEvoy et al., 2004). The AAAQ will be used in exploratory post-hoc analyses.

**Demographics.** Demographic information including gender, age, race, ethnicity, employment status and income, and education will be collected using a self-report questionnaire.

**Drinking History Questionnaire.** Alcohol use will be assessed using the Drinking History Questionnaire (DHQ). The DHQ is a 10-item survey based on work by Cahalan, Cisin, and Crossley (1969) that measures an individual's quantity and frequency of current and past



alcohol use and their subjective experiences and beliefs related to their own use. The DHQ will be used to conduct post-hoc exploratory analyses.

**Positive and Negative Affect Schedule.** The Positive and Negative Affect Schedule (PANAS; Watson et al., 1988) will be used to assess affect. The PANAS is a 20-item self-report measure that assesses positive (PA) and negative (NA) affect. Participants will indicate how much they are currently experiencing the 20 emotions measured by the PANAS by rating each one on a 5 point scale ranging from 1 (very slightly or not at all) to 5 (extremely). The PA and NA subscales of the PANAS have been shown to be reliable (Watson et al., 1988), and the instrument may be used to assess different periods of time (e.g., in the moment, today, past few days, past few weeks, in general). The PANAS will be used to determine baseline and post affect manipulation levels of positive and negative affect.

Alcohol Use Disorders Identification Test. The Alcohol Use Disorders Identification Test (AUDIT; Saunders, Aasland, Babor, De La Fuente, & Grant, 1993) is a brief 10-item measure frequently used to screen for potentially hazardous drinking. The AUDIT assesses the average quantity and frequency of alcohol consumed, drinking behaviors, and problematic outcomes related to drinking; a score of 8 or higher is considered indicative of problematic use. The AUDIT will be used to conduct post-hoc exploratory analyses.

Alcohol Dependence Scale. The Alcohol Dependence Scale (ADS; Skinner & Allen, 1982) is a 25-item measure that assesses drinking thoughts and behaviors, as well as negative psychological and physiological consequences. The ADS will be used to conduct post-hoc exploratory analyses.



**Drinker Inventory of Consequences.** The Drinker Inventory of Consequences (DrInC; Miller, Tonigan, & Longabaugh, 1995) is a 50-item questionnaire that measures negative consequences of drinking across 5 domains: physical, intrapersonal, social responsibility, interpersonal, and impulse control. The DrInc will be used to conduct post-hoc exploratory analyses.

**Depression Anxiety Stress Scales.** The short version of the Depression Anxiety Stress Scales (DASS-21; Lovibond & Lovibond, 1995) is a 21-item measure that assesses depression, anxiety, and stress that was proposed at the same time as the original 42-item version. The DASS-21 correlates strongly with the original DASS, as well as other measures of depression, anxiety and stress, has cleaner factor loadings than the original measure, and is valid and reliable for use in clinical and non-clinical samples (Antony, Bieling, Cox, Enns, & Swinson, 1998). The DASS will be used to conduct post-hoc exploratory analyses.

Affect Lability Scale Short Form. The Affect Lability Scale Short Form (ALS-SF; Oliver & Simons, 2004) is based on the 54-item Affect Lability Scale (Harvey, Greenberg, & Serper, 1989). The ALS-SF, an 18-item measure that assesses affective instability, has been found reliable and valid with both clinical and non-clinical samples (Look, Flory, Harvey, & Siever, 2010; Oliver & Simons, 2004). The ALS-SF will be used to conduct post-hoc exploratory analyses.

MINI Mental State Exam. The MINI Mental State Exam (MMSE; Folstein, Folstein, & McHugh, 1975) is a 19-item instrument that assesses cognitive functioning. A score of less than 23 out of 30 is indicative of severe cognitive impairment. The MMSE will be used to screen potential participants for study eligibility.



**Modified Drinking Motives Questionnaire – Revised.** The modified Drinking Motives Questionnaire – Revised (mDMQ-R; Grant, Stewart, O'Connor, Blackwell, & Conrod, 2007) is a 28-item measure that assesses five different motivations to use alcohol: enhancing social experiences, peer pressure to use alcohol, enhancing positive emotions, coping with anxiety, and coping with depression. The mDMQ-R will be used for exploratory post-hoc analyses.

**Stages of Change Readiness and Treatment Eagerness Scale.** The Stages of Change Readiness and Treatment Eagerness Scale (SOCRATES; Miller & Tonigan, 1996) is a 19-item instrument that assesses motivation to change in problem drinkers. The SOCRATES includes three subscales: problem recognition, ambivalence, and taking steps to change. The SOCRATES will be used to conduct post-hoc exploratory analyses.

**Readiness to Change Questionnaire.** The Readiness to Change Questionnaire (RCQ; Rollnick, Heather, Gold, & Hall, 1992) is a brief 12-item instrument that assesses motivation to change drinking behaviors. The RCQ will be used to conduct post-hoc exploratory analyses.

# Procedure.

Participants meeting criteria for an AUD were recruited from the community using newspaper and Craigslist advertisements. Potential participants were screened over the phone and informed that they were being recruited for a two hour study examining people's responses to pictures associated with common habits in which they will a) rate images of commonly consumed items, b) complete a decision making task, and c) fill out self-report questionnaires about their attitudes, beliefs, and past and present behavior. Participants were compensated with a \$50 Walmart gift card after completing the study. Eligible participants who gave informed consent and chose to enroll were randomly assigned to one of the following groups based on



order of study enrollment: positive affect induction (PAI) or negative affect induction (NAI). All participants will complete both phase I and II of study procedures.

**Phase I.** Participants completed the PANAS followed by the cue reactivity and decision making tasks, counter balanced within experimental condition. Participants also provided PANAS ratings after each of the tasks.

In the cue reactivity task participants viewed and rated 30 images from the NAPS (15 alcohol images, 10 nonalcoholic beverage images, and 5 food images). At the beginning of each image rating trial a preparatory slide was presented for four seconds to focus participants' attention on the screen. Following the preparatory slide a substance cue image was presented for six seconds before a 30 second rating/relaxation period. Based on previous studies using similar procedures (e.g., Schlauch, Crane, et al., 2015) it was expected that participants would complete their ratings in approximately 20 seconds, leaving them around 10 seconds to relax before the next preparatory slide. "Approach," and "Avoidance" ratings were obtained for each image presented.

In the decision making task participants were presented with side by side image pairs on a computer screen in front of them and asked to indicate which image contained more calories by pressing the right or left button on a response controller. Thirty images from the NAPS (15 alcohol images, 10 non-alcoholic beverage images, and 5 food images) were be used to form the image pairs, with each image pair consisting of one alcohol cue and one non-alcohol cue. Each image was used four times, to create a total of 60 trials. Images were presented in four back to back blocks without any breaks in between, with each block consisting of each image being shown once. The image order and side of the screen presented on (left or right) was randomized within each block. Eye movements during the task were recorded using the SMI



RED250MOBILE Eye Tracker to assess attentional bias. Similar procedures in previous studies (e.g., Schotter, Berry, McKenzie, & Rayner, 2010; Schotter, Gerety, & Rayner, 2012) have been used successfully to detect attentional bias.

Phase II. At the beginning of phase II participants completed another PANAS (mood rating). Following the PANAS, affect was manipulated by having participants view images while listening to music (Emery & Simons, 2015; Treloar & McCarthy, 2012; Wardell, Read, Curtin, & Merrill, 2012). Thirty-six images from the IAPS were displayed during the initial affect manipulation phase consistent with participant's assigned condition (positive or negative stimuli). The PAI group viewed images with positive valence, NAI viewed images with negative valence. Additionally, while viewing the slides each group listened to instrumental classical music with positive or negative valence depending on their experimental group. Following affect manipulation participants completed the PANAS again. Participants then completed the cue reactivity and decision making tasks in the same order as during phase I. Between the first and second tasks, participants viewed eighteen more IAPS slides while listening to music, both of which will be affectively consistent with their experimental condition (i.e., PAI or NAI). Participants also provided PANAS ratings after each of the tasks as in phase I.

## **Data Analysis**

**Preliminary Analyses.** Prior to analyses, all variables were examined for outliers and violations of normality. Outliers with values outside of the median  $\pm$  two interquartile ranges (IQRs) were reined in and replaced with the value of the median  $\pm$  two IQRs. Repeated measures ANOVAS were conducted to assess positive and negative affect at baseline to establish homogeneity of groups and to determine whether or not the affect manipulation was successful.



One way ANOVAS were also used to analyze difference scores between pre and post manipulation affect in order to evaluate group heterogeneity of affect manipulation strength.

Eye Tracking. Missing data of 6 lines or less (presumed to be blinks; approximately 100 milliseconds) were interpolated linearly and those trials were included in analyses. Trials were excluded where the initial dwell location was not recorded, the total viewing time was not captured correctly, or the initial saccade latency was less than 80 milliseconds (Mulckhuyse, Van der Stigchel, & Theeuwes, 2009). Participants with less than 50% of trials were not retained for analyses. A total of 3 participants were excluded from analyses due to computer malfunctions and an additional 18 were excluded because they were below the 50% threshold, leaving 39 participants for eye tracking analyses. The mean percentage of trials present for the 39 participants included was 84.23% with a standard deviation of 9.19%; the median number of trials was 85.83%, the range was from 58% to 96%, and 72.8% of participants had data available for over 80% of trials. Additionally, of those trials included, 58.21% of them included sampling data that was interpolated. The initial dwell location DV used is the percentage of trials in which participants initially oriented on the alcohol cue. Initial saccade latency, initial dwell time, and total viewing time DVs were calculated by subtracting values for non-alcohol cues from values for alcohol cues; therefore, negative values for initial saccade latency indicate bias toward alcohol cues, while positive values for initial dwell time and total viewing time indicate bias toward alcohol cues.

Aim 1. To examine the influence of positive and negative affect on cue-induced inclinations to approach and avoid alcohol. We predicted a main effect of affect manipulation on approach inclinations, such that those in the negative affect condition would report higher approach inclinations when compared to those in the positive condition (Hypothesis 1a). In



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addition, we predicted a main effect of affect manipulation on avoidance inclinations, such that those in the positive affect condition would report higher avoidance inclinations when compared to those in the negative condition (Hypothesis 1b). To examine this aim, repeated measures ANOVAs were conducted analyzing group differences in ratings of approach and avoidance reported during the cue reactivity task.

Aim 2. To examine the influence of positive and negative affect on measures of attentional bias. We predicted a main effect of affect manipulation on attentional bias, such that those in the negative affect condition would show more attentional biases in favor of alcohol cues when compared to those in the positive condition (Hypothesis 2). Similar to Aim 1, to examine Aim 2 repeated measures ANOVAs were conducted to analyze group differences on several eye-tracking indices including initial dwell location, initial saccade latency, initial dwell duration, and total dwell time captured during the decision making task.

**Aim 3.** To examine the relationship between approach and avoidance inclinations and measures of attentional bias. We predicted that approach inclinations would be a significant predictor of initial dwell location and initial saccade latency toward alcohol cues (Hypothesis 3a). We also predicted that avoidance would significantly moderate the association between approach and initial dwell duration and total dwell time, such that those low on avoidance will have higher initial dwell duration and total dwell time than those with high avoidance (Hypothesis 3b). To examine this aim, regression analyses were conducted using data from phase I for eye-tracking DVs, with both approach, avoidance, and their interaction entered as predictors. All predictors were centered around the mean prior to creating interaction terms. For significant interactions, follow-up analyses were conducted examining approach at low versus high levels of avoidance (defined at the 15<sup>th</sup> and 85<sup>th</sup> percentile).



#### Results

## **Affect Manipulation**

In testing the positive affect induction, repeated measures ANOVA revealed that the interaction between administration time and condition was not significant, F(6,330) = 1.41, p = 0.338. While positive affect did change significantly over time, F(6,330) = 6.098, p < .001, these changes were not influenced by which condition participants were in. Additionally, a one way ANOVA showed that the positive (M = 33.400, SD = 10.601) and negative conditions (M = 31.800, SD = 11.409) did not differ significantly in positive affect at baseline, F(1,58) = 0.317, p = 0.576. These findings indicate that the positive affect induction did not significantly change positive affect in the positive condition (see figure 1).

A repeated measures ANOVA conducted to test the negative affect induction found a significant interaction between condition and time, F(6,330) = 7.388, p < .001. A one way ANOVA did not detect a significant difference in negative affect between positive (M = 12.750, SD = 4.032) and negative conditions (M = 13.300, SD = 5.484) at baseline, F(1,58) = 0.196, p = 0.660). There were significant differences in negative affect among groups, such that participants in the negative group had higher levels of negative affect than the positive group at time points 4 (following initial affect manipulation) and 6 (following booster affect manipulation; see figure 2). These findings indicate that the negative affect induction was successful at inducing negative affect in the negative condition.



Aim 1

A 2x2 repeated measures ANOVA was conducted in order to test hypothesis 1a, that the negative condition would report higher approach inclinations. The findings indicated that the interaction between Time (Block 1 versus Block 2) and Condition (Positive affect versus Negative Affect induction) was non-significant, F(1,57) = 0.968, p = 0.329,  $\eta p^2 = 0.017$ . Further, there was no main effect of time, F(1,57) = 0.040, p = 0.843,  $\eta p^2 = 0.001$  or condition, F(1,57) = 0.281, p = 0.598,  $\eta p^2 = 0.005$ .

A 2x2 repeated measures ANOVA was also conducted to test hypothesis 1b, that the positive condition would have higher avoidance inclinations following mood induction when compared to those in the negative affect condition. Results indicated there were no significant interaction between time and condition, F(1,57) = 0.003, p = 0.956,  $\eta p^2 = 0.032$ . The main effects of time, F(1,57) = 0.003, p = 0.175,  $\eta p^2 = 0.001$  and condition F(1,57) = 0.296, p = 0.589,  $\eta p^2 = 0.005$  were also non-significant.

# Aim 2

A series of 2x2 repeated measures ANOVAS were conducted in order to test hypothesis 2, that those in the negative condition would show attentional bias on eye tracking measures including initial saccade latency, initial dwell location, initial dwell time, and total viewing time. There were no significant differences found on any of the indices measured (initial saccade latency, F(1,37) = 1.806, p = 0.187,  $\eta p^2 = 0.047$ ; initial dwell location, F(1,37) = 0.086, p = 0.771,  $\eta p^2 = 0.002$ ; initial dwell time, F(1,37) = 3.031, p = 0.090,  $\eta p^2 = 0.076$ ; total viewing time, F(1,37) = 3.663, p = .063,  $\eta p^2 = 0.090$ ). The main effect for time was non-significant for initial saccade latency, F(1,37) = 0.150, p = 0.700,  $\eta p^2 = 0.004$  and total viewing time, F(1,37) = 0.150, p = 0.700,  $\eta p^2 = 0.004$  and total viewing time, F(1,37) = 0.150, p = 0.700,  $\eta p^2 = 0.004$  and total viewing time, F(1,37) = 0.150, p = 0.700,  $\eta p^2 = 0.004$  and total viewing time, F(1,37) = 0.150, p = 0.700,  $\eta p^2 = 0.004$  and total viewing time, F(1,37) = 0.150, p = 0.700,  $\eta p^2 = 0.004$  and total viewing time, F(1,37) = 0.150, p = 0.700,  $\eta p^2 = 0.004$  and total viewing time, F(1,37) = 0.150, p = 0.700,  $\eta p^2 = 0.004$  and total viewing time, F(1,37) = 0.150, p = 0.700,  $\eta p^2 = 0.004$  and total viewing time, F(1,37) = 0.150.



2.161, p = ..150,  $\eta p^2 = 0.055$ ). The main effect of time was significant for initial dwell location, F(1,37) = 7.787, p = 0.008,  $\eta p^2 = 0.174$  such that participants were more likely to initially dwell on control images during block 2 than in block 1. The main effect of time for initial dwell time was also significant, F(1,37) = 5.641, p = 0.023,  $\eta p^2 = 0.132$ ; participants had shorter initial dwell times on alcohol images in block 2 than in block 1.

## Aim 3

Multiple regression was conducted to test hypothesis 3a, which stated that approach would predict initial saccade latency and initial dwell location. Results indicated that the association between approach and initial saccade latency and initial dwell location was not significant (see Table 2). Multiple regression analyses were also conducted to test hypothesis 3b, that avoidance would moderate approach in predicting initial dwell time and total viewing time; however, neither approach nor avoidance had significant associations with initial dwell time or total viewing time (see Table 2).

## Exploratory

Multiple regression was conducted to test an exploratory hypothesis, namely that baseline positive and negative affect will predict baseline approach and avoidance as measured with the cue reactivity task. The results indicated that neither positive nor negative affect were significant predictors of avoidance, while only negative affect was a significant predictor of approach (see Table 4).

A series of multilevel models were estimated to test the exploratory hypothesis that severity of alcohol dependence (measured using the ADS) would moderate aims 1 and 2. There was a significant three way interaction between Time, Condition, and severity predicting



approach (b = -0.140, SE = .055, p = .013), such that among those with higher levels of severity the negative condition reported lower approach scores (see Figure 3). The multilevel model specified was also a significant predictor of avoidance (b = -0.128, SE = .052, p = .016); among those with higher severity the negative condition had higher levels of avoidance (see Figure 4). Examining the eye-tracking variables, the severity of alcohol dependence did not interact with Time and Condition to predict initial saccade latency (b = -0.890, SE = 1.624, p = .587), initial dwell time (b = 5.632, SE = 4.725, p = .242), initial dwell location (b = -0.005, SE = .004, p = .196), or total viewing time (b = -9.471, SE = 5.721, p = .107).

A series of multilevel models were also estimated to test the exploratory hypothesis that readiness to change (measured using the action subscale of the RCQ) would moderate aims 1 and 2. The three way interaction between Time, Condition, and readiness to change was not a significant predictor of approach (b = 0.091, SE = .108, p = .403) or avoidance (b = -0.003, SE = .114, p = .979). Examining the eye-tracking variables, readiness to change did not interact with Time and Condition to predict initial saccade latency (b = 4.561, SE = 2.893, p = .124), initial dwell time (b = 4.501, SE = 8.679, p = .607), initial dwell location (b = 0.002, SE = .009, p = .823), or total viewing time (b = -10.516, SE = 10.569, p = .327).



# Table 1

Means, standard deviations, and correlations of alcohol related variables

	Variable	Mean	SD	1	2	3	4	5	6	7	8	9	10	11	12	13
1	AUDIT	20.68	7.61	-												
2	AAAQ Approach	5.37	1.66	.75**	-											
3	AAAQ Avoidance	2.65	1.72	26*	27*	-										
4	ADS	15.03	7.72	.80**	.78**	-0.11	-									
5	Drinking Quantity	4.95	2.12	.56**	.37**	-0.23	.51**	-								
6	Drinking Frequency	6.12	5.03	.56**	.45**	-0.25	.60**	.53**	-							
7	Ph 1 Cue Approach	4.54	1.95	.32*	.48**	51**	.31*	0.18	.38**	-						
8	Ph 2 Cue Approach	4.50	2.21	0.22	.38**	45**	0.22	0.17	0.17	.75**	-					
9	Ph 1 Cue Avoidance	3.20	2.01	-0.13	-0.19	.54**	-0.08	0.04	-0.09	69**	58**	-				
10	Ph 2 Cue Avoidance	3.47	2.23	-0.15	-0.23	.56**	-0.09	-0.06	-0.08	56**	77**	.75**	-			
11	Ph 1 In Dwell Loc	0.45	0.07	0.18	0.21	-0.09	0.08	-0.03	0.15	0.19	-0.02	-0.28	-0.18	-		
12	Ph 2 In Dwell Loc	0.41	0.10	0.02	0.04	-0.18	-0.09	0.12	0.14	.38*	0.3	-0.26	-0.23	.38*	-	
13	Ph 1 In Sac Latency	7.52	24.60	0.18	0.26	-0.04	.45**	-0.01	0.08	0.16	0.22	-0.17	-0.16	0.08	-0.06	-
14	Ph 2 In Sac Latency	6.05	27.34	0.07	0.01	0.17	0.26	0.11	0.16	0.18	0.15	0.2	0.2	-0.15	-0.04	0.22
15	Ph 1 In Dwell Time	-64.33	106.47	0.06	0.25	-0.09	0.15	-0.07	0.04	0.17	0.07	-0.06	-0.1	0.15	0.09	0.28
16	Ph 2 In Dwell Time	-23.18	89.36	0.07	0.18	0.12	-0.01	-0.16	-0.02	-0.03	0.06	0.23	0.11	0.11	0.02	0.02
17	Ph 1 TVT	-38.57	122.57	-0.09	-0.06	-0.09	0.02	-0.17	0	-0.08	-0.14	0.11	0.1	0.08	-0.13	.39*
18	Ph 2 TVT	-9.71	108.89	0.06	0.06	-0.06	-0.05	-0.01	0.02	-0.08	-0.11	0.17	0.11	0.16	0.21	0.03

Note: SD = Standard Deviation, AAAQ = Approach and Avoidance of Alcohol Questionnaire, ADS = Alcohol Dependence Scale, Ph = Phase, In = Initial, Loc = Location, Sac = Saccade, TVT = Total Viewing Time, \*\* Correlation is significant at the 0.01 level, \*\* Correlation is significant at the 0.05 level.
# Continued

		14	15	16	17
15	Ph 1 In Dwell Time	-0.02	-		
16	Ph 2 In Dwell Time	-0.01	.44**	-	
17	Ph 1 TVT	0.15	.48**	0.22	-
18	Ph 2 TVT	-0.04	.50**	.52**	.51**

Note: SD = Standard Deviation, AAAQ = Approach and Avoidance of Alcohol Questionnaire, ADS = Alcohol Dependence Scale, Ph = Phase, In = Initial, Loc = Location, Sac = Saccade, TVT = Total Viewing Time, \*\* Correlation is significant at the 0.01 level, \*\* Correlation is significant at the 0.05 level.



Multiple regression of approach and avoidance predicting eye tracking measures for aim 3

			95.0% CI B				
<b>R</b> <sup>2</sup>	Predictor	В	Lower	Upper	SE(B)	В	р
0.04	Initial Saccade Latency (Constant)	8.457	-0.799	17.713	4.560		0.072
	Approach	1.191	-4.053	6.435	2.583	0.094	0.647
	Avoidance	-1.254	-6.697	4.190	2.682	-0.102	0.643
	Approach x Avoidance	0.201	-1.876	2.279	1.023	0.037	0.845
0.04	Initial Saccade Latency (Constant)	8.050	-0.078	16.178	4.008		0.052
	Approach	1.220	-3.940	6.380	2.544	0.096	0.635
	Avoidance	-1.451	-6.427	3.525	2.454	-0.118	0.558
0.13	Initial Dwell Location (Constant)	0.445	0.420	0.471	0.013		0.000
	Approach	0.002	-0.012	0.016	0.007	0.057	0.770
	Avoidance	-0.013	-0.028	0.002	0.007	-0.368	0.085
	Approach x Avoidance	-0.004	-0.010	0.002	0.003	-0.265	0.146
0.08	Initial Dwell Location (Constant)	0.454	0.431	0.477	0.011		0.000
	Approach	0.001	-0.013	0.016	0.007	0.041	0.837
	Avoidance	-0.009	-0.023	0.005	0.007	-0.253	0.205
0.05	Initial Dwell Time (Constant)	-53.987	-93.731	-14.243	19.577		0.009
	Approach	10.486	-12.030	33.002	11.091	0.190	0.351
	Avoidance	6.979	-16.395	30.354	11.514	0.131	0.548
	Approach x Avoidance	3.976	-4.944	12.896	4.394	0.169	0.372
0.03	Initial Dwell Time (Constant)	-62.031	-97.317	-26.745	17.398		0.001
	Approach	11.049	-11.353	33.451	11.046	0.201	0.324
	Avoidance	3.084	-18.519	24.687	10.652	0.058	0.774
0.15	Total Viewing Time (Constant)	-45.706	-92.209	0.796	22.906		0.054
	Approach	-0.788	-27.133	25.558	12.977	-0.012	0.952
	Avoidance	3.155	-24.195	30.504	13.472	0.052	0.816
	Approach x Avoidance	-2.917	-13.354	7.520	5.141	-0.108	0.574
0.11	Total Viewing Time (Constant)	-39.805	-80.804	1.195	20.216		0.057
	Approach	-1.201	-27.230	24.828	12.834	-0.019	0.926
	Avoidance	6.013	-19.088	31.114	12.377	0.098	0.630

Note: B=unstandardized beta; B=standardized beta; SE=standard error; CI=confidence interval



# Means of experimental variables by condition

		Positive			Negative			Total	
	Mean	Ν	SD	Mean	Ν	SD	Mean	Ν	SD
Phase 1 Cue Approach	4.59	29	1.89	4.50	30	2.05	4.54	59	1.95
Phase 2 Cue Approach	4.74	29	2.21	4.28	30	2.22	4.50	59	2.21
Phase 1 Cue Avoidance	3.05	29	2.03	3.34	30	2.03	3.20	59	2.01
Phase 2 Cue Avoidance	3.33	29	2.35	3.60	30	2.15	3.47	59	2.23
Phase 1 Initial Saccade Latency	14.78	18	24.65	1.29	21	23.35	7.52	39	24.60
Phase 2 Initial Saccade Latency	5.86	18	24.55	6.22	21	30.13	6.05	39	27.34
Phase 1 Initial Dwell Time	-32.79	18	84.90	-91.37	21	117.26	-64.33	39	106.47
Phase 2 Initial Dwell Time	-22.39	18	83.99	-23.85	21	95.79	-23.18	39	89.36
Phase 1 Initial Dwell Location	0.45	18	0.07	0.45	21	0.07	0.45	39	0.07
Phase 2 Initial Dwell Location	0.40	18	0.10	0.41	21	0.10	0.41	39	0.10
Phase 1 Total Viewing Time	-7.13	18	82.18	-65.52	21	145.44	-38.57	39	122.57
Phase 2 Total Viewing Time	-15.05	18	103.19	-5.14	21	115.88	-9.71	39	108.89

Note: SD = Standard Deviation.

			95.0%	O CI B			
<b>R</b> <sup>2</sup>	Predictor	В	Lower	Upper	SE(B)	В	р
0.08	Approach (Constant)	2.180	-0.159	4.518	1.167		0.067
	Positive Affect	0.028	-0.020	0.075	0.024	0.153	0.248
	Negative Affect	0.114	0.007	0.221	0.053	0.279	0.038
0.01	Avoidance (Constant)	3.504	0.996	6.012	1.252		0.007
	Positive Affect	-0.013	-0.063	0.038	0.025	-0.069	0.614
	Negative Affect	0.008	-0.107	0.123	0.057	0.020	0.886

Multiple regression of baseline positive and negative affect predicting phase 1 cue approach and avoidance ratings

Note: B=unstandardized beta; B=standardized beta; SE=standard error; CI=confidence interval





Figure 1. Repeated Measures ANOVA for the positive affect induction





Figure 2. Repeated Measures ANOVA for the negative affect induction





Figure 3. Interaction between Time, Condition, and Severity predicting Approach.





Figure 4. Interaction between Time, Condition, and Severity predicting Avoidance



#### Discussion

The current study sought to examine the influence of both positive and negative affect on alcohol craving (i.e., approach and avoidance), as conceptualized by the AMC. While previous literature has shown a link between negative affect and craving (approach), most research has failed to examine the influence of both positive and negative affect on both approach and avoidance inclinations. However, recent research has shown the importance of examining both affect and craving as bi-dimensional constructs (i.e., positive and negative affect and approach and avoidance). We sought to replicate and extend the findings of a correlational study (Schlauch, Gwynn-Shapiro, Stasiewicz, Molnar, & Lang, 2013a) that found significant associations between positive and negative affect and avoidance, using experimental methods which included both positive and negative affect induction. Additionally, we investigated associations between positive and negative affect and attentional biases toward alcohol cues, as well as between approach and avoidance and attentional biases.

The primary aim of the current study was to determine whether manipulating positive and negative affect would influence approach and avoidance ratings of alcohol cues. We hypothesized that the negative affect condition would exhibit higher approach inclinations toward alcohol on a cue reactivity task; this hypothesis was not supported as no group differences were found. Of note, while past studies have found that inducing negative affect has caused approach inclinations (e.g., Cooney et al., 1997; Fox et al., 2007), the current study did not. One possible reason for this difference is that the aforementioned studies used different methods of inducing negative mood, namely a guided imagery procedure. The guided imagery



paradigms used in those studies required participants to recall a previous negative situation that they recently experienced, which may have also evoked memories of alcohol cravings that went along with those experiences. Another key difference in the cited studies is that they both utilized treatment samples of individuals with an AUD. While the current sample met criteria for an AUD, they were not treatment seeking and thus it may be that this difference in treatment status affected how craving (i.e., approach and avoidance) was influenced by negative mood. Of note, Mason et al. (2008) used a similar affect induction method with IAPS images in a sample of alcohol dependent non-treatment seeking individuals and also found that the negative affect condition did not result in increased craving. Further, although the negative affect induction was successful, the mean change was only approximately seven points, or less than one point per item on the PANAS. The resulting change in negative affect was of medium effect size (d =(0.382; Cohen, 1988) as compared to the rather large effect size (d = 1.255) found by Cooney et al. (1997) in their study that found inducing negative affect increased approach inclinations (Fox et al., 2007 did not report sufficient information necessary to calculate effect sizes for their affect manipulation). While the change in our study was a significant increase, it was a modest one and possibly not strong enough to elicit craving in the present sample, which already showed fairly high levels of approach inclinations.

We further hypothesized that the positive affect condition would show higher avoidance ratings for alcohol cues; this hypothesis was also not supported, unsurprisingly as the positive affect induction was unsuccessful, despite using previously validated methods (e.g., Emery & Simons, 2015; Treloar & McCarthy, 2012; Wardell, Read, Curtin, & Merrill, 2012). While these methods have been used successfully in the past, it is important to note that the samples were all comprised of college students, as opposed to the current study which sampled members of the



community who met criteria for an AUD. Students in those samples drank an average of approximately 15-18 drinks per week, while in the current sample the mean was approximately 36 drinks per week. Additionally, the mean number drinking occasions per week that participants in our sample drank was over 6, and the quantity of drinks per occasion was approximately 5, indicating that many of them were binge drinking nearly every day. As participants had to refrain from drinking in order to participate in this study, consistent with the opponent process model (Solomon & Corbit, 1974), this may have suppressed their positive mood. In fact, we saw a trend across both groups in which positive affect decreased as time passed.

Considering our findings, exploratory analyses examined whether baseline positive and negative affect predicted baseline approach and avoidance as measured by the cue reactivity task in phase I. While neither positive nor negative affect were significant predictors of avoidance, we did find that negative affect was a significant predictor of approach. These findings failed to replicate the novel results of Schlauch et al. (2013a), which found that positive affect predicted decreased approach and increased avoidance toward alcohol cues. As with Cooney et al. (1997) and Fox et al. (2007), Schlauch and colleagues used a treatment sample in their study, namely patients in an acute detoxification unit. As our sample was non-treatment seeking, and given the fact that Mason et al. (2008) had similar findings to ours with regard to negative affect and craving in a non-treatment seeking alcohol dependent sample, it may be that treatment status influences how affect elicits approach and avoidance. Indeed, as avoidance is more predictive of abstinence during and after treatment (e.g., Stritzke et al., 2007), it may be that avoidance is related to positive affect in treatment seekers because it is more likely that those higher in avoidance will be more successful in treatment, which elicits positive mood. It may be that alcohol avoidance inclinations and positive affect are only related among those who are actively



attempting to reduce or eliminate their drinking. As such, we examined the influence of readiness to change on aims 1 and 2 as a proxy for treatment status. Multilevel models were constructed to examine whether readiness to change interacted with Time and Condition to predict group differences in approach and avoidance, as well as our eye-tracking variables of interest; however, we did not find that readiness to change was a significant moderator.

Lastly we explored whether severity of alcohol use moderated time and condition for aims 1 and 2. Findings showed that the 3-way interaction between severity, Time, and Condition was a significant predictor of approach and avoidance, but not the eye-tracking indices. Contrary to what we would have hypothesized we found that, among those high in severity, participants in the negative condition had lower approach and higher avoidance than those in the positive condition. One possible factor that may explain this discrepancy is the method we used to induce negative affect. The images used included some stimuli that may have elicited thoughts of negative consequences of drinking, such as a man vomiting, auto accidents, and a battered woman and child. As those with the highest severity of alcohol use are more likely to have experienced negative consequences as a result of their drinking, it may be that these cues only affected the approach and avoidance ratings of those highest in severity.

A strength of the current study was the inclusion of psychophysiological methods of measuring craving, namely attentional bias indices as measured by eye-tracking methodology. Thus, a secondary aim was to determine whether affect manipulation would influence attentional bias toward alcohol cues. Initial saccade latency and initial dwell location are thought to be representative of automatic approach mechanisms, while initial dwell time and total viewing time are thought to be more effortful and controlled involving avoidance. We hypothesized that the negative affect condition would show attentional bias compared to the positive condition on



eye tracking measures including initial saccade latency, initial dwell location, initial dwell time, and total viewing time. This hypothesis was not supported as there were no significant differences found on any of these measures between the positive and negative conditions.

These findings were partly in contrast to a previous study (Bradley, Garner, Hudson, & Mogg, 2007) which found that smokers in a negative mood induction group showed attentional bias for smoking cues as indicated by initial dwell location, however, they did not display bias when comparing initial dwell time. Another study using a sample of heavy drinking college students found that drinking to cope was an important factor in how affect manipulations influence attentional bias (Field & Powell, 2007). Among those with high drinking to cope motives, participants in the stress condition showed attentional bias on a dot probe task while those in the control group did not. However, among those with low drinking to cope motives attentional bias was not found in either condition. These findings were later replicated in a subsequent sample of social drinking college students (Field & Quigley, 2009). In light of these findings we explored whether this phenomenon was present in our data, and while we did find some trends in the expected direction for initial saccade latency, we did not find any significant results. It is important to note that the present study is likely not sufficiently powered to handle this type of three way interaction and the analyses resulted in small and uneven cell sizes with heterogeneous variances. Despite our failure to replicate the moderating effects of drinking to cope on attentional bias and affective manipulation, this previous research highlights the importance of potential moderators and how they may function differently in varying populations, namely in clinical versus non-clinical samples. As previously mentioned, our sample was comprised of individuals who met criteria for alcohol use disorder and engaged in binge drinking six times per week on average; as such, it is not surprising that a variable such as



drinking motives might function differently in clinical samples with signs of physiological alcohol dependence than in samples comprised of college student drinkers.

A further secondary aim of the study was to examine the relationship between approach and avoidance inclinations and eye-tracking measures of attentional bias. We hypothesized that approach would be associated with initial dwell location and initial saccade latency; however, the findings did not support these hypotheses. We further hypothesized that approach would be moderated by avoidance in predicting initial dwell time and total viewing time. This hypothesis was not supported; no significant associations were found between approach or avoidance and initial dwell time or total viewing time.

As previously mentioned, a recent meta-analysis showed support for an association between craving and attentional bias (Field et al., 2009). Field and colleagues found that the strength of the association significantly varied depending on factors such as method of measuring attention (direct measures r = .36, indirect measures r = .18, p = .001) and strength of craving at the time of measurement (high r = .23, low r = .08, p = .015). However, despite these findings, the results of subsequent research on this subject have been mixed. In fact, later research involving the same author failed to find an association between attentional bias (i.e., reaction time and dwell time) and alcohol consumption, AUDIT score, and craving (Christiansen, Mansfield, Duckworth, Field, & Jones, 2015), causing them to conclude that "theoretical models of attentional biases in substance use disorders may require some modification (p. 173)." In other attentional bias research, a study examining personalized alcohol related stimuli in the alcohol stroop task failed to find any differences in attentional bias between alcohol dependent participants and non-alcohol dependent control participants (Fridrici et al., 2013); a further study with heavy social drinkers failed to find an association between attentional



bias (i.e., reaction time and dwell time) during the dot probe task and ad lib drinking, however they did find that approach predicting the amount of alcohol consumed (Christiansen, Cole, & Field, 2012). Loeber et al. (2009) also failed to find an association between attentional bias measured using the dot probe task and both severity of alcohol dependence and craving among alcohol dependent participants in treatment; however, they did find a negative correlation between duration of alcohol dependence and attentional bias. Follow up analyses showed that those with shorter durations of dependence were biased toward alcohol (i.e., had faster reaction times when the probe replaced alcohol cues), while those with longer durations of dependence did not exhibit any bias. The authors theorized that, consistent with incentive habit theories of addiction (e.g., Di Chiara, 2000), "the effect of incentive sensitization processes on behavior diminishes as addiction progresses because of a switch to more habit-based responding (p. 201)." Although these findings may help to explain inconsistent attentional bias and craving research, we were unable replicate this finding in the current study; as mentioned earlier, this may be due to our study being underpowered to detect these interactions. Nevertheless, the findings of Loeber and colleagues highlight the possibility that potential unidentified moderators may be important in the study of how affect influences attentional biases in individuals with AUD.

### Limitations

The current study is not without limitations. A significant limitation of this study is the small sub-sample of only 39 participants available for eye-tracking analyses. We are unsure why our data resulted in the exclusion of so many participants, as the procedures we followed usually result in very little data loss. Although this low number of participants may have resulted in insufficient power for some analyses, it does not appear as though it affected aim 2, as the means for all eye-tracking indices post-manipulation are very similar for the positive and negative



conditions (see table 2). However, insufficient power may have influenced the findings for aim 3, as evidenced by the large confidence intervals of the regression beta coefficients seen in Table 2. Additionally, the small amount of data available likely affected our ability to find potentially significant moderating effects that were found in previous research. Future research examining this issue would benefit from larger sample sizes to ensure that the analyses are carried out with adequate power.

Of note, the current study was originally designed to be carried out using a sample of individuals currently undergoing inpatient treatment for AUD who were within their second week of treatment. Due to logistical complications, we changed our recruitment strategy to focus on individuals who met diagnostic criteria for AUD but were not undergoing treatment. Much of the previous literature cited in this paper that studied affect and craving used treatment samples; we were unable to find any literature that investigated these effects in samples of our type. This may help to explain our failure to not only replicate but extend previous findings of positive and negative affect differentially predicting approach and avoidance inclinations for alcohol (Schlauch, Gwynn-Shapiro, et al., 2013a). Additionally previous literature (e.g., Levine et al., 2019) suggests that avoidance strengthens as a function of treatment; it may be that among those in treatment positive affect helps to reinforce the life changes one is making, and thus increases their avoidance inclinations. Consistent with this idea, Marlatt and Donovan (2005) highlight the importance of cultivating positive affect through pleasant activities as an important coping skill to help prevent relapse. Additional research is needed to investigate how changes in affect influence craving in individuals who are undergoing treatment for AUD in order to help elucidate this issue.



### Conclusions

Despite our failure to replicate previous research findings that negative affect inductions increase approach inclinations for alcohol, or extend cross-sectional findings that positive affect is related to avoidance, we continue to feel that the ways in which positive and negative affect differentially influence approach and avoidance is an important topic worthy of future study. Of note, studies we cited that found an increase in negative affect was predictive of alcohol approach inclinations used personalized guided imagery techniques focusing on previous stressful situations, as opposed to the current study which used non-personalized negative IAPS images and classical music to induce general negative affect. It may be that stress is a more specific type of negative affect which elicits craving, while more generalized negative affect may not. Additionally, as noted earlier, these personalized guided imagery techniques may have increased craving by eliciting memories of previous stressful situations in which they wanted to drink. Future research in this area would do well to investigate the differences between personalized and non-personalized affect manipulations, as well as differences between stress and more generalized negative affect in eliciting craving.

Our study also failed to find an association between affective manipulation and attentional bias and craving and attentional bias. As highlighted in the discussion and limitations section, our study resulted in small sample sizes of data available to analyze for our eye-tracking variables of interest, which may have influenced our null findings. Additionally, we are likely underpowered to detect significant three-way interactions that have been found in past research necessary to determine whether moderators such as drinking to cope and length of alcohol dependence may be important in answering our research questions. As such we are unsure whether the results of the current research are a due to a lack of actually occurring phenomenon



or a lack of power necessary to carry out analyses including potential moderators that might help to answer these questions. Future research would benefit from larger sample sizes and the inclusion of potential moderators to help investigate associations between affect and attentional biases and craving.



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# Appendix A



RESEARCH INTEGRITY AND COMPLIANCE Institutional Review Boards, FWA No. 00001669 12901 Bruce B. Downs Blvd., MDC035 • Tampa, FL 33612-4799 (813) 974-5638 • FAX(813)974-7091

6/8/2017

Jacob Levine

Psychology

4202 E Fowler Ave

PCD4118G

Tampa, FL 33620

RE:Full Board Approval for Initial ReviewIRB#:Pro00029660Title:Mood and Decision Making

# Study Approval Period: 4/21/2017 to 4/21/2018

Dear Mr. Levine:

On 4/21/2017, the Institutional Review Board (IRB) reviewed and **APPROVED** the above application and all documents contained within, including those outlined below.

Approved Item(s): Protocol Document(s): Study Protocol Ver 1 05.25.2017

Consent/Assent Document(s)\*: Consent Ver 1 05.10.2017.docx.pdf


\*Please use only the official IRB stamped informed consent/assent document(s) found under the "Attachments" tab. Please note, these consent/assent documents are valid until the consent document is amended and approved.

#### **Research Involving Prisoners as Participants (45 CFR 46, Subpart C)**

This research involving prisoners as participants was approved under 45 CFR 46.305(a) and 46.306(a)(2): (i) Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects.

As the principal investigator of this study, it is your responsibility to conduct this study in accordance with IRB policies and procedures and as approved by the IRB. Any changes to the approved research must be submitted to the IRB for review and approval via an amendment. Additionally, all unanticipated problems must be reported to the USF IRB within five (5) calendar days.

We appreciate your dedication to the ethical conduct of human subject research at the University of South Florida and your continued commitment to human research protections. If you have any questions regarding this matter, please call 813-974-5638.

Sincerely,

1 CAn

Kristen Salomon, Ph.D., Vice Chairperson

USF Institutional Review Board



**Appendix B** 



# Informed Consent to Participate in Research Involving Minimal Risk

IRB Study # Pro00029660

You are being asked to take part in a research study. Research studies include only people who choose to take part. This document is called an informed consent form. Please read this information carefully and take your time making your decision. Ask the researcher or study staff to discuss this consent form with you, please ask him/her to explain any words or information you do not clearly understand. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

We are asking you to take part in a research study called: Mood and Decision Making

The person who is in charge of this research study is Jacob A. Levine. This person is called the Principal Investigator. However, other research staff may be involved and can act on behalf of the person in charge. He is being guided in this research by his faculty advisor, Robert C. Schlauch, Ph.D.

The research will be conducted in the Department of Psychology at the University of South Florida.

#### **Purpose of the study**

The purpose of this study is to gain a better understanding of how mood influences decision making as it relates to drinking alcohol. Greater understanding of this topic has the potential to aid in future development of interventions targeting people with problematic alcohol use.

#### Why are you being asked to take part?



We are asking you to take part in this research study because you responded to our advertisement and met criteria during telephone screening.

#### **Study Procedures:**

Participation in this study will consist of a single session that takes approximately two hours. If you take part in this study, you will be asked to:

- Answer questions regarding: basic demographic information, mood, and alcohol use.
- Give ratings in response to alcoholic and non-alcoholic photographs.
- Complete a decision making task comparing the caloric content of food and beverages.

# **Total Number of Participants**

We anticipate enrolling 90 individuals to participate in this study at USF.

## **Alternatives / Voluntary Participation / Withdrawal**

You do not have to participate in this research study.

You should only take part in this study if you want to volunteer. You should not feel that there is any pressure to take part in the study. You are free to participate in this research or withdraw at any time.

#### **Benefits**

We are unsure if you will receive any benefits by taking part in this research study. However, participants may learn more about alcohol use disorders and their impact on individual functioning. This increased knowledge may increase motivation to remain abstinent or moderate future substance use.

## **Risks or Discomfort**

This research is considered to be minimal risk. However, you may be asked to view images that are graphic in nature and trauma related. It is possible that viewing these images may cause discomfort. You may choose to discontinue participation at any time for any reason if these images or any other aspect of the study are too distressing. Further, although we make every effort to keep the information you provide to us confidential, you may decline to answer any questions that you are afraid may affect your legal status.

Additionally, you may experience some discomfort due to answering questions about anxiety, mood, and alcohol use as well as from viewing pictures of alcohol and other substances. Further, there is a risk of breach of confidentiality. However, numerous security measures are in place to keep the information you report confidential. Data collected for research purposes will be stored in locked file cabinets or password-protected files in the Department of Psychology at USF. For the purpose of scientific publication, only group means will be reported, and individual participants will never be identified. To ensure participant anonymity, a separate list with the participants' names and signed consent forms will be stored in a different location from the data and only the research staff will have access to this file.

# Compensation

Individuals completing the eligibility screening in-person at USF will be compensated with a \$10 Walmart gift card. Participants who enroll in the study will complete a two hour session in which they



will 1) fill out self-report questionnaires about their attitudes, beliefs, and past and present behavior and 2) rate images of commonly consumed items and complete a decision making task comparing the caloric content of food and beverages. Participants will be compensated with a \$40 one-time payment in the form of Walmart gift cards after completing the two hour study. Thus, total compensation for completing all study activities (in-person screening, 2-hour session) is \$50 in gift cards.

# Costs

Participants agreeing to participant may incur costs associated with transportation to and from the research site. There will be no additional costs to you as a result of being in this study.

# **Conflict of Interest Statement**

The researchers do not have any conflicts of interest in this study.

# **Privacy and Confidentiality**

We will keep your study records private and confidential. Certain people may need to see your study records. Anyone who looks at your records must keep them confidential. These individuals include:

- The research team, including the Principal Investigator, research assistants, and all other research staff.
- Certain government and university people who need to know more about the study, and individuals who provide oversight to ensure that we are doing the study in the right way.
- The USF Institutional Review Board (IRB) and related staff who have oversight responsibilities for this study, including staff in USF Research Integrity and Compliance.

However, in some circumstances, we are required to break confidentiality.

The following disclosures are **NOT CONFIDENTIAL**, and require research staff to notify the proper parties (including law enforcement) and/or potential victims:

- Maltreatment of children, elderly individuals, or people with developmental disabilities;
- When suicide or homicide is intended;
- When we must warn a potential victim of possible harm;

We may publish what we learn from this study. If we do, we will not include your name. We will not publish anything that would let people know who you are

#### You can get the answers to your questions, concerns, or complaints

If you have any questions, concerns or complaints about this study, or experience an unanticipated problem, call Jacob Levine at (813) 974-0839.

If you have questions about your rights as a participant in this study, or have complaints, concerns or issues you want to discuss with someone outside the research, call the USF IRB at (813) 974-5638 or contact by email at RSCH-IRB@usf.edu.



#### **Consent to Take Part in this Research Study**

I freely give my consent to take part in this study. I understand that by signing this form I am agreeing to take part in research. I have received a copy of this form to take with me.

Signature of Person Taking Part in Study

Date

Printed Name of Person Taking Part in Study

#### **Statement of Person Obtaining Informed Consent**

I have carefully explained to the person taking part in the study what he or she can expect from their participation. I confirm that this research subject speaks the language that was used to explain this research and is receiving an informed consent form in their primary language. This research subject has provided legally effective informed consent.

Signature of Person Obtaining Informed Consent Date

Printed Name of Person Obtaining Informed Consent

