

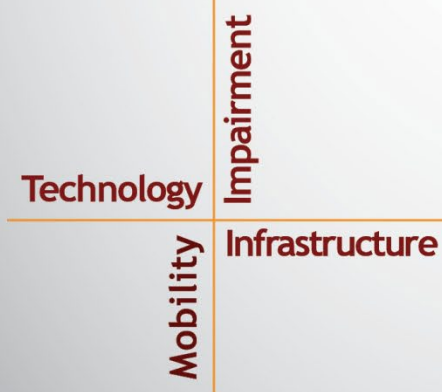
# NSTSCCE

## National Surface Transportation Safety Center for Excellence

### Naturalistic Driving Study on Cannabis Use in Washington and Virginia

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## EXECUTIVE SUMMARY

This study examined the consumption behavior of cannabis users and its influence on driving performance through a comprehensive naturalistic driving study (NDS) conducted in Washington and Virginia. The study aimed to address gaps in research by leveraging real-world data to evaluate how cannabis consumption impacts driver behavior, safety-critical events, and crash risk.

### Objectives and Approach

The study's objectives included assessing the prevalence of driving under the influence of cannabis (DUIC), examining variations in impairment across different consumption methods and doses, and exploring the relationships between self-reported intoxication levels and objective performance metrics. Participants were selected based on their regular cannabis use and self-reported DUIC history. Data was collected via in-vehicle instrumentation, a smartphone-based journal app, breathalyzer readings, and oral fluid tests.

### Results

The study offered key insights into the impact of self-reported cannabis consumption on driving behavior, with cannabis trips occurring alongside sober trips with similar frequency and temporal distributions. Self-reported substance use data revealed that cannabis consumption methods differed between regions, with dabs being the preferred form in Washington and smoking cannabis flower (e.g., joints, pipes, bowls) dominating in Virginia. Polysubstance use, particularly with alcohol, was prevalent, with 13.7% of Washington and 20.1% of Virginia journal entries involving multiple substances. Breathalyzer data showed that 20% of Washington's and 14.5% of Virginia's alcohol-positive trips exceeded the 0.08% blood alcohol concentration (BAC) limit. Quantisal oral fluid tests highlighted variations in tetrahydrocannabinol (THC) levels, with mean delta-9 THC levels significantly higher in Washington (1,662 ng/ml) compared to Virginia (260.9 ng/ml). While 85% of Quantisal tests were successfully submitted, challenges such as outlier THC readings due to participant noncompliance with testing protocols were noted, indicating the complexity of linking subjective impairment levels to objective performance metrics.

### Implications

The findings highlight the complexity of DUIC and the need for further research to inform public policy, law enforcement practices, and safety guidelines. The dataset provides a valuable resource for understanding cannabis-related driving risks and developing targeted interventions.

### Future Research

Further analyses should explore the nuanced effects of cannabis potency, user tolerance, and polysubstance interactions on driving performance. Enhanced data collection techniques could improve the reliability of future studies.



# TABLE OF CONTENTS

LIST OF FIGURES.....	v
LIST OF TABLES.....	vii
LIST OF ABBREVIATIONS AND SYMBOLS .....	ix
CHAPTER 1. INTRODUCTION.....	1
BACKGROUND .....	2
<i>Cannabis Impairment</i> .....	2
<i>How the Body Processes Cannabis</i> .....	3
<i>Does Cannabis Impact Driving Performance?</i> .....	4
<i>Combined Impairment Effects of Cannabis and Alcohol</i> .....	6
<i>Relationship Between Cannabis Impairment and Estimated Crash Risk</i> .....	7
<i>Relationship Between Risk Perception and DUIC</i> .....	8
CHAPTER 2. METHODS .....	11
PARTICIPANT RECRUITMENT .....	11
SUBSTANCE USE DATA COLLECTION.....	16
<i>Intake Questionnaires</i> .....	16
<i>Self-Reported Substance Use Journal Entries</i> .....	17
<i>Compliance</i> .....	25
CHAPTER 3. RESULTS.....	27
DATA ANALYSIS APPROACH.....	27
SUMMARY RESULTS.....	27
<i>Demographic Information</i> .....	27
<i>Driving Under the Influence of Cannabis</i> .....	27
<i>Substance Use Journal Entry Results</i> .....	31
<i>Quantisal Test Data</i> .....	33
CHAPTER 4. DISCUSSION .....	37
<i>Limitations</i> .....	38
APPENDIX A. ABBREVIATED RECRUITMENT SCRIPT.....	41
APPENDIX B. ABBREVIATED PARTICIPANT INFORMED CONSENT SHEET .....	43
APPENDIX C. QUANTISAL KIT SAMPLE INSTRUCTIONS .....	53
APPENDIX D. REPRESENTATIVE PHOTOS OF NATURALISTIC DRIVING DATA COLLECTION INSTRUMENTATION .....	55
REFERENCES .....	57



**LIST OF FIGURES**

**Figure 1. Map. Current state of cannabis legalization/decriminalization in the United States (updated as of December 2023, original creation). ..... 1**

**Figure 2. Graph. Report to Congress on rate of THC absorption in plasma after smoking marijuana (Compton, 2017). ..... 4**

**Figure 3. Photo. Substance use data collection equipment. .... 16**

**Figure 4. Diagram. Step-by-step process for substance use journal entry process. .... 18**

**Figure 5. Screen capture. Data diary app sample screenshots of user interface. .... 19**

**Figure 6. Chart. Occurrence of baseline and cannabis trips identified in the dataset. .... 28**

**Figure 7. Chart. Subject-wise comparison of average trip length (mileage) for baseline and cannabis trips. .... 29**

**Figure 8. Chart. Comparison of trip start time based on hour of the day. .... 30**

**Figure 9. Chart. Comparison of trip start time based on day of the week. .... 30**

**Figure 10. Charts. Cannabis consumption methods for Washington and Virginia sites. .... 31**

**Figure 11. Chart. Trip count distribution across participants for different substance types. .... 32**

**Figure 12. Chart. Trip miles distribution across participants for different substance types. .... 32**

**Figure 13. Chart. Delta-8 high and low values of THC results from laboratory tested Quantisal test kits. .... 34**

**Figure 14. Chart. Delta-9 high and low values of THC results from laboratory tested Quantisal test kits. .... 34**

**Figure 15. Chart. Weekly cannabis consumption behavior based on self-reported journal entries. .... 35**



## LIST OF TABLES

<b>Table 1. Recorded contacts from different recruitment advertising methods.....</b>	<b>14</b>
<b>Table 2. Facebook (FB) recruitment statistics. ....</b>	<b>14</b>
<b>Table 3. Data Diary App cannabis selections of consumption form with dosing quantities and explanations.....</b>	<b>21</b>
<b>Table 4. Journal entry options for daily prescription and over-the-counter drugs.....</b>	<b>23</b>
<b>Table 5. Demographic information. ....</b>	<b>27</b>
<b>Table 6. Substance use journal entries.....</b>	<b>31</b>



## **LIST OF ABBREVIATIONS AND SYMBOLS**

ADAS	advanced driver assistance systems
BAC	blood alcohol concentration
BrAC	breath alcohol concentration
CoC	Certificate of Confidentiality
DUIC	driving under the influence of cannabis
FARS	Fatality Analysis Reporting System
NDS	naturalistic driving study
THC	tetrahydrocannabinol
VTTI	Virginia Tech Transportation Institute





(e.g., driving slowly, allowing larger headways) (Riexinger et al., 2019a, 2019b; Dean & Riexinger, 2022; Terranova et al., 2022). This human behavior complexity also makes it difficult to find generalizable findings from experimental studies that would apply to an authentic real-world traffic situation (Compton, 2017).

Naturalistic driving studies (NDSs) may hold a key to resolving the discrepant research findings regarding the effects of cannabis on driving performance. NDSs utilize unobtrusive in-vehicle instrumentation within a participant's own vehicle as they go about their daily routines, allowing a precise assessment of driving performance in real-world conditions that reflect the true task complexity of driving (Hartman & Heustis, 2013; Sarkar et al., 2023; Galloway et al., 2023; Perez et al., 2024; Jain, 2025). About a decade ago, the Virginia Tech Transportation Institute (VTTI) conducted the Rocky Mountain NDS pilot study ( $n = 23$ ) in Colorado at the time of recreational legalization. The Rocky Mountain NDS study's primary objective was to assess the efficacy of collecting data on cannabis use in relation to driving performance. Analyses determined that a high percentage of participants completed the daily substance use surveys (69% of expected journals completion) and that oral fluid assessments could be linked to a specific drive in a large proportion (74%) of the samples obtained. Preliminary analyses also indicated that hard braking rates were higher among participants when they were cannabis-positive versus negative, possibly reflecting higher levels of inattention after consumption. However, reliably linking the plentiful daily substance use surveys to actual driving data proved troublesome. Consequently, to date, no other substantial or significant findings associated with cannabis use and driving performance have emerged from the NDS data collection (Jain, 2025).

Thus, while informative, the Rocky Mountain NDS experience suggested the need for a comprehensive and user-friendly set of approaches to accurately capture self-reported qualitative and quantitative data of cannabis use in relation to specific driving trips. As a result, VTTI engaged in the current effort, intended to collect cannabis consumption and associated driving data within the states of Washington (which has legalized recreational cannabis for a decade) and Virginia (which was at the onset of recreational legalization in July 2021 but it remains only decriminalized at this point). The intention of this study was to collect naturalistic driving data that could not only be analyzed on its own but also could be compared to the data collected from participants enrolled in the Rocky Mountain NDS. In doing so, the NDS described in this report is the first full-scale NDS among cannabis users. The resulting dataset has the potential to provide new information about the driving behavior of cannabis users in real-world settings, to give insight into variations of self-reported impairment between different substance forms and doses (along with insight into self-reported length of impairments for different user groups), and examine associations between cannabis use, driving performance, and safety-critical event risk.

## **BACKGROUND**

### **Cannabis Impairment**

While the first study of impairment related to cannabis use dates back to the 1960s (Gaoni & Mechoulam, 1964), cannabis was classified as a “controlled” substance within the U.S. in 1970. As such, many advancements in the study of cannabis impairment relative to driving have only emerged within the last two decades as legalization has become more widespread and research has been easier to conduct. While cannabis impairment research studies have used a wide variety

of assessments, many studies share the common approach of assessing psychomotor and cognitive impairment by having user's complete tasks requiring focus to measure executive function, division of attention, decision-making, psychomotor vigilance, and reaction time to motion stimuli.

In medical studies, cannabis has been shown to effect both cognitive and psychomotor abilities. Some of these effects include diminished executive function, difficulty with impulse control, increased risk taking, and slowed reaction time, short-term memory, and visual processing (WHO, 2016). The effects can vary greatly depending on a variety of subjective, cognitive, and psychomotor factors of the user, including tolerance level and frequency of use. To date, however, a biological or behavioral indicator of time of consumption (recent cannabis use) relative to driving impairment does not exist. Some studies have found that diminished psychomotor effects, such as division of attention, error compensation, and postural sway, are found to persist beyond acute intoxication. It is also found that post-acute intoxication there may be continued cognitive effects on impulsivity control and executive function (Károly et al., 2020; Pearce, 2023).

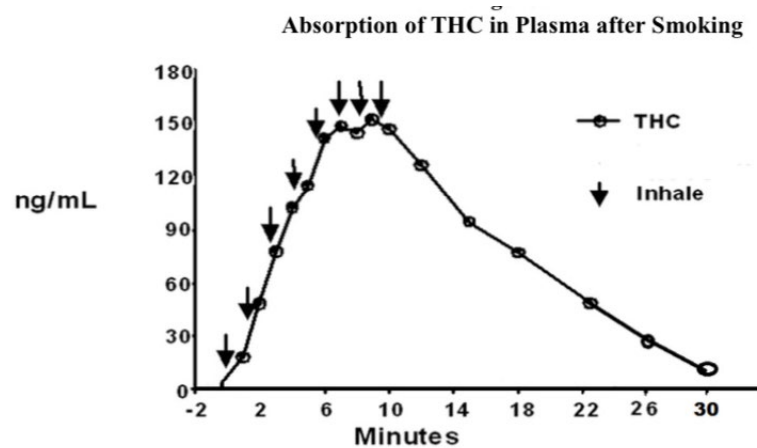
Brain imaging has also been critical in understanding the effects of THC impairment on cerebral function. Cannabis is thought to increase brain metabolism (e.g., expenditure of increased energy, such as actively processing or engaging in complex tasks) in the areas related to attention and motor coordination yet decrease brain metabolism in areas that use visual integration of motion—potentially suggesting mechanisms for possible effects on the driving task as it pertains to required connected cognitive-motor skills. However, brain imaging has also suggested a tolerance effect for heavy users who show little of these effects related to recent cannabis consumption (Bondallaz et al., 2016; Jain, 2021).

In almost all of these studies, impairment effects from cannabis were noted almost immediately after consumption. Where the literature disagrees, however, concerns the reduction rate of impairment levels and the recovery rate of the impaired capabilities. For example, some studies administering low levels of THC found that capabilities recovered after 1 hour duration, while other studies indicated a peak of objective impairment after 1 hour of usage (Hartman and Huestis, 2013; Károly et al., 2020). A meta-analysis of such studies found that most of the impairment effects occur within the first 2 hours of cannabis flower consumption and dissipate entirely 3 to 6 hours after consumption. (Bondallaz et al., 2016). Most recently, a simulator study by the Center for Medical Cannabis Research in San Diego, California, found that 4.5 hours marked the resolution of any THC-associated reduction in driving ability (Marcotte et al., 2022). Most likely, much of this disagreement around the timeline of impairment effects relates to the complicated way the body processes cannabis and differences in study design, as well as participants' natural consumption behavior (e.g., heavy users).

### **How the Body Processes Cannabis**

The way cannabis metabolizes can vary for each individual, which adds complexity to studying its effects. Each user may metabolize this substance at a different rate depending on a variety of factors. Unlike alcohol, cannabis is fat soluble rather than water soluble, so determining the rate at which a certain gender or weight might metabolize this over the course of several hours provides challenges in accurately calculating impairment based on blood, fluid, or urine testing

levels. Certain THC metabolites continue to be stored in blood and urine samples long after impairment subsides, while certain metabolites are found to rapidly decline. For example, within 4 hours of a single acute exposure, blood THC levels can drop rapidly from 100 ng/ml to <2 ng/ml (Figure 2) (Compton, 2017; Brands et al., 2021).



**Figure 2. Graph. Report to Congress on rate of THC absorption in plasma after smoking marijuana (Compton, 2017).**

Gender has also been found to have a varying effect in the way in which level of impairment manifests both cognitively and in psychomotor functionality post cannabis consumption. Self-reported cognitive effects of cannabis appear to not vary by sex and are reported equally by males and females. This is interesting despite higher blood concentrations and higher amounts of consumptions by males. Females often report more symptoms of drowsiness when compared to males (Brands et al., 2021).

To add further complexity, the form of the substance (e.g., oil, combustion of plant matter “flower,” edibles, tinctures) may vary in potency and the rate at which the body processes it. Edibles can take from 30 minutes to 2 hours for the body to process depending on the individual (Centers for Disease Control and Prevention, 2024). However, most studies that administer titrated doses to participants have been exclusive to smoked marijuana flower. With impairment levels varying between frequency of use, it is imperative that future research include varying participant user profile types with different substance consumption forms to further test these theories. It is also important to note that the majority of today’s potencies for cannabis sit at the 19%–22% level of THC, while past studies were only testing low potencies in the 1%–3% range (Brands et al., 2021). More research is needed to determine the effect of higher potencies that have gradually increased for both recreational and medical cannabis in legalized states.

### **Does Cannabis Impact Driving Performance?**

THC, the main psychoactive compound in cannabis, can impact motor functioning, cognition, and attention, which can potentially impair an individual’s ability to operate a motor vehicle (Rogeberg et al., 2018). THC’s effects can be time dependent. The most effective way to determine *recent* use of cannabis is through blood sampling. While peak blood concentrations

can occur 10 minutes after consumption for certain drug delivery methods, they rapidly drop and are found at low detection levels 4–8 hours post-consumption (Bondallaz et al., 2016).

However, this estimate may vary due to individual metabolism, the form of drug delivery (i.e., most studies examine smoking administration only and do not take into account edibles, food and drink, cannacaps, tinctures, topicals, or patches), the range of THC concentrations in cannabis products, and the range of psychoactive versus non-psychoactive metabolites. Research to date, for example, has been unable to account for variances in blood concentrations based on substance form and tolerance level (McCartney et al., 2022). Inactive THCOOH (11-nor-9-carboxy-tetrahydrocannabinol, which is a metabolite of THC) concentrations, in addition, may be detectable for days or even weeks after consumption and could be inaccurately associated with cannabis impairment long after the psychoactive effects have worn off (McCartney et al., 2022).

Simulator studies have generally been regarded as the safest method for testing cannabis impairment and driving performance, especially for high THC concentration administrations. However, the artificial simulation environment also has many limitations, including the nearby presence of experimenters and the lack of the actual consequences of “crashing” (Hartman and Heustis, 2013; Smiley, 1999; Lenne et al., 2010; Gieringer et al., 1988; Lugiori, Gatto, and Robinson, 1998; Chait and Parry, 1994; Valente et al., 2023; Jain & Perez, 2025). Moreover, the same driver is generally not followed over time, so it is unknown if any effects of recent use of cannabis on driving performance are moderated by routine use (e.g., adaptation to driving under the influence), or if driving performance and risk vary in combination with other drugs, or if cannabis use patterns influence driving real-world decision-making or driving risk management, such as speed and following distances (Terranova & Perez, 2023). Naturalistic driving methods are needed to address these types of questions.

Early studies using driving simulators indicated some degradation of driving performance (e.g., reduced lane keeping ability) combined with less risky driving behavior in the form of slower speeds and longer headway (Hartman and Heustis, 2013; Rafaelsen et al., 1973; Smiley, 1999). More recent studies have found that divided attention tasks, reaction time measurement, urgent task response, and critical tracking of tasks are most affected after recent cannabis use for both occasional and moderate users. These effects are attributed to a THC-induced increased mental capacity load, making information processing more difficult and therefore impairing performance ability on a central task. In heavy users, however, this effect can be minimal or negligible, with one study indicating an improvement in driving performance after THC inhalation—potentially indicative of an adaptation to long-term cannabis exposure (Bondallaz et al., 2016). Other studies have failed to find any measurable THC effects on sensory elements such as visual processing or on sensory discrimination, time perception, and headway variability (McCartney et al., 2022). These discrepancies in findings may be due to an array of reasons, including the varying effects of THC on different individuals and variations in study design, including dosing protocols.

In summary, studies identifying the relationship between the psychomotor and cognitive effects of cannabis and driving performance, and correspondingly crash risk estimates, are thus far inconclusive. While psychomotor and cognitive skills can be observably affected post cannabis consumption, subsequently linking these changes to driving performance can be quite

challenging (Sevigny, 2021). There is also conflicting research on whether neurobehavioral deficits can be long-lasting, even after a prolonged period of abstinence of cannabis in chronic cannabis users (Brown et al., 2021). Furthermore, tolerance development, delivery method of the substance, and timing of consumption all influence how impairment can vary for each individual. Thus, more research is needed to determine the real-world implications of cannabis effects on driving performance in individuals and different subgroups that properly account for these factors (Sevigny, 2021).

### **Combined Impairment Effects of Cannabis and Alcohol**

Cannabis and alcohol are frequently detected together in motor vehicle crashes. The combination of both substances is often considered more harmful than if either substance is used alone (Simmons et al., 2021; Goncalves et al., 2021). Some studies, for example, posit the combination of alcohol and cannabis as a leading cause of fatal impaired-driving crashes (Fowles and Loeb, 2021). A potential reason for these observations is that the combination of alcohol and cannabis has been linked to poor driving performance, affecting a driver's longitudinal and lateral control, along with response time, more intensely than for individuals who are driving under the influence of only alcohol, or only cannabis, and to individuals that are completely sober (Simmons et al., 2022; Terranova et al., 2025). Furthermore, it has been suggested that concurrent users of alcohol and cannabis tend to imbibe frequently and at higher doses of both substances compared to other users and tend to engage more often in impaired driving (Yurasek et al., 2017).

Examining these combined effects can be complicated by the different metabolic processing of alcohol and cannabis by the human body. Alcohol is water soluble, allowing precise measurement of BACs that are highly correlated with driving performance. Alcohol is also metabolized at a relatively stable rate, reducing BAC steadily over time. A BAC of 0.08 g/dL, which is the legal driving limit in most states, would decline after a few hours to < 0.05 g/dL, which is legal in all states. On the other hand, cannabis is fat soluble and is stored and released slowly over time. THC (i.e., delta-9-THC to be specific), the primary psychoactive component of cannabis, peaks about an hour after use, which may or may not reflect peak impairment, and declines rapidly to relatively low levels that are not well correlated with impairment or cognitive performance (Compton, 2017).

Another challenge is that the dose-response relationship between increased blood THC levels and degraded driving performance is not clear. Without such evidence, many legislators have chosen to implement either a zero-tolerance policy or a very stringent one. For example, some jurisdictions have placed a 2–5 ng/ml limit on blood levels of delta-9-THC. This is based on a recent meta-analysis suggesting that ~3 ng/ml blood levels of delta-9-THC were comparable to a BAC level of .05%. However, as noted, cannabis and alcohol may have very different effects on driving performance. Thus, comparisons between delta-9-THC levels and BAC levels have limited practical validity. The ensuing absence of appropriate, repeatable, and consistent sensitivity testing makes it difficult for law enforcement to accurately determine THC level of impairment relative to crash culpability (Brands et al., 2021).

From a neurological standpoint, cannabis and alcohol are both considered in the substance effect category as “depressants” and share activation of a receptor pathway. Cannabis often induces a

lethargic effect and hypervigilance in relation to driving performance. Cannabis-positive drivers are commonly found to have slower reaction time and significantly reduced driving speed. Alcohol-impaired drivers, on the other hand, tend to speed and express overconfidence in driving ability. When these two drugs are combined, performance has been shown to decrease beyond the individual effect of each substance, though findings differ depending on dosages administered (Hartman and Huestis, 2013; Hartman et al., 2016; Simmons et al. 2021).

### **Relationship Between Cannabis Impairment and Estimated Crash Risk**

Internationally, cannabis has increasingly been found to be one of the most common substances detected in drivers involved in road traffic crashes (Christopherson et al., 2016). In this context, the relationship of cannabis impairment to crash risk is often framed in terms of case-control testing, or culpability ratings. The metabolic complexity for cannabis, however, makes it difficult to determine true and accurate culpability when controlling for other factors such as how a THC test was administered. Furthermore, studies rarely take into account polysubstance use, inaccuracy or unreliability in providing the full truth during crash interviews by law enforcement, the long window of THC detection after acute effects have dwindled, the varying levels of THC between time of crash and time of testing (e.g., blood collection 90 minutes post-arrest vs. 3 hours after crash), and uncertainties in the different impacts of THC-positive vs. THC-impaired driving.

An examination of data collected during the National Highway Traffic Safety Administration's (NHTSA) Drug and Alcohol Crash Risk study over a 20-month period, was mostly unable to find any association between cannabis use and risk of crash involvement. The only significant crash risk was observed for older drivers (i.e., age 64 and above), a risk that could also be attributed to age-related declines in cognitive and psychomotor functioning abilities (Johnson et al., 2021). Drug data recorded in the Fatality Analysis Reporting System (FARS) provides conflicting evidence of the association between cannabis and traffic fatalities (Dean et al., 2023). Although collected and managed by NHTSA, researchers have been explicitly warned of the limitations of this dataset and discouraged from using it for drugged driving related research and determining crash risk (Berning & Smither, 2014).

Many state law enforcement agencies operate under the assumption that oral measures of THC concentration provide the best evidence of recent use. Recent use may be associated with cognitive impairment, which may pose a risk to safe driving. More specifically, important THC metabolites include hydroxy THC and carboxy THC, which are detectable in oral fluids and blood as they are released. Hydroxy THC reflects cannabis use in recent days, while carboxy THC reflects cannabis use over several weeks or months. These residual measures of THC reflect patterns of use that may be associated with latent and variable cognitive decrements that may pose a risk to safe driving behaviors, possibly interacting with other drugs such as alcohol (Crean, Crane, and Mason, 2011; Compton, 2017). For example, cannabinoid blood and plasma concentrations were significantly higher in frequent smokers compared with occasional smokers (Moore et al., 2006). In oral fluids, THC levels above 2 µg/L have been detected in occasional smokers for 26 hours while frequent smokers had higher levels for >72 hours (Concheiro, 2013). THC can also be detected in a urine sample for several weeks or longer following the use of cannabis. The main concern with the use of these tests is that, while they have been shown to indicate the amount of THC in the system, those levels have not been directly and reliably linked

to specific levels of impairment at the time of test administration (McCartney et al., 2022). In fact, there is no scientific evidence showing a direct correlation between level of impairment and levels of THC in blood, urine, or oral fluid (Preuss et al. 2021). Detection cutoffs can vary between tests and, particularly when not reported, can lead to questions about the validity of specific studies (Hartman and Huestis, 2013). In addition, toxicology reporting is not always accurate and greatly depends on the cannabinoid validity of the test, as well as the collection method, analytes, storage containers, and environment in which the sample was stored. Finally, many jurisdictions will only pay to test the suspected substances, such as alcohol or cannabis, without a full panel test for all substances. This creates a lack of evidence to isolate the effects of one substance from those of other substances (Woodall et al., 2015).

### **Relationship Between Risk Perception and DUIC**

Estimates suggest that in the United States about 29% of adults report using cannabis in the last month and about 10% report regular use (20+ occasions in the past 30 days) (Patrick et. al., 2022). Relatedly, another study found about 53% of those who reported DUIC drove within an hour after cannabis use (Hill et. al., 2025). In addition, some research suggests that nearly 10% of nighttime drivers may be under the influence of THC (Compton & Berning, 2009; Lacey et al., 2009). Nevertheless, these estimates may suffer from selection bias of specific populations, such as addiction treatment patients with higher risk-taking propensities or those deceased from crashes (Hartman and Huestis, 2013). Thus, to truly understand the prevalence of DUIC, it is important to take into account factors such as an individual's propensity towards risky driving behaviors in conjunction with their propensity to engage in DUIC (Wickens et al., 2022).

Evidence related to risk perception and DUIC is mixed but tends to suggest a limited perception of association between cannabis use and crash risk. Potentially due to legalization and normalization in recent years, the risk perception of youth in the United States in regard to cannabis consumption appears to have decreased (Moncaleano et al., 2019). More generally, recent surveys of drivers who consume cannabis indicated that most drove within 2 hours of consumption, and that the perception of the effects cannabis had on their driving behavior was nonexistent. This latter finding was especially true for individuals categorized as heavy users (Brown et al., 2021). In addition, individuals who actively consume cannabis and choose to drive under the influence were also more likely to perceive low risk of being a passenger in a vehicle driven by someone under the influence of cannabis (Moncaleano et al. 2019).

These findings were supported by a recent simulator study, where at 30 minutes post consumption there was hesitation to drive after smoking cannabis. That hesitation decreased, and confidence in the ability to safely drive increased, at the 90-minute mark. Simulator driving performance, however, indicated a reduction in driving ability and increased likelihood of lane deviation during the drive where confidence was higher (Marcotte et al., 2022). In general, additional real-world research is needed to truly determine the extent of individual self-regulation in relation to perceived level of impairment before making a decision to drive.

Altogether, the evidence described in this chapter suggests that there is still a lot to learn when it comes to DUIC, specifically in real-world settings, where the potential negative consequences are serious. Thus, the research team engaged in an effort to collect data that could relate actual driving performance to reported substance use, particularly cannabis. The resulting database was

designed to have the potential to inform all the aforementioned areas and provide substantial context into what cannabis-impaired driving looks like, how often it happens, and if there are any safety implications.



## CHAPTER 2. METHODS

This effort leveraged two separate studies: an NDS data collection focused on vehicles with advanced driver assistance systems (i.e., minimum requirement of lane-keeping assist and adaptive cruise control features) (Hankey et al., 2024) and a journal-based substance use survey. Participants were required to participate in the NDS in order to be eligible for the substance use study.

The NDS instrumented participants' personal vehicles with data acquisition technology that captured metrics characterizing the vehicle state, kinematics, and location, along with information about the driving environment and video from several camera views (i.e., driver's face, forward roadway, and instrument panel; see Appendix D). For the substance use study, participants were asked to complete (while parked) a drug consumption journal each time they drove. A customized smartphone app, named Data Diary, was developed specifically for this research. After completing the survey questions, participants that reported driving unaccompanied were also asked by the app to complete a breathalyzer sample using a BACtrack Mobile Pro breathalyzer, provided to participants as part of the study. Additionally, about once per month, the app pinged the driver to provide an oral fluid sample using a Quantisal Kit and mail it to the processing laboratory within 48 hours for more comprehensive testing.

Given the naturalistic nature of the study, no drugs were administered to participants, nor any encouragement of drug use was provided. Participants were simply asked to consume as they naturally would and drive as they naturally would. Nevertheless, participants were also provided a resource sheet of information about their local laws related to driving under the influence and a list of both local and national websites and phone numbers to contact should they need information or someone to talk to regarding drugs, drug abuse, or related support.

The primary objective of this study was to collect data that would allow future examination of the variability in driver behavior and risk, including the prevalence of alcohol-, cannabis-, and other drug-positive driving, safety-critical driving events, exposure to different driving environments, and the use and utility of automation, as a function of (1) frequency and amount of routine cannabis use; (2) recent and coincident cannabis use; and (3) driver characteristics such as demographics, previous behavior, and dispositions.

### **PARTICIPANT RECRUITMENT**

The research protocol and all participant materials, including the recruitment script (Appendix A) were approved by Virginia Tech's Institutional Review Board. Participants were first screened for eligibility. Those who were deemed eligible received full details about the two studies, including their rights as volunteer participants. Participants who provided informed consent (Appendix B) then proceeded to complete intake paperwork along with survey questionnaires related to substance use, demographics, driving history, and risk taking.

Participants then scheduled an appointment to drop off their personal vehicle so that research technicians could install the required instrumentation. Equipment to collect substance use information (e.g., BACtrack, Quantisal kits) was then securely and discretely mailed to their home address. Subsequent to this, there was an additional private meeting between the research

team and the participant to train the participant on the smartphone application and on the use of the substance use data collection equipment. Once participants felt comfortable using all of these applications and devices, there was limited interaction between the research teams and the participants, who were expected from that point on to drive and consume substances as they normally would.

Participants were compensated on a recurring monthly basis at a flat rate during their enrollment in the study. They also received hourly rate compensation during consent, intake, training, vehicle instrumentation, and equipment maintenance appointments.

### ***Inclusion Criteria***

In order to be eligible for the cannabis impairment study, participants were first required to participate in the VTTI L2 NDS. The NDS had strict criteria related to vehicle year, make, and model that would support the instrumentation technology. Generally, participants had to drive a vehicle that was 2017 or newer and equipped with ADAS, such as lane keeping assist and adaptive cruise control. The use of these systems was the focus of the VTTI L2 NDS, but they also were expected to add some safety (e.g., by potentially mitigating lane deviations and circumstances leading to hard braking events) to any potential impaired driving that could occur in the cannabis impairment study.

In addition to this vehicle requirement, participants in the cannabis impairment study had to be U.S. citizens or permanent residents over the age of 18 who reported using cannabis at a minimum of two times over the last two weeks, with preference for recreational users who report more frequent use. They also needed to possess a valid U.S. driver's license for at least 1 year. Participants were required to self-report driving at least 3 days/week and at least 5,000 miles per year, on average. Specific to cannabis use, participants had to self-report having previously driven under the influence of cannabis (i.e., within 2 hours after consumption) at some point during their lifetime. While medical users were not excluded, preference was for recreational users given potential differences in typical THC content between medicinal and medicinal marijuana. Ultimately, only one participant in the study reported to be a medical user. Participants self-disclosed race and ethnicity within demographic questionnaires, and efforts were made to balance for these factors as much as possible.

In order to use the app created by VTTI for self-reported substance use journal entries, participants were also required to have a personal smartphone (i.e., not a work phone or one provided by an employer). These smartphones needed internet access outside of at-home Wi-Fi and had to run iOS 10 or greater or Android 8 or greater at the time they were enrolled.

### ***Recruitment Methods***

A variety of recruiting methods with differing degrees of effectiveness were used to find potential participants (Table 1). Contrary to some studies involving only driving, this effort required participants to trust the VTTI organization with very sensitive information about their substance consumption. Therefore, contact approaches where participants could easily find information about VTTI seemed to be more effective. Differences in available advertising

approaches, geographical distance to VTTI, and the availability of dispensaries for recreational cannabis also modified the team's ability to use specific recruitment methods at each study site.

All dispensaries in Spokane, Washington, and within a 2-hour driving radius in the surrounding region were visited. The least frequented dispensary was visited three times over the course of 9 months to distribute flyers, drop off or refill business card displays, or perform parking lot solicitation. The most frequented dispensary was visited 12 times during the 9-month period. The willingness to advertise and advertising location varied by dispensary: some had designated areas for business advertising, others created the space for it around registers, while others were hesitant. The main cause of hesitancy was a potential perception within the state-run Washington State Liquor and Cannabis Board, who issues recreational dispensary licenses, that the dispensary was encouraging patrons to drive under the influence. These dispensaries feared that such perception could potentially lead to a revocation of their business license. Additionally, advertising materials were posted in local coffee shops, restaurants, college campuses, grocery stores, and places of recreation such as dog parks, arcades, and bowling alleys.

Virginia recruitment leveraged participants from a pre-existing database of individuals interested in participating in VTTI driving studies. In particular, many of the contacts made were to current participants of the VTTI L2 NDS, as an additional opportunity given the legalization of recreational cannabis in Virginia during the study period. A researcher either called or emailed individuals from the database and gave them a brief overview of the study. Interested participants who responded were then screened for eligibility by the research team. In-person recruiting booths were also held at local community events, in particular a cannabis legalization event in a convention center.

Recruitment efforts for this study were complicated by the many COVID-19 protocols (e.g., masking, limited business hours, indoor capacity limits) that were still mandated when recruitment began in 2021. Due to these protocols, both Washington and Virginia recruitment relied heavily on virtual recruitment methods via paid radio advertisements; Facebook, LinkedIn, and newspaper advertisements; and interviews with local news agencies. Digital tools, in particular, provided substantial visibility about the engagement of potential participants with the ad content (see Facebook statistics example in Table 2).

**Table 1. Recorded contacts from different recruitment advertising methods.**

Project Location	Completed Volunteer Survey	Craigslist	Event	Word of Mouth	Flyer	LinkedIn	Newspaper	None	Other	Radio	Social Media	VT Newsletter	VTTI Initiated	VTTI Website	Total
Virginia			20	70	1		9	30	30	2	572	5	174	14	<b>927</b>
Washington	2	2		7	3		5	8	12	13	40			1	<b>93</b>
<b>Total</b>	<b>2</b>	<b>2</b>	<b>20</b>	<b>77</b>	<b>4</b>	<b>0</b>	<b>14</b>	<b>38</b>	<b>42</b>	<b>15</b>	<b>612</b>	<b>5</b>	<b>174</b>	<b>15</b>	<b>1,020</b>

**Table 2. Facebook (FB) recruitment statistics.**

	Reach (# who saw/read ads on FB)	Impressions (# of total views on FB)	Unique Link Clicks	Link Clicks	Post Shares	Post Comments	Post Engagement	Post Reactions
<b>Virginia</b>	19,749	21,733	474	484	18	10	530	17
<b>Washington</b>	7,932	9,007	81	83	1	3	92	4

To further facilitate potential participant access to study information, a website providing study details, photos of the instrumentation, and a screening survey for participation was also deployed for both the VTTI L2 NDS and the cannabis impairment study. The website had 395 page views between January 18, 2021, and April 11, 2021. The website stayed active until February 2022.

Interestingly, the most cited reason for non-participation after initial engagement was not having an eligible 2017 or newer vehicle equipped with ADAS features that were required for participation in the larger VTTI L2 NDS. Other cited reasons related to spouse or partner discomfort with the recording equipment and fear of privacy breaches.

### ***Privacy Measures***

Given the sensitive nature of the data collected, substantial privacy measures were taken during this study. First and foremost, a Certificate of Confidentiality (CoC) from the U.S. Department of Health and Human Services National Institutes of Health was obtained. With this certificate, neither the researchers nor study sponsors could be forced to disclose information that may identify the driver, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. This protection was expected to increase reliability and truthfulness in self-reported participant data, particularly for information related to drug use. In line with CoC limitations, participants were encouraged to not share their participation in the study with others.

In addition, all consent sessions were conducted virtually so that participants could be in a comfortable private space where their responses could not be heard. During this session, they were assured that all data they submitted would be assigned a random participant number, ensuring that their personal identifiable information would never be associated with the recorded data. Test results received by the lab were also labeled with randomly generated QR codes that could not be traced back to the participant without the use of an encrypted key available only to a subset of the VTTI researchers participating in the study.

The driving data collected during the study was encrypted in the vehicle and could only be decrypted by authorized research personnel. None of the recorded NDS data was “live,” or viewable in real time. More specifically, data were collected and stored on encrypted USB drives and mailed anonymously and periodically by the participant to VTTI headquarters. In addition, the participant data was only available to researchers for analysis once a driver’s participation period had completely ended and the vehicle was deinstrumented, which was an unusual restriction in NDS research.

As an additional safeguard to external knowledge of their participation in this study, participants were asked during each of their journal entries if they were driving alone that day. Participants were not required to submit a breathalyzer sample or a Quantisal kit (if due within the 30-day window) unless they indicated that they were driving alone. Nevertheless, many participants expressed they were comfortable selecting “yes” for that question when they were in the presence of trusted companions such as a spouse, significant other, family member, or friend.

As a final privacy protection measure, participant enrollment in both studies, and particularly the journal entry data, were kept entirely separate. Participants in the VTTI L2 NDS were assigned

different randomized participant IDs than participants in the cannabis study, even when the two participants were the same person. Data was always stored in secure, encrypted, and password-protected network folders that could only be accessed by researchers approved for data use by the Institutional Review Board.

## **SUBSTANCE USE DATA COLLECTION**

A key element of this data collection effort was the ability to accurately and effectively assess cannabis and other drug use in relation to driving in the same individuals, longitudinally, and using multiple approaches. Since there are currently no noninvasive measures of cannabis use, like a breathalyzer for alcohol, this study used a novel self-reporting procedure to obtain information about recency and amount of use of cannabis, alcohol, and other drugs, along with perceived impairment. In addition, objective information was routinely obtained about alcohol consumption by using breathalyzer data, and cannabis and other drugs occasionally by using oral fluid collection. These objective measures of substance use were expected to allow for periodic validation of the self-reported measures.

Each of these approaches, along with a set of intake questionnaires that provided baseline self-reported information about driving and substance use habits, are discussed in more detail below. The data collection was facilitated by a suite of substance use data collection equipment (Figure 3).



**Figure 3. Photo. Substance use data collection equipment.**

### **Intake Questionnaires**

Questionnaires were administered shortly after participants provided informed consent, via a secure and confidential Qualtrics survey tool:

- *Daily Prescription and Over-the-Counter Drug Use Survey*: This questionnaire captured the use of daily prescriptions and over-the-counter drugs that were not required to be reported in substance use journal entries. However, prescription pills that were taken recreationally without their own prescription, such as Adderall or Xanax, should have been recorded as a “recreational drug” in substance use journal entries.

- *Driving History Questionnaire:* Participants answered questions related to average mileage, speeding citations, length of licensure, crash history, and insurance history to capture a baseline assessment of past potentially risky driving behavior.
- *Discounting Measures Survey:* This questionnaire captured the participant's level of risk perception using decision-making questions. Participants answered a series of prompts to choose their preferred consequence, particularly with respect to their preference for temporal-based rewards (e.g., receiving \$500 now, or waiting 5 years to receive \$1,000).
- *Demographic Survey:* The questionnaire gathered baseline data on sex, weight, height, race, and ethnicity, along with marital status, household status, occupation, and income.

### **Self-Reported Substance Use Journal Entries**

Prior to each driving trip (i.e., while parked at the beginning of the trip), participants were pinged by the Data Diary smartphone app to complete a journal entry about their drug use. This self-report journal entry could usually be completed in less than 1 minute and generally did not take more than 3 minutes. In these entries, participants answered questions related to (1) substance use during that day (i.e., since the participant got up) or since their last trip, including what, how much, and when the participant had consumed alcohol, cannabis, and other drugs; and (2) current and peak levels of intoxication (i.e., based on their perceived level of impairment). If the beginning-of-trip notification to complete a journal entry was ignored, the app sent a reminder at the end of the trip. If the driver confirmed during the journal entry that they were unaccompanied, they were asked to complete, while parked, the breathalyzer test. To facilitate that test, all participants were provided with a BACtrack Mobile Pro,<sup>1</sup> a commercial device that provides information about blood alcohol concentration to the custom mobile app. The BACtrack reading was not visible to the driver.

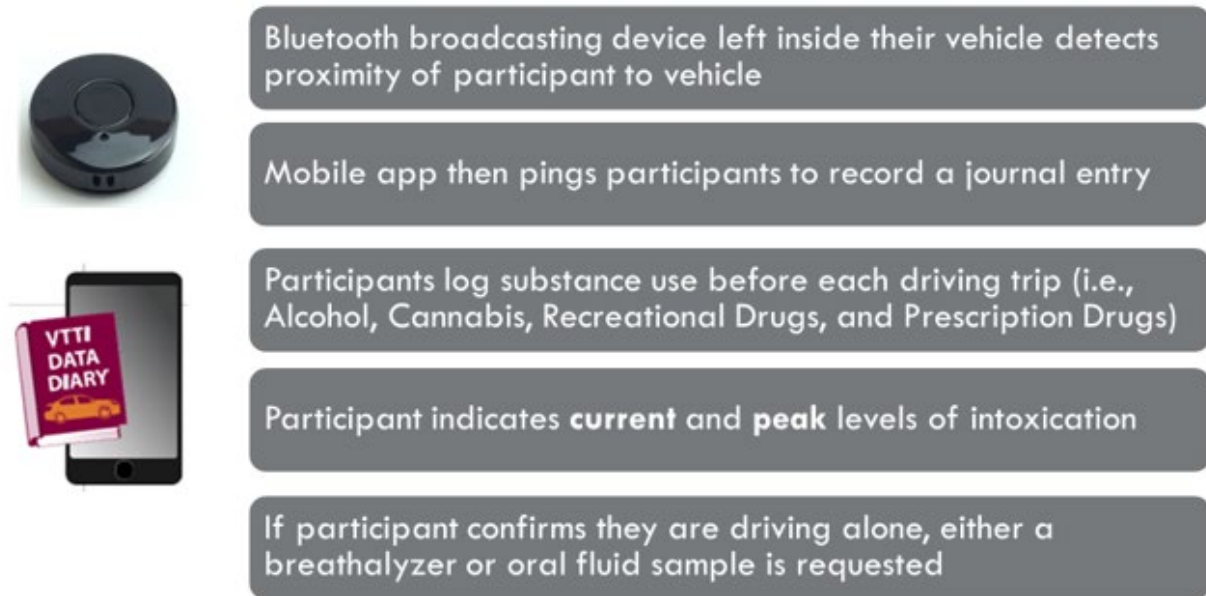
An iBeacon (i.e., a Bluetooth broadcasting device) would prompt the custom mobile phone app to ask participants for an entry as the phone (and presumably the participant) came into proximity with the vehicle. However, participants were instructed to complete a journal entry when entering their vehicle even if they did not receive a ping. This approach was intended to ensure journal entry completion when participants did not have their phone's Bluetooth connection active, when the beacon battery was low or depleted (beacon batteries were replaced every 9 months), or when interference with other devices occurred (e.g., if the smartphone connected to the vehicle's Bluetooth before it connected to the beacon). Researchers provided virtual troubleshooting assistance to correct these issues when notified by participants about their occurrence.

Given the diverse equipment required to support journal entries, the research team spent a considerable amount of effort designing and streamlining the process used by participants. The research team also met with participants, at study onset, for a virtual equipment activation session. During the session, researchers:

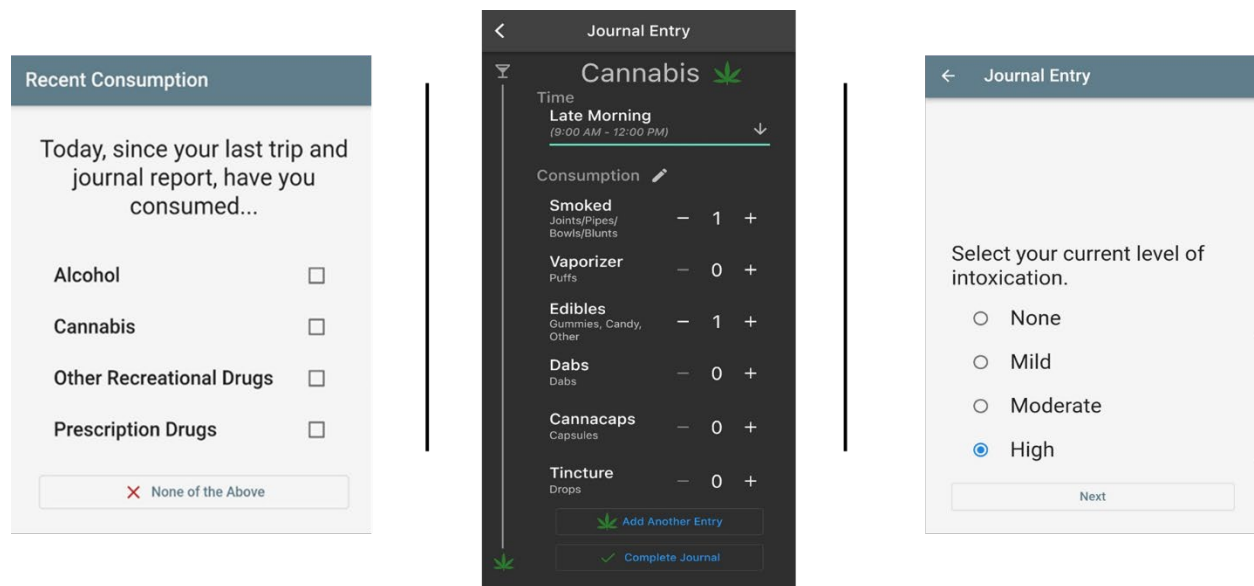
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<sup>1</sup> <https://www.bactrack.com/products/bactrack-c8-breathalyzer#description-tabs4>

- Facilitated the download and activation of the Data Diary app on the participant's smartphone, guiding the participant through completion of a journal entry, including use of the BACtrack using the phone interface (Figure 4 and Figure 5);
- Provided support for placing the battery-powered iBeacon in the vehicle;
- Asked the participant to collect an oral fluids sample using one of the Quantisal kits, with corrective guidance and additional demonstration completed as needed (participants were asked to discard the sample after the session); and
- Answered any questions regarding use of any of the devices.



**Figure 4. Diagram. Step-by-step process for substance use journal entry process.**



**Figure 5. Screen capture. Data diary app sample screenshots of user interface.**

### ***Substance and Dosing App Options***

Participants could report recreational cannabis, alcohol, prescription drug, or other drug use through each journal entry. All substance use reports required an associated time of consumption. The app provided the following time periods as potential options:

- Early Morning (12:00 a.m.–6:00 a.m.)
- Morning (6:00 a.m.–9:00 a.m.)
- Late Morning (9:00 a.m.–12:00 p.m.)
- Afternoon (12:00 p.m.–3:00 p.m.)
- Late Afternoon (3:00 p.m.–6:00 p.m.)
- Evening (6:00 p.m.–9:00 p.m.)
- Late Evening (9:00 p.m.–12:00 a.m.)

For example, if the participant drove home at 5 p.m. from work, consumed a glass of wine and cannabis around 7 p.m., yet did not drive until the next day at 7 a.m., they would have entered the consumption in the journal entry for the 7 a.m. trip. In that entry, the consumption would have been logged as happening the “Evening” of the previous day. This was accounted for in data processing by comparing entry timestamps against the earliest overlap of time in which the substance consumption could have occurred in the previous 24-hour period.

In terms of dosage, participants selected quantities in the form of whole numbers for alcohol and cannabis. They could not enter values such as 0.5 or 0.75. For the recreational and prescription drug categories, only a check box confirming consumption of the substance was offered without associated dosage. As the main objective of the investigation was to measure cannabis-related impairment, consumption of other drugs was deemed a tertiary variable to assess the presence of polysubstance use rather than provide details on the non-alcohol and non-cannabis consumption.

To facilitate dosage entry by participants, substances were grouped according to standardized measurements typically tendered at retail stores or dispensaries. While not a perfect measurement, the units provided a quick and efficient way for self-reporting and captured a comparative estimated range of dose. Perceived level of impairment at the time of intoxication and the current feeling of intoxication were also reported, allowing for assessment of correlations between an individual's reported feeling of intoxication relative to their dosing value.

Doses for alcohol were fairly straightforward since the consumption options are generally limited to beer, wine, and liquor, and accepted equivalencies between the different consumption options exist. The dosing options provided in the app for alcohol were:

- Beer 12 oz.
- Beer 16 oz.
- Wine 6 oz.
- Wine 9 oz.
- Liquor 1.5 oz.

In contrast, the options provided for cannabis needed to consider a variety of consumption methods. As very little scientific research has compared consumption methods (with the notable exception of a subset of consumption approaches considered in Budney et al., 2022; Mahmoudinoodezh et al., 2022; and Mariani et al., 2011), the majority of the dosage options provided in the app were determined based on a collection of cannabis blogs and resource websites for cannabis users. In addition, cannabis retailer websites were searched for average THC content in different products sold in the states of Washington and Colorado. Table 3 details the dosing breakdown and estimated THC content ultimately used in the app for each consumption method. Details and justifications for these values and notation of exceptions are included as notes in the table. In general, THC content was measured in terms of grams of flower or, for other consumption forms, estimated servings of milligrams of the transformed flower.

**Table 3. Data Diary App cannabis selections of consumption form with dosing quantities and explanations.**

<b>Consumption Method Option</b>	<b>Measured in Number of</b>	<b>Estimated Grams of Flower</b>	<b>Notes</b>
<b>Smoked</b>	Joints/Pipes/ Bowls/Blunts	.3–.5 g of flower	While this category includes four varying administration methods, they all consistently fall within the same range depending on the THC content of the flower. Smoking marijuana accounts for at least 60% of THC content loss due to burning as combustion at high temperatures destroys half the cannabinoids and terpenes. So, while a blunt uses significantly more marijuana than a joint, the burning process comes out to be about 1.5 joint equivalents for each blunt, still within the range of a single bowl or single joint with a high THC content between approximately 36 mg and 115 mg (e.g., joints/blunts: ~ 40 – 115 mg (full length of rolling paper/leaf; pipes/bowls: ~36 mg–96 mg (1 to 3 hits total).
<b>Vaporizer</b>	Puffs	.3 g of flower; 4–10 mg of THC (per puff)	This category includes vape cartridge pens and dry herb vaporizers. Dry herb vaporizers use direct and low temperature settings on flower that do not combust into smoke particles, resulting in less flower and stronger THC content without having to be absorbed by combustion through the lung membranes. Dry herb vaporizer companies advertise around 10–20 puffs as equivalent to smoking a bowl (36 mg–96 mg). If it is a vape pen with concentrate or live resin, it is approximately 3 to 5 puff equivalents. During each activation session, participants voluntarily discussed in depth with the researcher their administration methods to determine how to most accurately report.
<b>Edibles</b>	Gummies, Candy, Other	25 mg of concentrate; average 10 mg per serving	Edibles are a cannabis extract-infused product that can be ingested, often in the form of gummies, lozenges, cookies, mints, honey, etc. While much of the THC content is lost as the body breaks down the food in the digestive system (from 25 mg to 10 mg absorbed), it is processed throughout the bloodstream more directly and often effects are reported to be felt more strongly by users. The majority of dispensaries distribute products in 10 mg servings; some manufacturers may be slightly lower, such as 5 mg, or slightly higher, such as 20 mg.
<b>Dabs</b>	Dabs	15–30 mg	Dabs are THC concentrates that can take the form of many consistencies and are typically administered in glass rigs using high heat via torches. This is the most concentrated form of THC, up to 90%. Similar to flower, much of the content is lost in the combustion process. While the consistency can take many forms, often referred to as glass shatter, butter, crumble, or live resin, the small size generally remains consistent for users at 0.025 grams to 0.05 g = 15 to 30 mg of THC. This size for a quantity of 1 dab was described to participants as the size of a grain of rice, a weed seed, or tip of a ballpoint pen. While it is possible some users may dose much higher at half or full grams (300–600 mg of THC), according to cannabis websites this is rare and exclusive to users of extremely high tolerance.
<b>Cannacaps</b>	Capsules	10–20 mg	Cannacaps are similar to edibles in that they are administered capsules of THC concentrated powder or oil that is consumed orally like a pill. Suppositories were included in this category. Average dose per capsule is similar to edibles, ranging from 10- to 20-mg THC doses.
<b>Tincture</b>	Drops	5 mg to 60 mg per dose	Tinctures are an oil-infused oral cannabis product that use an eyedropper or spray to place under the tongue for sublingual absorption into the blood stream. Tinctures are typically found in 1 fl oz (30 mL) glass bottles with droppers to administer for accurate dose administration. Doses are determined by number of drops or spray according to the bottle and are generally equivalent amounts.

Consumption Method Option	Measured in Number of	Estimated Grams of Flower	Notes
<b>Oil</b>	Drops	0–.5 mg per dose	This was primarily included as a control method. Tinctures contain THC, whereas oils are typically labeled for CBD products. As some CBD products can potentially contain trace amounts of THC, or be bought in Virginia off market from other unknown locations without recreational dispensaries yet available, this was included to account for THC in this substance form.
<b>Drink</b>	12 ozs	10 mg	Many drinks such as seltzers combine CBD and THC. A 12-oz drink often only results in a 10-mg dose of THC. While many dispensaries have higher concentrated drinks such as 6.7-oz shot bottles of 100 mg, there are markings on the bottle for each 10 mg of consumption for dosing control. Participants were instructed that, despite the ounce amount, to think of the bottles in terms of 10-mg doses, and if they consumed up to 100 mg like a whole 6.7-oz cannabis shot, then to list a quantity of 10 drinks.
<b>Lotion</b>	Applications	5–50 mg per .15 oz-1.7 oz container	Similar to tinctures, lotions (this category includes other consistencies such as salves and gels) generally are a combination of both CBD and THC and have overall low THC content. While the skin can deliver this into the bloodstream via veins and arteries into the circulatory system, it would take high amounts to achieve any noticeable effect as an entire container can contain on average as low as 5 mg. Depending on the size of the container, the typical user can get 10–20 applications.
<b>Patch</b>	Individual Patches	10 mg over 12 hours	Transdermal patches are extended-release forms of cannabinoids that stick to the skin and slowly enter the bloodstream. Patches are stuck on the skin and stay there for hours as cannabinoids slowly enter the bloodstream. One patch takes up to 12 hours for all ingredients in the patch to be fully absorbed, and on average has 10 mg of THC content.

## Other Recreational Drugs

Possible recreational drugs that could be listed by participants in their journal entries were:

- Heroin
- Barbiturates
- Tranquilizers
- Cocaine
- Methamphetamine
- Ecstasy/MDMA
- LSD/Acid
- Peyote/Mescaline
- Mushrooms/Psilocybin
- Ketamine
- PCP/Phencyclidine
- Diviner’s Sage/Salvia Divinorum
- Opioids

## Prescription Drugs

Daily prescriptions directly prescribed to the participant were captured in the *Daily Prescription and Over-the-Counter Drug Use Survey* and were not required to be reported in journal entries.

However, participants were asked to record in their journal entries any prescription drugs that were not prescribed directly to them or that were used recreationally, as well as occasional over-the-counter drugs. Given the large array of drugs that could have been listed, this journal entry field allowed free-typed responses. Among possible drugs that could have been included in this category are shown below (Table 4).

**Table 4. Journal entry options for daily prescription and over-the-counter drugs.**

<b>Prescription Drug Name</b>	<b>Alternative Brand Names</b>
Diphenhydramine	Benadryl, NyQuil, Z-Quil, Compoz, Unisom, Somnax
Meclizine	Antivert, Dramamine, Bonine
Ondansetron	Zofran
Doxylamine	Unisom, Nytol, Aldex
Hydroxyzine	Atarax, Vistaril
Morphine	Duamorph, Infumorph P/F, Arymo ER
Oxycodone	Oxycontin, Roxicodone, Xtampza ER
Hydrocodone	Norco, Vicodin, Lorcet, Rezira, Zutripro
Fentanyl	Duragesic, Subsys, Abstral
Codeine	Co-codamol, Atasol Codeine, Paracod, Panadeine, Tylenol with Codeine
Tramadol	Ultram, ConZip, Ultracet
Buprenorphine	Suboxone (combo w/ naloxone)
Naloxone	Suboxone (combo w/ buprenorphine), Narcan, Evzio

<b>Prescription Drug Name</b>	<b>Alternative Brand Names</b>
Naltrexone	Revia, Vivitrol
Gabapentin	Gralise, Neuraptine, Horizant, Neurontin
Diazepam	Valium, Diastat Acudial
Alprazolam	Xanax, Niravam
Oxazepam	Serax
Midazolam	Versed, Dormicum, Hypnovel
Clonazepam	Klonopin, Rivotril
Lorazepam	Ativan
Chlordiazepoxide	Librium
Flunitrazepam	Rohypnol
Temazepam	Restoril, Normison
Methocarbamol	Robaxin
Carisoprodol	Soma
Cyclobenzaprine	Flexeril, Amrix, Fexmid
Baclofen	Gablofen, Lioresal, Ozobax
Tizanidine	Zanaflex
Dantrolene	Dantrium
Zolpidem	Edluar, Ambien, Intermezzo, Zolpimist
Eszopiclone	Lunesta
Suvorexant	Belsomra
Ramelteon	Rozerem
Carbamazepine	Tegretol, Temporal, Neurotol
Phenytoin	Dilantin
Oxcarbazepine	Trileptal, Oxtellar
Lisinopril	Prinivil, Zestril, Lotensin, Vasotec, Accupril, Altace

### **BAC Breathalyzer Readings**

Participants were instructed to periodically charge their breathalyzer once a month using the included USB cord. The breathalyzer came with multiple mouthpieces and a carrying case. Participants did not receive the breathalyzer reading within the Data Diary application afterwards, but were told they could download and install a separate manufacturer app on their smartphone device if they wished to see this data or obtain readings when they were not providing a measurement as part of a journal entry.

### **Quantisal Oral Fluid Testing**

The previous “Rocky Mountain” VTTI study required participants to take a weekly oral fluid test throughout their participation period. Given the way in which the body generally metabolizes and stores cannabis for routine users, weekly testing yielded the same average laboratory results as a monthly test would have. Therefore, to minimize participant burden, participants in the current study were only requested to provide Quantisal oral fluid samples every 30 days. For

convenience and to increase compliance, the app provided reminders at 30-day intervals with a forced response feature.

VTTI provided participants with up to three Quantisal testing kits<sup>2</sup> at a time. Kits included a factory-packaged Quantisal oral fluids collection device, transport tube, participant identification QR code, and stamped mailer addressed to the drug testing facility. Participants were sent additional kits as needed throughout the data collection period. The instructions provided to participants are included in Appendix C. Briefly, in order to complete a fluid collection successfully, the participant placed the provided swab under the tongue until the plastic indicator (visible to the participant during the process) turned blue. This could take 2 minutes or longer. After collection, the participant sealed the collector in the transport tube, scanned the QR code affixed to the outside of the transport tube into the Data Diary app, and mailed the mailer within 24 to 48 hours. Each QR code contained only the unique participant drug test ID, not the participant ID. If participants forgot to scan the QR code before taking the test, they were advised to let a researcher know. The researcher could then cross-check the laboratory mailings to find the non-tagged sample and make the association within the study database. Once the lab received the test, it was either immediately tested or stored securely until testing could be administered.

Participants were given several training samples and performed their first practice test with a researcher present to ensure accurate collection and compliance. Participants were also instructed not to perform the test unless there had been a minimum of 15 minutes since they last ate or drank, and a minimum of 2 to 4 hours since they last smoked, dabbed, vaporized, or ate an edible containing cannabis. This last requirement was established to avoid falsely inflated readings of THC metabolites after recent consumption. Participants that accidentally spilled the liquid or otherwise spoiled the sample could simply use another kit available to them.

## Compliance

All substance use journal entries were sent to a review dashboard where researchers monitored participant compliance. If participants were going to take extended vacations or tolerance breaks, or if they experienced trouble with their equipment, they were requested to notify researchers as soon as possible so that any data lapses could be logged. However, not all participants followed this guidance.

If the research team noticed an apparent pattern of participant-specific noncompliance regarding use of the journal, the breathalyzer, or the Quantisal swab, that participant initially received a push notification on the app that stated, “It appears you may be having problems with the app. Please email. [###@vti.vt.edu](mailto:###@vti.vt.edu) for assistance.” If the pattern persisted, the research team contacted the participant by phone or email to follow up and troubleshoot any issues with the app or concerns the participant may have. The research team, however, did not contact participants (via notification, call, or email) more than once per week.

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<sup>2</sup> <https://immunoanalysis.com/products/oral-fluid/quantisal/>



## CHAPTER 3. RESULTS

While the resulting dataset from this study is intended to inform a vast array of research questions in future research efforts, this specific effort was geared towards the collection of a robust dataset. Therefore, the results reported in this section provide descriptive statistics based on the intake questionnaires and substance use data. These descriptive statistics can be used to assess the applicability of the dataset to specific research questions targeted in future research.

### DATA ANALYSIS APPROACH

As the sample sizes between locations were unequal and the sample size limited, formal statistical cross-site comparisons could not be performed. Descriptive statistics were computed from the study databases using MATLAB R2023a and Microsoft Excel.

### SUMMARY RESULTS

A total of 41 participants enrolled in the study at various points between January 2021 and March 2022. Participation period ranged from 3.5 months to 19 months (mean=12.5 months) for the Washington cohort and from 2 weeks to 19 months (mean=11.0 months) for the Virginia cohort. Due to data quality issues with both the naturalistic driving data and the self-report journal data, only 34 of the 41 participants are included in the analyses.

### Demographic Information

Demographic information was relatively consistent across sites, but participation in Virginia was much higher than Washington (Table 5). Attempts to balance the sample were successful in attaining sex balance, but not racial balance, despite targeted recruiting efforts. The larger sample in Virginia also allowed a wider age range than the Washington location.

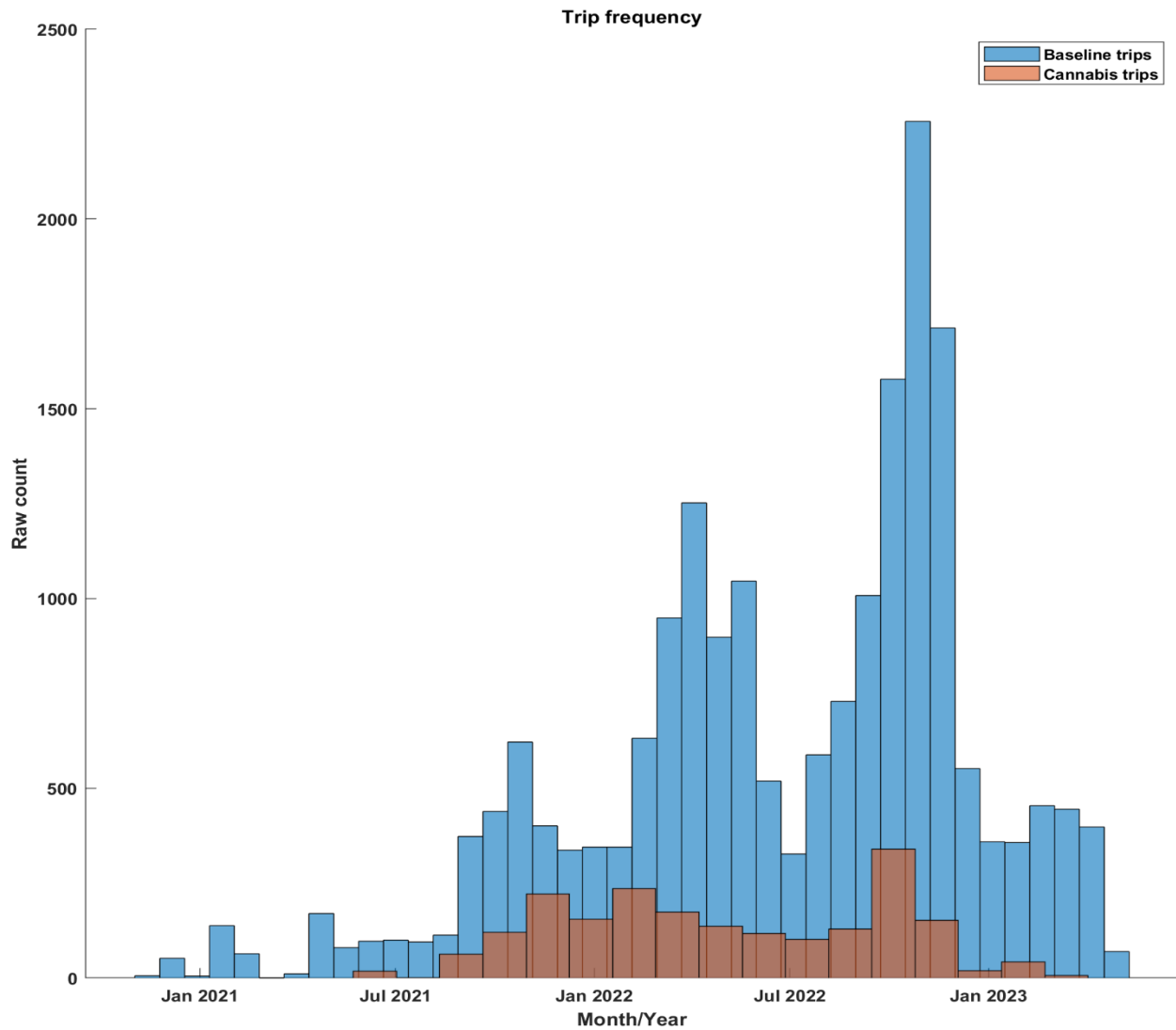
**Table 5. Demographic information.**

Collection Site	No. of subjects	Age-Mean, [Range]	Sex	Race
Washington	6	38.7 [34-45]	60% F, 40% M	80% White
Virginia	35	38.8 [21-70]	50% F, 50%M	76% White

### Driving Under the Influence of Cannabis

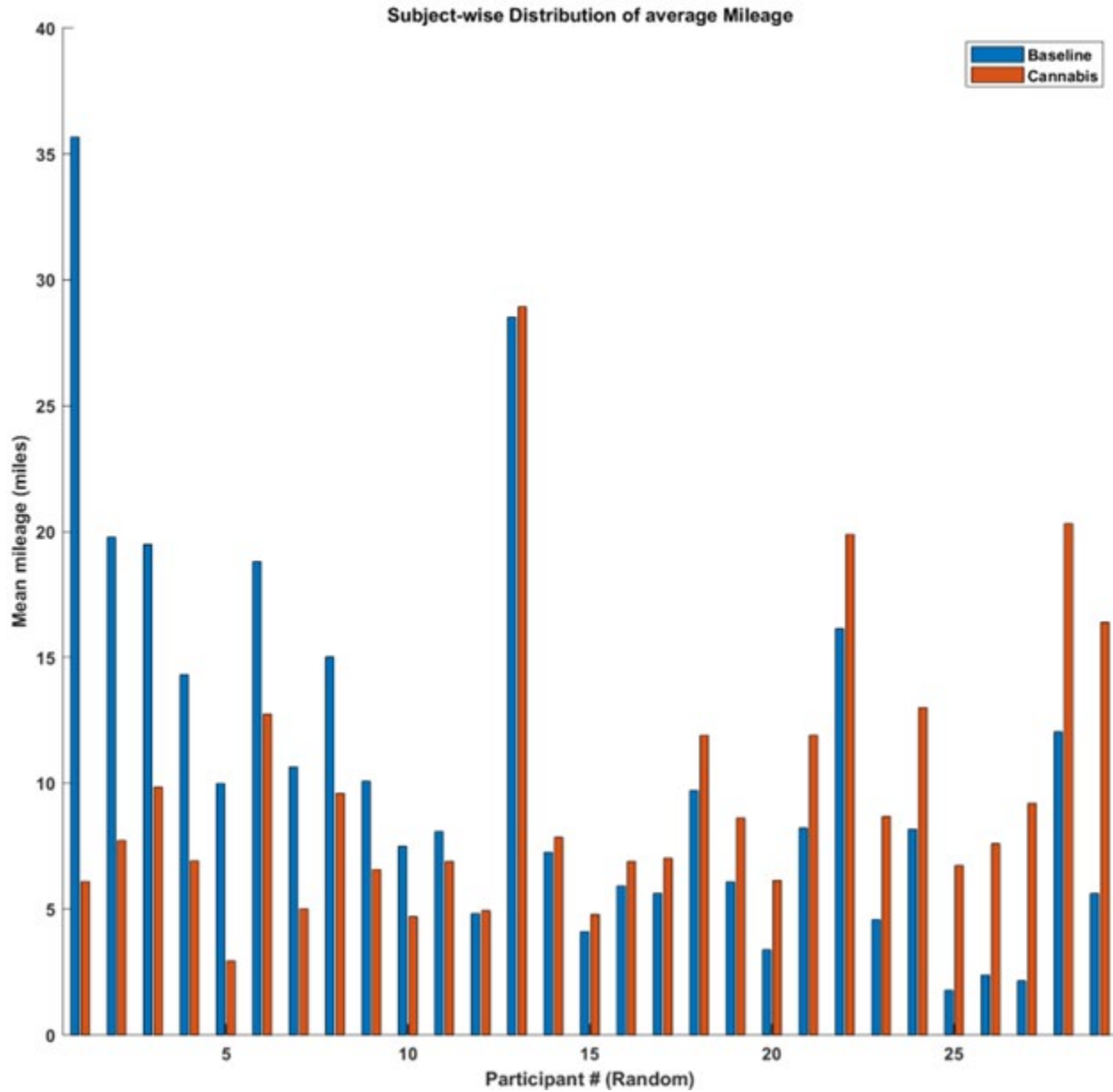
Self-reported annual mileage for study participants ranged from 6,000 to 30,000 miles (mean=14,400 miles) for the Washington cohort, and 4,500 to 26,000 miles (mean=14,000 miles) for the Virginia cohort. Per the screening criteria, all participants self-reported previously driving under the influence of cannabis at least once. Trips were classified as “cannabis trips” based on self-reported consumption of cannabis prior to the trip and self-perception of impairment. The number of cannabis trips, based on the combination of journal entry logs and the collected data, ranged from 25 to 635 (mean = 232) among the Washington subjects, and

from 5 to 750 (mean = 158) across the Virginia subjects. Cannabis trips and baseline trips followed similar distributions during the data collection period, albeit the frequency of baseline trips was much larger than the frequency of cannabis trips (Figure 6).



**Figure 6. Chart. Occurrence of baseline and cannabis trips identified in the dataset.**

The average mileage (i.e., number of miles driven per trip) for each participant’s baseline and cannabis trips (Figure 7) could potentially be used to classify the participants into three categories: heavy users, or participants who drove twice as far after cannabis consumption versus their baseline sober driving, cautious users who drove less than half as far after consuming cannabis compared to their baseline, and moderate users who drove 0.5 to 2 times as far after consuming cannabis than when sober.



**Figure 7. Chart. Subject-wise comparison of average trip length (mileage) for baseline and cannabis trips.**

Comparing the baseline and cannabis trips’ start times across participants with respect to the hour of day (midnight to 11:59 p.m.) (Figure 8), and with respect to day of week (Monday to Sunday) (Figure 9), yielded some interesting trends. There were observable spikes (25%–33% increase) in the frequency of cannabis trips undertaken around 12–1 p.m., 4–5 p.m., and 6–7 p.m. Moreover, there was a dip on Wednesdays and a rise on Fridays in the frequency of cannabis trips.

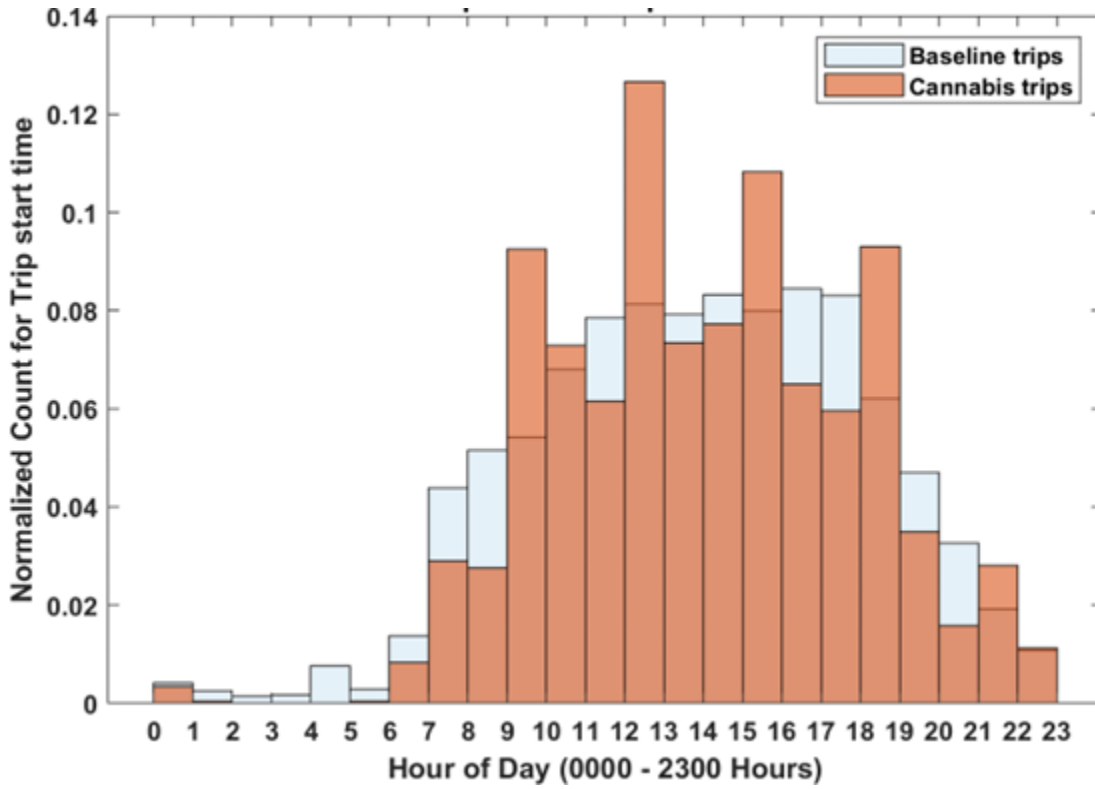


Figure 8. Chart. Comparison of trip start time based on hour of the day.

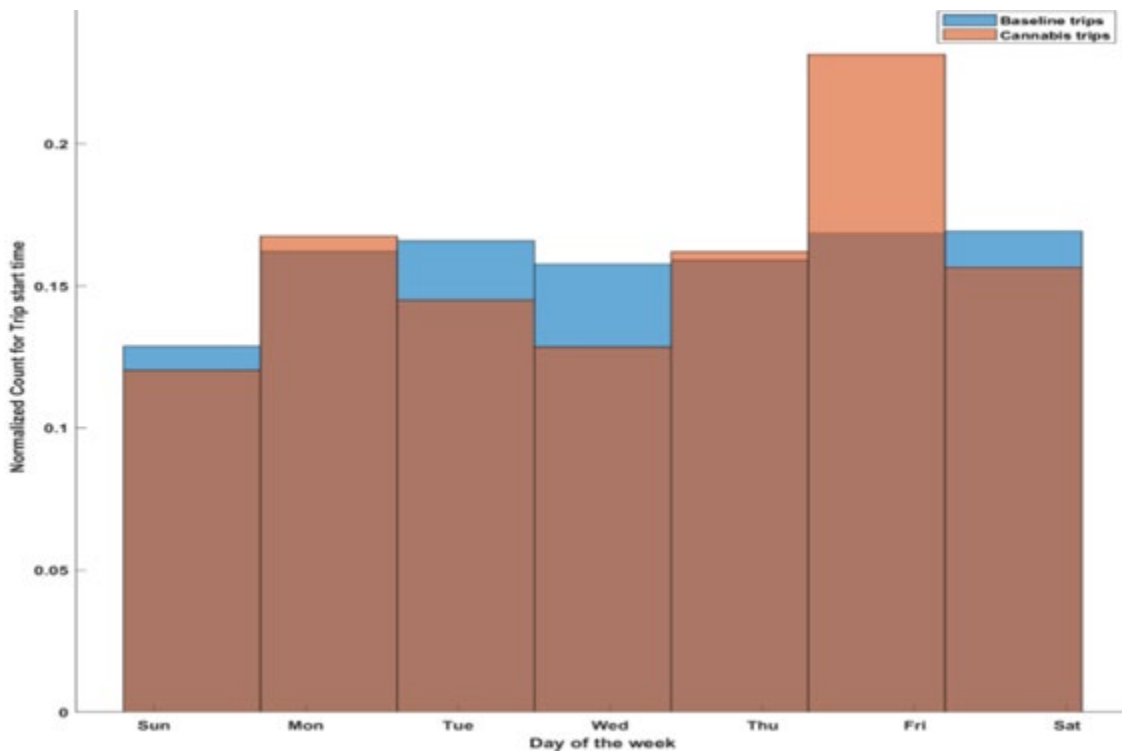


Figure 9. Chart. Comparison of trip start time based on day of the week.

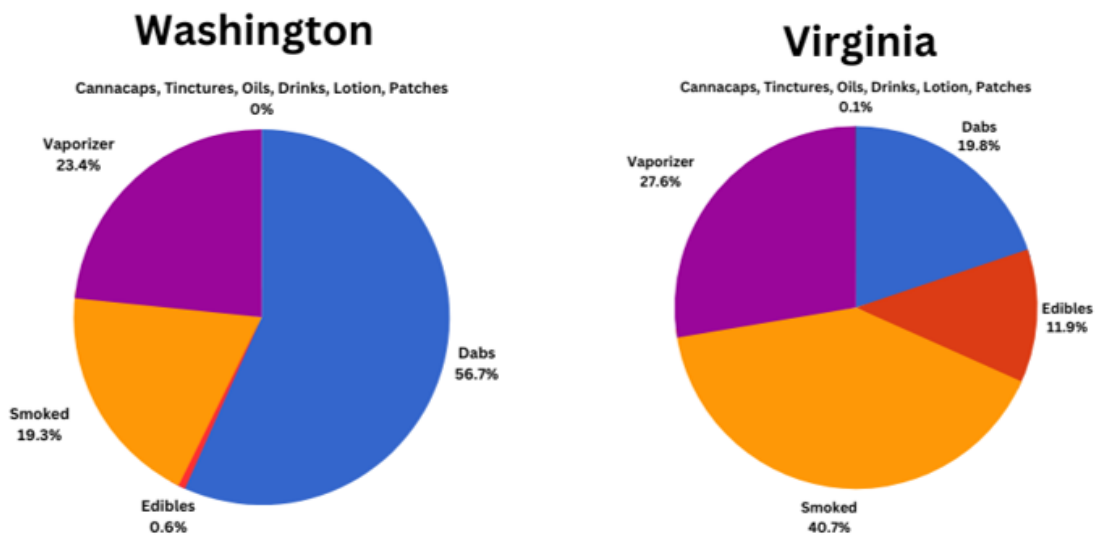
## Substance Use Journal Entry Results

Table 6 shows the total counts of self-reported consumption journal entries, split by substance, and Quantisal swabs. The totals exclude any fake or practice journal entries and Quantisal swabs. Note that journal entries could indicate consumption of multiple substances; therefore, the substance journal entries add up to more than the total. More specifically, out of a total of 10,081 entries, 13.7% of all Washington entries (212 entries) were related to polysubstance use while 20.1% of all Virginia entries (1,195 entries) were related to polysubstance use. The majority of polysubstance use cases related to the consumption of both cannabis and alcohol. Only two subjects admitted to consuming other recreational drugs one time each in the Washington cohort (<1% of all entries). In contrast, nine subjects in the Virginia cohort admitted to using other recreational drugs one or more times (~4% of all entries).

**Table 6. Substance use journal entries.**

Total Journal Entries	Alcohol Entries	Cannabis Entries	Recreational Drug Entries	Prescription Drug Entries	Blood Alcohol Counts	Quantisal Swab Counts
10,081	1,259	8,021	28	455	3,402	424

The most commonly consumed forms of cannabis varied between the Washington and Virginia cohorts (Figure 10). The majority of journal entries from Washington reported consumption of cannabis in dab form. Alternatively, the Virginia cohort was dominated by smoking of cannabis in flower form, whether through joints, blunts, pipes, or bowls.



**Figure 10. Charts. Cannabis consumption methods for Washington and Virginia sites.**

Breathalyzer data for both cohorts indicated occasional consumption of alcohol. About 20% of the samples obtained in Washington were at or above the legal limit of 0.08%. A slightly lower proportion (14.5%) of BAC readings from the Virginia cohort were at or above the legal limit. Driving data associated with the different entries (Table 6) was captured across all participants (Figure 11 and Figure 12).

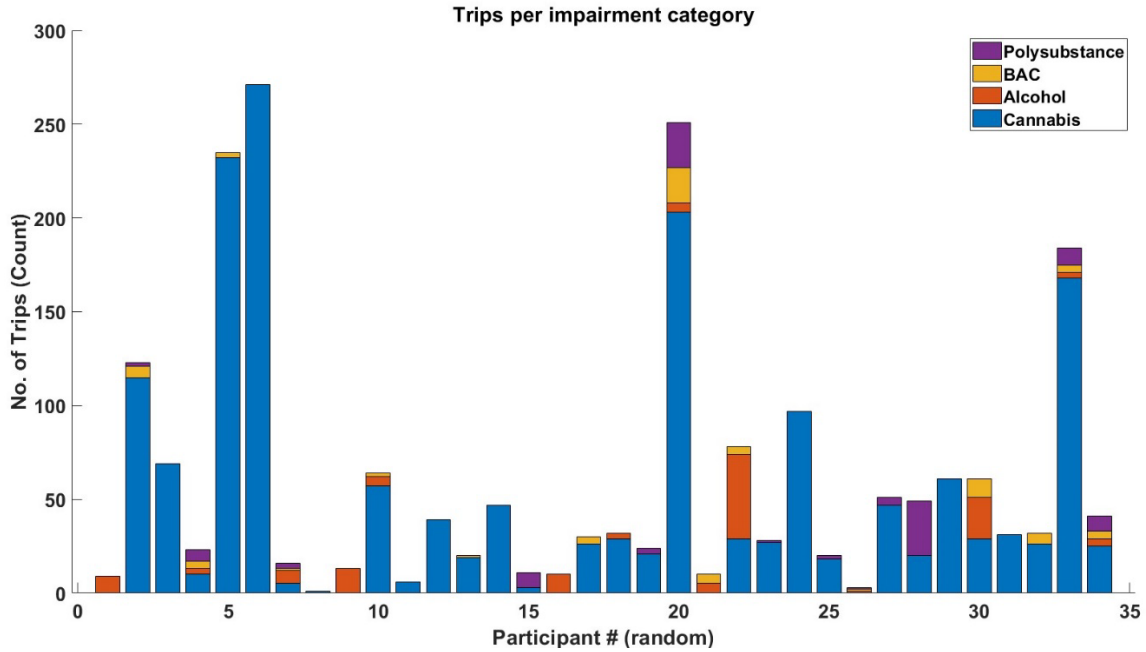


Figure 11. Chart. Trip count distribution across participants for different substance types.

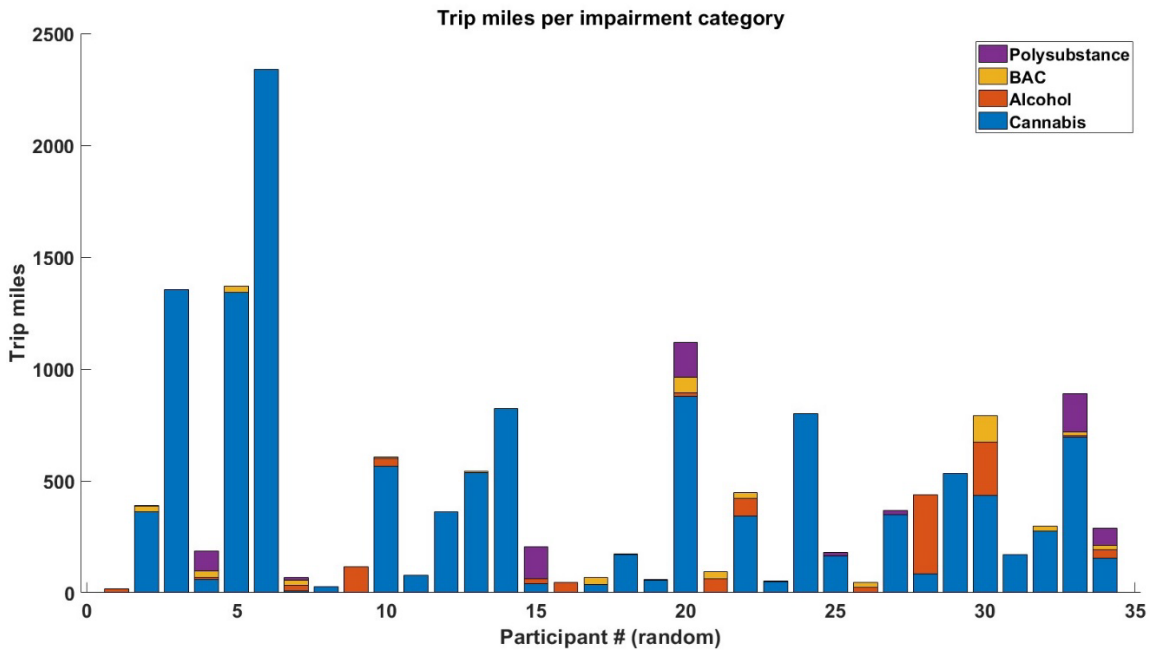
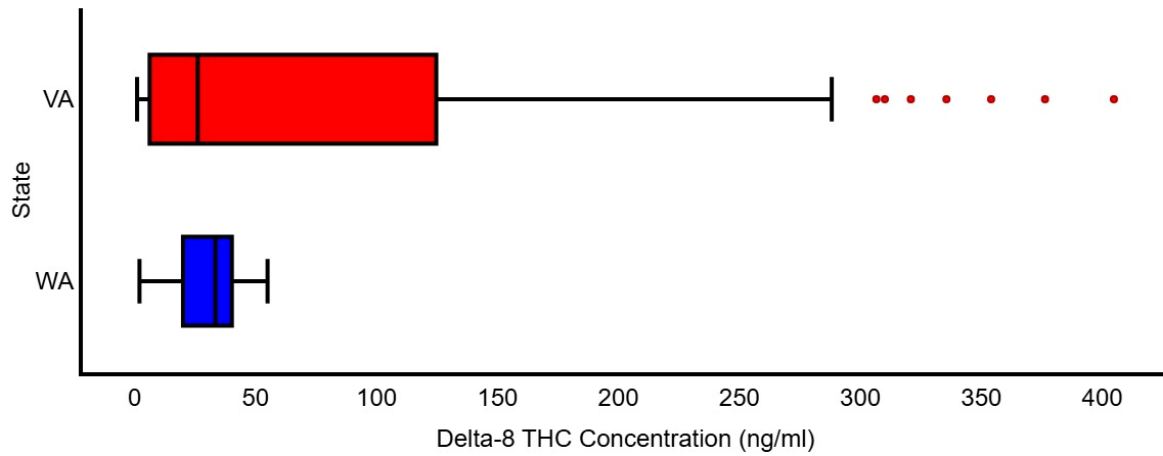


Figure 12. Chart. Trip miles distribution across participants for different substance types.

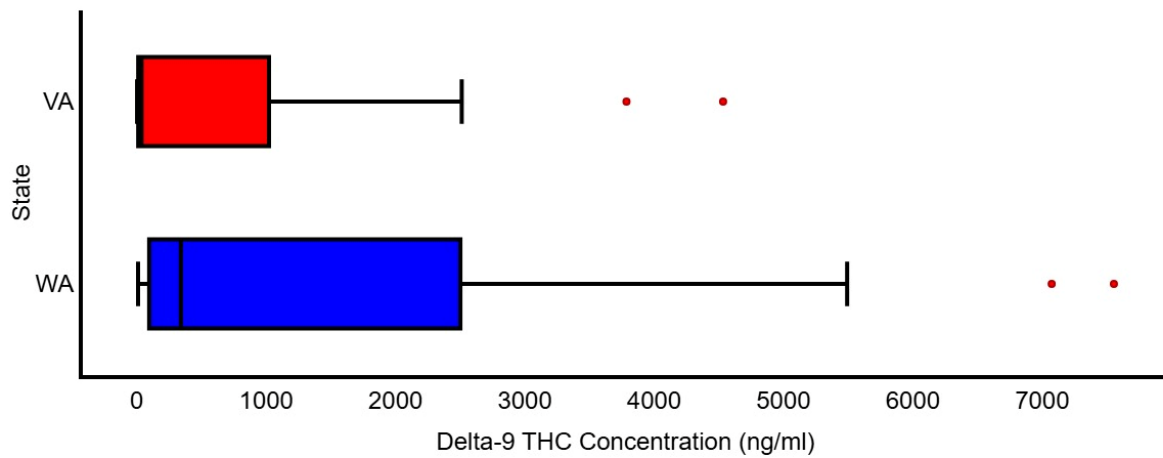
## Quantisal Test Data

There were some notable issues related to the Quantisal tests. First, many outlier high THC concentrations were observed in the tests, despite instructions and reminders to participants to avoid taking the Quantisal kits oral fluid test within 4 hours of consuming cannabis. Second, while participants were instructed to mail kits once a month, some Quantisal tests were not submitted or lost in transit based on the laboratory records. Overall, however, the compliance rate was approximately 85% for Quantisal test submissions. Future analyses could use these data as an extension or validation of specific journal entries.

The Quantisal tests allowed a better understanding of the different THC types consumed by participants (Figure 13 and Figure 14 (note that the x-axis scales in these two figures differ by an order of magnitude)). These figures exclude all zero values of THC as well as outliers. For delta-8 THC, 58 and 116 instances of zero THC were excluded for Washington and Virginia, respectively. For delta-9 THC, 11 and 232 instances of zero THC were excluded for Washington and Virginia, respectively. In general, the tests showed mean delta-9 THC levels of 260.9 ng/ml in the Virginia cohort and 1,662 ng/ml in the Washington cohort. Corresponding levels for delta-8 THC were 120.8 ng/ml (Virginia cohort) and 2.4 ng/ml (Washington cohort). The results suggest differential availability of THC types between the two cohorts, with delta-9 predominating in the Washington cohort, whereas delta-8 was dominant in the Virginia cohort. Delta-9 is more potent than delta-8 in terms of its psychoactive properties, making it a more commonly used recreational substance in places where recreational use and retail sales are legal. Delta-8, on the other hand, is less potent and more common in medicinal applications, as well as locations which have not legalized recreational use or do not allow retail sales of cannabis. The prominent differences found between the two cohorts can potentially be explained considering the legalization status at each site. Recreational cannabis use had been legalized in Washington since 2013, whereas Virginia was at the onset of legalization in 2021 when the data collection began. This could have possibly influenced the availability of delta-9 products in Virginia as dispensaries for recreational cannabis are still not available, making delta-8 the more consumed variant. As a reminder, the Quantisal tests results indicate merely the presence of different THC types in the cannabis products used by the participants. These values are not suitable for or intended to estimate THC levels in blood or the impairment levels in these individuals. Numerous studies have established that THC found in the saliva only indicates recent use but does not correlate to the concentrations of THC in the blood or the subject's impairment levels (Robertson et al., 2022).

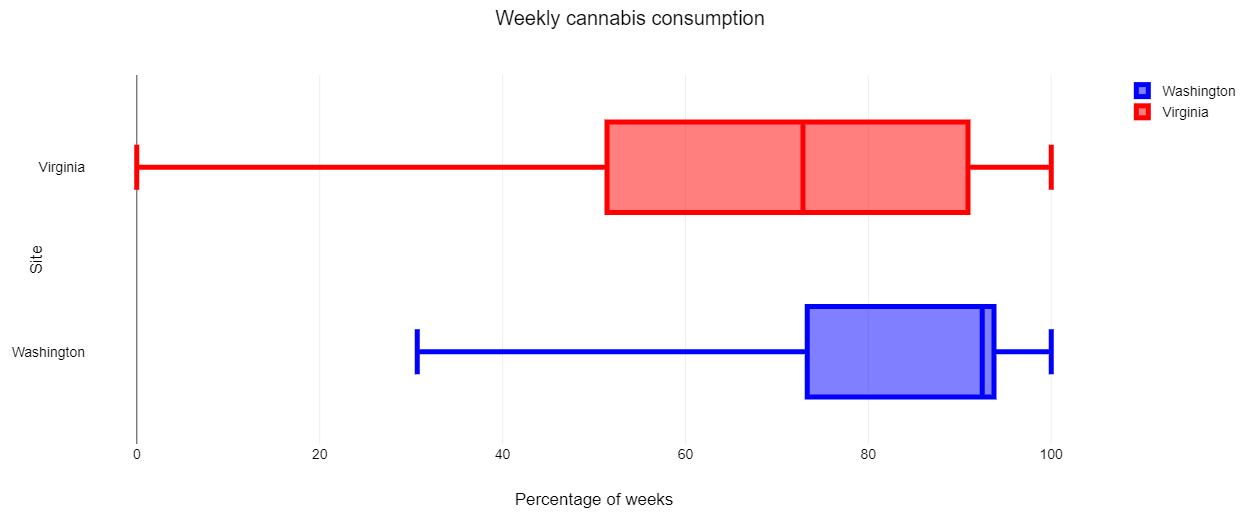


**Figure 13. Chart. Delta-8 high and low values of THC results from laboratory tested Quantisal test kits.**



**Figure 14. Chart. Delta-9 high and low values of THC results from laboratory tested Quantisal test kits.**

The frequency of consumption also differed between study cohorts. On average, participants in Virginia consumed cannabis at least once for 69% of all the weeks they participated in the study, compared to 80.5% for the Washington cohort (Figure 15).



**Figure 15. Chart. Weekly cannabis consumption behavior based on self-reported journal entries.**



## CHAPTER 4. DISCUSSION

This study is the first of its kind to examine detailed cannabis use in a limited sample using a naturalistic driving data collection. The data will allow linkage of self-reported substance consumption, intoxication level, and BAC levels with a wide range of driving behaviors. The resulting observations could then be contrasted with non-impaired driving data **from the same driver**. The diversity in the sample demographics will allow these examinations to occur across a range of user types, ages, and genders. More importantly, the journal entry approach used, and detailed reporting elicited, will also allow some examination of potential dose-response relationships between cannabis use and changes in driving performance and behavior.

The initial step towards successful use of this dataset will require preliminary analysis and video annotation where substance use data collected for each trip is matched with driving data from the same trip. This step should also include the development of a categorization scheme for each cohort that helps to identify frequent, occasional, and heavy substance users and provide some additional context that can be used to stratify driving data analyses. Once this step is complete, subsequent analyses could compare the driving performance over time (e.g., by examining rates of kinematic or safety-critical events) among drivers categorized according to use frequency and dosage, as assessed by both self-report and from oral fluid samples. Regression models could be developed to examine, for example, between- and within-driver kinematic rates (i.e., abrupt maneuvers), lane position, vehicle following behaviors, and occurrence of safety-critical events (i.e., crashes and near-crashes) as a function of routine and acute use of cannabis and other drugs (Sonth et al., 2023).

While this study did not include a specific non-user control group that completed journal entries, between-subject comparisons could leverage similar vehicle types, demographics, and other variables in the larger VTTI L2 NDS to increase the size of a normative subject pool. Individuals within the substance use study could also be observed longitudinally to assess their non-impaired (i.e., baseline) driving performance against their driving performance when they report having recently used cannabis, alcohol, or other drugs. In addition, the self-ratings of current and peak intoxication levels could be isolated and compared to actual consumption to determine driver self-perception of risk and gain understanding of the decision-making processes for individuals in the presence and absence of drug use. Answers to questionnaires related to making the decision to drive could also be useful in these potential analyses.

In parsing and using these data, future researchers should be aware that Virginia passed legislation effective July 1, 2021, which laid the groundwork for the legalization of recreational cannabis. As of the publication of this report, recreational cannabis is legalized for personal consumption, yet is not publicly available for sale in retail stores or dispensaries, and there is not a state management board appointed for regulation of THC levels. This legislation differs from Washington in its restrictions on levels of THC and led to observable differences in consumption between the two cohorts. In addition, while Virginia has a restricted level of THC for medical marijuana, Washington does not. THC levels are also likely to vary substantially for recreational users in Virginia and Washington because commercial sales of cannabis were not permitted in Virginia throughout the duration of the study. Home-grown personal crops, which may represent a sizeable proportion of the Virginia consumption, may have lower THC levels than the more regulated, and purportedly consistent, commercial products available in Washington.

Overall, this dataset is expected to provide valuable future insights into cannabis-related driving research. Particularly, the data has the potential to provide further evidence on how cannabis affects driving to

better inform policymakers, detection device development, and law enforcement efforts. The data may also illuminate the effects of polysubstance use on driving behaviors. In addition, the use of 2017 or newer ADAS-equipped vehicles could help to assess the potential role of L2 features on mitigating the effects of impaired driving through examination of associated human behaviors, like reliance or feature disengagement (Chaka et al., 2019). If other previous datasets are any indication, future research will likely also extend well beyond these areas.

## **Limitations**

As with any research study, the NDS presented here is subject to several important limitations that should be considered by future users of the dataset. First, the research team is cognizant of the potential of daily journal entries to introduce the Hawthorne effect, whereby the frequent reminder of a participant's involvement in a research study may affect the validity of the collected data. A number of factors, however, mitigate this effect and increase data integrity. First, this research employed multiple approaches to collect data related to substance use. In addition to the daily journals, breathalyzer readings were collected for trips where the participant was driving unaccompanied, and oral fluid was collected on a monthly basis. Second, while the cameras and instrumentation in the vehicle could also serve as a reminder of participation, previous VTTI experience with large-scale NDSs suggests that participants habituate to these cues within a few hours of driving the vehicle. Based on this previous experience, it is likely that participants quickly habituated to the instrumentation and possibly that they similarly habituated to the journaling task. It is also noteworthy that a systematic review of the Hawthorne effect was somewhat inconclusive in the extent of its effect on research findings (Compton, 2015). Additionally, participants' knowledge of being monitored is a common side effect of consenting participants for research in general, not just NDS research (Jain & Perez, 2025). In any case, as for other cannabis research in the context of driving (Dutra, Farrelly et al. 2022), the knowledge gained from this study is expected to outweigh the potential limitations introduced by the presence of the Hawthorne effect.

Second, given the different study sites, the limited regulation and oversight of cannabis production and distribution, and the wide array of consumption approaches, consistency in the THC content of the cannabis consumed by participants cannot be expected. Many cannabis products do not have a standardized THC content and can vary from brand to brand, anywhere from 12% to 27%. Furthermore, cannabis strains not accounted for may have included sativa products, which elicit uplifting and energizing head-highs that are claimed to simulate creativity and focus; indica products, which are associated with relaxing and sleep-inducing effects and are claimed to alleviate pain through a body-high and produce euphoria; or hybrid products, which have a combined body and cerebral effect of sativa and indica characteristics. Strain types could have a substantial impact on the type and intensity of impairment felt, and the limitation of the present study in cataloguing these aspects provides justification for further research.

Third, one of the intake questionnaires was centered around the propensity for risk-taking, as some literature shows (Brands, 2021) that risk taking propensities are associated with the likelihood of DUIC. That said, risk-taking may be interpreted differently in a legalized policy environment of cannabis versus states where cannabis is still illegal. Our two sites differed in this respect, and therefore this effect is nested with any inherent risk propensity for individual participants.

Finally, as with all self-report studies, there is a potential risk for inaccurately reported data, especially when participants were under the influence of drugs. This was certainly possible for journal entries. Likewise, Quantisal test collection methods come with their own suite of risks relative to cannabinoid stability within oral fluid, proper collection method by the participant, and mailing issues that could delay sample testing or result in lost samples. Breathalyzer devices, in turn, may have reported inaccurate readings when the testing occurred after consumption of alcohol-based products, such as mouthwash. BrAC readings may also have been lost due to lack of device charge or connection issues between the breathalyzer and the app.



## APPENDIX A. ABBREVIATED RECRUITMENT SCRIPT

Hello! The Virginia Tech Transportation Institute, in Blacksburg, VA, is currently recruiting people to dually participate in two research studies in your area <insert recruiting area>.

Any information you give us today will be treated as strictly confidential and limited to designated research personnel. If you are eligible, we will add your name to the list of potential participants; if you are not eligible, or if you are not selected for participation, you may elect to have your information saved in our private participant database for consideration in future research opportunities. Should you not wish to do so, your contact information will be removed from our database and any record of responses you provide destroyed.

The goal of the first study is to learn how people drive cars equipped with newer technologies called advanced driver assistance systems, or ADAS, such as adaptive cruise control or lane keep assist. VTTI has conducted numerous similar studies all over the country for over fifteen years.

If you are eligible and choose to participate, data collection equipment will be temporarily installed in your vehicle.

The data collection equipment we install in your vehicle is very unobtrusive - it won't affect your vehicle's performance. The main purpose of this system is to gather valuable data on how people interact with newer vehicle technology in the real world. The system we install includes GPS and other sensors that will record driving data, such as speed and acceleration. It will also have cameras that record the forward roadway, the driver's face, and the dashboard. In addition, we will mount a sensor on the front of your vehicle near your front license plate. There is NO audio recording unless you, initiate the 'incident' button to record a message up to 30 seconds. This is not live audio and will not be accessed by researchers until a later date.

Secondly, as part of the substance use study, we would also like to collect data on your use of cannabis/marijuana, alcohol, medications and other substances. We will do this in three ways, the first method is by asking you to complete a brief questionnaire via our secure journal entry app before you begin driving. When prompted by the app, you will perform an easy-to-use breathalyzer test with equipment we provide. It will take about 30-90 seconds to perform both tasks. Before some driving trips, about once a month, we will ask you to swab some oral fluid from your mouth using a sterile cotton applicator provided by us; then mail it to a secure, independent lab site in a self-addressed, stamped envelope also provided by us. Your lab results and all of the data collected by the equipment installed in the vehicle during this research will be treated as confidential and will not be associated with your personal information.

None of the recorded data is 'live', or viewable in real time; they will only be available to researchers once they are collected and reviewed at a later time. None of the equipment will automatically alert the researchers of any findings while you are driving. Your data will be assigned a random participant number, ensuring that your personal information will never be associated with the recorded data. All of the data we collect are secure – all driving data will be encrypted and can only be decrypted by authorized research personnel.

To help protect privacy, including at both the local and federal level, a Certificate of Confidentiality has been obtained for this project, from the U.S. Dept of Health and Human Services National Institutes of Health. With this Certificate, neither the researchers nor study sponsors can be forced to disclose information that may identify the driver, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. If eligible and you proceed as a

participant, more information about this certificate will be provided prior to scheduling any appointments.

The first step to your participation is to review and sign a consent document that describes the purpose of each study and your role in it. A copy of each consent document will be emailed/mailed to you in advance for you to review. If you have any questions you may contact the researchers listed on the consent documents. After consenting to participate, a data acquisition system will be installed and later removed by trained professionals. No permanent changes will be made to your vehicle. The equipment will not alter your vehicle or its performance in any way. Installation will take place at a convenient location in your area. Installing the equipment usually takes between 4-8 hours. You do not have to be present the whole time.

Due to the cameras involved, this study is not suitable for people who frequent areas where video recordings are not allowed, for example some military installations, high security facilities, or border crossings. If you choose to participate, full details of what is required of you as a participant will be provided to you before any installation of study equipment occurs.

< Below are examples of anticipated frequently asked questions. Researchers will respond with the sample script below in the event they are asked these questions >

Here are some frequently asked questions:

1. If I speed, run a stop sign, etc. will I be reported to police?

Answer: No, we understand this is human behavior. We ask that you drive as you naturally would. Similar to a doctor or counselor, we may be required to report the endangerment of the lives of others or minors.

2. Will vehicle occupants have their conversations recorded?

Answer: There is NO audio recording unless you, initiate the 'incident' button. The open audio channel will only last for 30 seconds if the button is pressed.

3. Does the equipment track where I am?

Answer: The trip information (e.g., GPS location) is recorded, but again, this data is not viewable in real time. The data will not be viewed by researchers until a later date. We are mainly interested in how people drive, not personal details of places they frequent.

4. How will the data on my cannabis and other substance use be treated?

Answer: Your data will be held in strict confidence; each participant will be assigned an ID number, such as #10. Privacy provisions prevent your identity from being linked to your data.

Any questions yet? If you are interested in possibly participating, I need to go over some screening questions to see if you meet all the eligibility requirements for this study. Any information given to us will be kept secure and confidential.

## APPENDIX B. ABBREVIATED PARTICIPANT INFORMED CONSENT SHEET

### VIRGINIA POLYTECHNIC INSTITUTE AND STATE UNIVERSITY Consent to Take Part in a Research Study

**Principal Investigator:** Dr. Jon Hankey, [jhankey@vtti.vt.edu](mailto:jhankey@vtti.vt.edu), 540-231-1512

**Primary Contact:** Kaitlyn (Fitzgerald) Bedwell, [KFitzgerald@vtti.vt.edu](mailto:KFitzgerald@vtti.vt.edu), 540-231-1535

**Key Information:** The following is a short summary to help you decide whether or not you would like to be a part of this study. More detailed information is included below this summary.

Why am I being invited to take part in a research study?

We invite you to take part in this research study because you've indicated that you sometimes use cannabis and you drive a vehicle with advanced driver assistance system (ADAS) features.

What should I know about being in a research study?

- Someone will explain this research study to you. Participation is optional.
- The data collected will be held under a high level of security.
- The data we collect during the study and information about your identity will be maintained in separate, secure locations so that it can only be linked by the study investigators after the data collection period is over.
- Your data will be protected by a Certificate of Confidentiality through the National Institute for Drug Abuse (NIDA) at the National Institutes of Health (NIH). This allows the research team and others who have access to your data to refuse to disclose identifying information related to you in any federal, state, civil, criminal, administrative, legislative, or other proceeding.
- If you decide to take part, you are always free to change your mind and exit the study at any point without penalty.
- You are welcome to ask all the questions you want before you decide

**Why is this research being done?**

The purpose is to examine the driving behavior of adults who use cannabis.

**How long will the research last?**

Participation in this study will last up to 3 months. You may be offered the option to renew your consent at the end of the 3-month period.

**What will I need to do if I choose to participate?**

If you choose to participate, you will need to do the following:

1. Talk with a member of the research team on the phone or video chat after you review this form. The researcher will help you enroll in the study.
2. Complete intake surveys that assess your attitudes and behavior related to substance use; this should take no more than 30 minutes.
3. Install VTTI's free and confidential Data Diary app on your smartphone. A researcher will assist you with setting up this app.
4. Each driving trip provide a brief report using the app on your phone about your recent cannabis, alcohol, or other substance use - about 1 minute.
5. Each time you drive alone, complete breathalyzer assessment using provided equipment, at the beginning of the trip; this should take no more than 30-90 seconds total.
6. On occasional driving trips, about one time each month, provide an oral fluids sample and mail the sample to an independent laboratory using a pre-marked and stamped envelope that VTTI provides; this should take about 5-10 minutes.

### **Is there any way being in this study could be bad for me?**

There are risks associated with documentation of substance use. Despite substantial safeguards to assure confidentiality, the unlikely release of information about a participant's substance use has the potential to affect the perceptions of friends, family, and employers, which could result in social and economic harms (e.g., lost wages). Additionally, the release of this data may have legal implications. The Certificate of Confidentiality protects this data from being released to anyone other than the research team. The research team follows strict protocols on data storage, transfer, and viewing. However, you are also advised to keep your participation in the study confidential.

More detailed information about the risks of this study can be found under ***“Is there any way being in this study could be bad for me? (Detailed Risks)”*** on page 11.

### **Will being in this study help me in any way?**

There are no benefits to you from your taking part in this research. However, there are potential benefits to society of learning from this study about marijuana and driving.

### **What happens if I do not want to be in this research?**

Taking part in research is completely up to you. You can decide to participate or not to participate.

**Detailed Information:** The following is more detailed information about this study in addition to the information listed above.

### **How many people will be studied?**

We plan to include about 100 people in both Virginia and Washington state.

### **What happens if I say yes, I want to be in this research (Detailed Study Procedures)?**

## Steps involved in Enrollment

Participate in an Informed Consent Interview via videoconference (about 30 minutes):

- a. The researcher will
  - i. begin a video chat with you
  - ii. confirm your eligibility to participate by asking you to present:
    1. A valid U.S. Driver's License
  - iii. Answer any questions you might have and ask you some questions to make sure you understand what will be expected of you as a participant;
  - iv. Help you sign the consent form;
  - v. Demonstrate the process of completing the app-based substance use journal, breathalyzer, and oral fluids collections.
- b. After the consent interview, we will provide you with a copy of the consent form with your signature page attached.

**2. Complete online surveys (about 30 minutes) about substance use, sleep habits, and psychology.** You can choose not to answer any questions without penalty.

Participate in an Equipment Activation Session videoconference (about 30 minutes)

- a. Once you've signed the consent form, you will receive the following items in the mail:
  - i. A BacTrack Mobile Pro breathalyzer device
  - ii. Four Quantisal oral fluid collection kits, one to be used during the activation session and three to be used during the study.
  - iii. An iBeacon device you will place in your vehicle for the duration of the study
- b. After receiving this equipment, contact the research team at 540-231-1583 to schedule an Equipment Activation Session.
- c. The session will be held using the Zoom videoconferencing application. You will receive a confirmation with details ahead of your appointment.
- d. During this session, a VTTI researcher will:
  - i. Answer any questions about placing the iBeacon device in your vehicle.
  - ii. Provide you with an ID code to activate your Data Diary app. All of the data collected through the app will be associated with this code rather than with your name or other information that identifies you.
  - iii. Answer any questions you may have about completing the substance use journal using the app or responding to prompts from the app to provide a Breathalyzer reading using the BacTrack device or collect an oral fluids sample using the Quantisal kit.
    1. Links to detailed information about using these will be included in the email you receive confirming your appointment.
  - iv. Ask you to collect an oral fluids sample for practice. You can discard this sample after the session.
  - v. This session should take about thirty minutes.

## Study Tasks

Complete a substance use journal every time you drive using the app installed on your phone.

- a. As you approach the vehicle, the app will ping you to complete the journal **while parked**.
- b. The journal will ask about when and how much you used alcohol, cannabis and other substances since the last time you drove (about 1 minute and never more than 3 minutes).
- c. Once you submit a journal entry, you won't be able to see or edit it.

Before you drive the app will prompt you to complete a breathalyzer assessment if you are driving alone. (about 30-90 seconds).

**2. About once a month upon ignition, the app will alert you to provide an oral fluids sample while parked and only when driving without passengers.**

- a. The sample will be analyzed to determine the presence and concentration of cannabinoids and alcohol.
- b. The procedures will be demonstrated as part of the consent interview. An instruction sheet for completing the test is also provided.
  - i. Place the collection swab under your tongue briefly (1-2 minutes).
  - ii. You can see the tip of the indicator turn blue when a sufficient amount of saliva has been collected.
  - iii. Place the collection device into the stamped, pre-addressed mailer provided.
  - iv. Scan the QR code into the Data Diary app
  - v. Store the package out of sight until you mail it within 2 days.
  - vi. The team will follow-up with you if oral fluids samples are not being submitted on time.
  - vii. In rare instances the research team may need to contact you about the procedure.

**3.** During the study, a member of the study team will contact you to assist with troubleshooting if you have any difficulty with the Data Diary app, breathalyzer, or oral fluids swabs.

**4.** The breathalyzer device and oral fluids collection kits function best when stored at room temperature. Please do not store them in your vehicle.

### After the study is over:

1. You will receive a stamped, preaddressed envelope to use to send the BacTrack Mobile pro and the iBeacon back at the end of the study.
2. Complete a short online exit survey about your experience in the study (about 10 minutes).

### What happens if I enroll in the study, but I change my mind later?

1. You can leave the research at any time, for any reason, and it will not be held against you.
2. You can leave this study or choose not to renew your 3 month consent period and remain a participant in the NDS study..
3. We would not keep any of the data collected after you tell us you want to leave.

## **Data Collection**

Information will be collected about you, as necessary, in order to conduct the research. Data will be collected to be analyzed as part of this research and in future research efforts. Both are stored securely and used as described below.

1. **Contact information** includes your name, address, email address, phone numbers, and similar information used to contact you when needed.
  - a. It will be stored securely in electronic form during the course of the study and destroyed one year after the study is complete (unless you grant permission on the exit survey for us to keep your contact information when the study is over).
  - b. This information will not be linked to or mingled with your study data and will not be used in any research or analysis.
2. **Auxiliary study information** includes your Social Security Number. This information is used to compensate you for your participation.
  - a. This information will be stored at VTTI in electronic form (securely encrypted) and destroyed one year after data collection is complete.
  - b. This information will not be linked to or mingled with your study data and will not be used in any research or analysis.
3. **Substance use data** includes the daily prescription and over-the-counter medication use you complete at consent, app-based substance use journal data collected every time you drive, breathalyzer data collected each time you drive unaccompanied and oral fluids swabs collected up to 3 times (about once per month) during the study. After data collection is over, your substance use data will be linked with the driving data collected in the NDS study. Researchers will not connect specific breathalyzer readings or oral fluids results with driving data until after data collection is complete.
4. The Data Diary app installed on your personal phone will prompt you to complete tasks that document your recent alcohol, cannabis, and other substance use.
  - a. The app will ping you as you approach your vehicle to record when and how much cannabis, alcohol and other substances you used since the last time you drove.
  - b. The app will then ask you whether you are driving alone. If you are, the app will prompt you to complete the breathalyzer using the BACtrack Mobile Pro. This device will be provided to you once you enroll in the study.
  - c. Up to 3 times during the study, the app will ask you to provide an oral fluids sample using a Quantisal kit, about once a month. Three kits will be provided when you enroll.
    - i. The oral fluids samples will be sent to a laboratory certified by NSF International. Samples will be destroyed by the lab after analyses within one year of collection. The lab won't have access to any information that personally identifies you.
5. A battery-powered iBeacon device (pictured below) will be placed in your vehicle. This device will interact with the Daily Data app to allow for secure transmission of substance use journal data to servers at VTTI.



*Beacon device (pictured beneath a quarter for perspective)*

6. Substance use data will be securely stored separately from contact information that personally identifies you. Therefore, in the unlikely case that data were revealed, they would not be linked to your identity.

### **What happens to the information and data collected for the research?**

We will make every effort to limit the use and disclosure of your personal information only to people who have a need to review this information. We cannot promise complete confidentiality. Organizations that may inspect and copy your information include the IRB, Human Research Protection Program, and other authorized representatives of Virginia Tech.

**Data not containing Personally Identifiable Information (PII):** We will separate your private information from data that are collected during this research; de-identified data (which cannot be associated with your identity) could be used for future research studies or distributed to other qualified investigators for future research studies without your additional informed consent.

**Data containing Personally Identifiable Information (PII):** Information that can be used to identify you will not be stored with the study data. However, the data collected in this study will be linked and analyzed with the data collected in the the naturalistic driving study. The driving study does contain data that can be used to identify you (face video and GPS of trips).

The substance use data will only be linked to this identifiable data while conducting specific analyses. Researchers who are not part of the original team will be required to submit proof of IRB approval and sign a data use agreement before being granted temporary access to data that could potentially identify you. These researchers will only be allowed to access data that could potentially identify you in a secure environment.

We will plan to keep and use your data indefinitely.

You will not have access to your study data; we will not offer to share your data with you.

The research team will publish their findings in journal articles, reports, and at scientific conferences. Participant personally identifying information will not be associated with these findings. If video clips from the driving data collected as part of the NDS study are shown at scientific conferences, images of your face will be blurred.

### **Certificate of Confidentiality**

Throughout the study, we will take all possible steps to protect your privacy and keep confidential your role in the study and the confidentiality of your personally identifying information. To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institute on Drug Abuse (NIDA) within the National Institutes of Health (NIH). With this Certificate, neither the researchers nor study sponsors can be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings.

Identifying information for the purposes of this study includes your contact information.

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide written consent to allow the researchers to release it.

This Certificate of Confidentiality does not mean that the Federal government endorses this study. The protections of the Certificate of Confidentiality described herein may not apply to passengers of the vehicle who have not consented to being in this study.

Throughout the study, we will take all possible steps to protect your privacy and keep confidential your role in the study and the confidentiality of your personally identifying information. However, similar to a doctor or counselor, this privacy protection does not prevent the researchers from disclosing a participant's threatened or actual harm to self or others. If this type of behavior is observed we reserve the right to remove you from the study and inform the appropriate authorities of what we have observed.

You, too, are responsible for taking steps to protect your privacy. Do not post or disclose your participation on any public forum including websites, Facebook, newspapers, radio and television. Protect your role in the study the same way that you protect other personal and private information. If you do not keep confidential your role in the study, there is a risk that some of the data collected during the study, including your personally identifying information, may be used against you in a court case or other legal proceeding. The Certificate of Confidentiality protects you by ensuring that researchers and study sponsors cannot be forced to disclose information that may identify you, even by a court subpoena, in any **federal**, state, or local civil, criminal, administrative, legislative, or other proceedings.

Please know the research team is attempting to study substance use and driving as it naturally occurs. Do not make unhealthy or at-risk changes to your substance use and driving based on participation in the study.

### **Is there any way being in this study could be bad for me? (Detailed Risks)**

We are not asking you to change your daily driving or substance use behavior. Through your participation the research team may have data on cannabis, alcohol, and other substance use that will later be linked to your driving. All possible steps will be taken to protect this information. Multiple subject codes will be used in connection with storage and collection of your study data. Separate codes will be used for oral fluids analyses. Only members of the research team will have access to the key that links your identity to the subject codes. The key will be stored in a secure VTTI server. The research team also has a Certificate of Confidentiality that protects your data. This is further detailed below.

There is also the risk that you will intentionally or inadvertently disclose details of your cannabis and alcohol usage to others while reporting your usage to the research team. This could happen if someone near you were to observe your journal responses. The research team does not expect nor want you to feel obligated to disclose details of your substance use in the presence of others. If you do not feel that you can comfortably complete the journal, then you should not complete that activity. We encourage you to be careful disclosing study information. Also, passengers could be curious about why you are providing an oral fluids sample or breathalyzer reading. We ask you to not complete the breathalyzer or collection of oral fluids samples in the presence of others.

With the Certificate of Confidentiality, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. More details about the Certificate, its protections and limitations are included above in the Certificate of Confidentiality section.

We are taking a number of steps administratively to protect your privacy:

1. Only select members of the study team study will have access to information that identifies you as a participant during data collection.
2. The platform used for the consent session is secure. We encourage you to participate in this session from your home rather than a public place where people around you could become aware of your involvement in the study. The researcher will be in a private space during the interview.

### **Can I be removed from the research without my OK?**

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include being uncooperative (not following instructions) or habitual behavior that is unsafe or dangerous for you or others. We will tell you about any new information that might affect your health, welfare, or choice to stay in the research.

Your NDS consent form states that you may be removed from that study if you habitually drive in an unsafe manner. Substance use data collected as part of the NDS study would not be considered in making that determination. If you are removed from that study, your participation in the substance use study would end as well.

### **What else do I need to know?**

This research is being funded by Virginia Tech Transportation Institute.

Participants in a study are considered volunteers, regardless of whether they receive compensation for their participation. Under state law, workers compensation does not apply to volunteers; therefore, the participants are responsible for their own medical insurance for bodily injury. Appropriate health insurance is strongly recommended to cover these types of expenses.

The participant agrees that this agreement shall be construed in accordance with the laws of the Commonwealth of Virginia, notwithstanding any conflicts of law provisions. Further, any and all claims and/or actions against Virginia Tech or the Commonwealth of Virginia shall be brought in a court of the Commonwealth of Virginia.

### **Who can I talk to?**

If you have questions, concerns, or complaints, or think the research has hurt you, you can talk to Kaitlyn Fitzgerald, [KFitzgerald@vtti.vt.edu](mailto:KFitzgerald@vtti.vt.edu), 540-300-5505. This research has been reviewed and approved by the Virginia Tech Institutional Review Board (IRB). You may communicate with them at 540-231-3732 or [irb@vt.edu](mailto:irb@vt.edu) if:

- You have questions about your rights as a research subject
- Your questions, concerns, or complaints are not being answered by the research team
- You cannot reach the research team
- You want to talk to someone besides the research team to provide feedback about this research

By signing below, you affirm that:

1. You will complete the Data Diary substance use journal every time you drive for a 3 month period.
2. You will collect an oral fluids sample and send it to a lab when the app prompts you to do so (about once a month).
3. You will perform the Breathalyzer test as prompted by the app for trips when you are driving alone.
4. Note that the research team is attempting to study substance use and driving as it naturally occurs. Do not make unhealthy or at-risk changes to your substance use and driving based on participation in the study.
5. You understand that we will not share your data with you.
6. You are allowing us to link the data on substance use collected in this study with the driving data we collect in the NDS driving study under the secure and confidential terms discussed in this informed consent document.



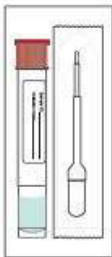



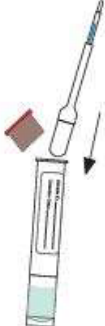

## APPENDIX C. QUANTISAL KIT SAMPLE INSTRUCTIONS

### Oral Fluid Testing Procedure

For the Pioneer study you will be asked to collect one oral fluid sample per month prior to a drive. This document provides you with information on study procedures and how to successfully complete the collection. You will specifically be using the Quantisal™ Oral Fluid Collection Device.

1. **Select your trip.** Once a month, the Data Diary app will prompt you to complete the oral fluid drug test at the beginning of a randomized trip. This prompt will be preceded by a question about whether you are driving solo. If you indicate you are driving with passengers, the app will wait for a solo trip to prompt you about the sample.
2. **Take the oral fluid device out of package.** This package will contain the drug collection device, pre-stamped envelope, and sticker.
3. **Provide an oral fluid sample.** While seated normally on the driver-side of the vehicle, please collect the oral fluid sample. Specific instructions are provided below. Instructions are also provided on the packaging of the oral fluid collection device.
4. **Scan the QR code on the inside lid of the testing kit box.** Your Data Diary app will prompt you to perform this scan.
5. **Place the labeled transport tube into the stamped envelope and seal the envelope.**
6. **Mail the sealed envelope within 24 hours of taking the test.**
7. **Please contact the research team with any questions.**

### How to collect a specimen with Quantisal

<p><b>1</b> Check expiration date on Quantisal packaging and ensure donor has refrained from consumption of food or beverage for 10 minutes prior to specimen collection.</p> 	<p><b>2</b> Instruct donor to peel open package and remove collector.</p> <p>To expedite the collection process, have donor move tongue side to side to accumulate saliva in mouth before starting. Keep the tip of the device pointed down.</p> 	<p><b>3</b> Instruct donor to position collector under tongue and close mouth. Keep head down to allow gravity to help with saliva collection.</p> <p><b>IMPORTANT:</b> ensure donor does not chew on pad, talk, or remove collector from mouth until indicator turns BLUE, or until 10 minutes have passed.</p> 
<p><b>4</b> Instruct donor to hold transport tube in an upright position and uncapped by pushing up with thumb(s).</p> <p>Do not stand tube on table. Do not spill or empty the liquid from tube.</p> 	<p><b>5</b> Instruct donor to insert collector into the uncapped transport tube and replace cap.</p> 	<p><b>6</b> SNAP CAP firmly for transport. Place center of specimen seal on top of tube and press down both sides.</p> 



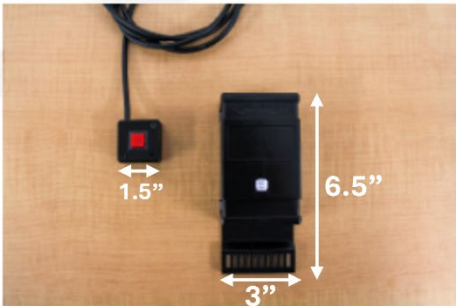
**APPENDIX D. REPRESENTATIVE PHOTOS OF NATURALISTIC DRIVING DATA COLLECTION INSTRUMENTATION**



*Interior camera installations and Incident Button Box*



*Sensor Installation next to front license plate*



*Incident Button Box and Data Collection System*



*Face Camera View*



*Forward Camera View*



*Instrument Panel Camera View*



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