01. General Study Information

The forms menu on the left displays all sections and pages of the application. Pages in **bold** are required. Pages in *italics* may not apply to your project. Use the "Continue" button to advance through the smartform, as it will only display the sections that must be completed.

All questions marked with a red asterisk (*) are required. Questions without a red asterisk may or may not be required, depending on their relevance to the study.

1.1* Study Title:

A investigation into psychoactive drugs and their impact on programming environments

1.1.1 Full Study Title:

1.1.2 If there are other U-M studies related to this project, enter the eResearch ID number (HUM#) or IRBMED Legacy study number. Examples of related projects include, but are not limited to:

- Projects funded under the same grant
- IRBMED Legacy study being migrated into eResearch
- Previously approved Umbrella applications (such as Center Grants or approvals for release of funding)
- Previously approved projects for which this is a follow up study

This study is a follow-up study to HUM00187787

1.1.3* Does this application include the study of COVID-19?

For example:

- **testing or studying the COVID-19 virus,**
- **exploring treatment options,**
- **studying the impact of the COVID-19 pandemic (This could included epidemiological, social, behavioral, or educational research).**

Note: Answer "Yes" only if this project includes the study of COVID-19. Inclusion of study procedures solely intended to allow the research to be conducted under pandemic constraints, such as remote interactions with subjects, remote consenting, or at-home drug delivery are not considered the study of COVID-19.

◯ Yes ● **No**

1.2* Principal Investigator:

Madeline Endres
Note: If the user is not in the system, you may Create A New User Account...

1.3 Study Team Members:

Study Team Member	Study Team Role	Appointment Dept	Appointment Selection Complete?	Student	Friend Account	COI Review Required	Edit Rights	Accepted Role?	PEERRS Human Subjects?
Madeline Endres	PI	EECS - CSE Division	N/A	yes	No	no	yes	N/A	yes
Kaia Newman	Co-Investigator		No	yes	No		yes	N/A	yes
Westley	Faculty	EECS - CSE							

Weimer	Advisor	Division	Yes	no	No	no	yes	Yes	yes

1.8* Project Summary:

Main Research Question: What is the relationship between mental or physical health and the use of mind-altering substances in software working environments? (Additional research questions are available in a document uploaded to this application).

Significance: Productivity in software engineering workplaces is impacted by individual employees' physical and mental health. Simultaneously, mental and physical health is often ameliorated by the use of mind-altering or psychoactive substances (e.g., anti-depressants, cannabis, ADHD medication, etc.). These substances can either be prescribed, self-prescribed, or used recreationally. A recent study from our team (HUM00187787) found that 18% of software developers in our sample used one mind-altering substance, cannabis, while programming, some of whom cited health-related reasons. In addition, many respondents mentioned using mind-altering substances other than cannabis while programming [1]. Despite this use of mind-altering substances by software developers, many companies have anti-drug policies that can conflict with developers' practice, potentially leading to additional stress. In this study, we aim to clarify and deepen our understanding of the regularity of use and effects of psychoactive drugs on software workplaces and while doing programming tasks in general. Our main questions are in areas such as individual physical and mental health (including perceived and actual performance enhancement and symptom alleviation), social environments, and self-regulatory behavior. To our knowledge, this would be the second study on mind-altering substances and programming after [1].

Study Overview: To deepen our understanding of the use of mind-altering substances in professional programming environments, we will be conducting a qualitative study using interviews. To recruit study participants, we will reach out to participants from our previous survey on cannabis who indicated they would be interested in further studies. We will recruit additional participants using flyers, social media posts, and through word of mouth. From the results of this survey and interested previous participants, we will select up to 30 based on the amount of experience we perceive they have with psychoactive drugs in software engineering workplaces. We will interview these recruits for up to an hour on their first or secondhand experiences with psychoactive drugs in the workplace. At the end of the interview, participants will be compensated with a $40 gift card or check. This study is a collaboration with an external collaborator, Professor Brittany Johnson, at George Mason University. Funding from this study will come from a 2019 faculty award from google. There are no reporting requirements or obligations from this grant, and the funds are unrestricted. Data security information is available in our separate data management plan.

[1] Hashing It Out: A Survey of Programmers' Cannabis Usage, Perception, and Motivation, Madeline Endres, Kevin Boehnke, Westley Weimer, ICSE 2022 (to appear)

1.9* Select the appropriate IRB:

Health Sciences and Behavioral Sciences

1.10* *Estimated* Study Start Date (Not required for IRBMED): (mm/dd/yyyy)

3/15/2022

1.11* *Estimated* Duration of Study:

1 year

View: VIEW000072_customAttributes._attribute186_Study Team Detail
Section: 01. General Study Information

Study Team Detail

1.4 Team Member:

Madeline Endres

Preferred email: endremad@umich.edu
Business phone
Business address: EECS - CSE Division 2260 Hayward 48109-2121

1.5 Function with respect to project:

PI

1.6 Allow this person to EDIT the application, including any supporting documents/stipulations requested during the review process:

Yes

Credentials: Required for PI, Co-Is and Faculty Advisors

Upload or update your CV, resume, or biographical sketch.

Name	Version
Resume(0.03)	0.03

Conflict of Interest Detail: Required for all roles except Administrative Staff

Current Disclosure Status in M-Inform: *This study team member has not yet disclosed in M-Inform.*

D1 Do you or your family members **have an** outside activity, relationship, or interest **with a** non-UM entity**, where the non-UM entity:**

- Provides financial or non-financial support for this project;
- Supplies a product used in this project (e.g., an app, device, compound, drug, software, survey, evaluation) either for free or at a cost (e.g., purchased);
- Holds an option or license to intellectual property used in this project (e.g., a device, compound, drug, software, survey, evaluation, code, data, schematics, algorithms) that you or your family member developed;
- Will perform work on this project (e.g., subcontract, service agreement, unfunded agreement); or
- Has a financial stake in the outcome of this research?

No

D2 If "Yes" to the question above, provide the name of the outside entity or entities and a brief description of the interest/relationship(s):

View: VIEW000072_customAttributes._attribute186_Study Team Detail
Section: 01. General Study Information

Study Team Detail

1.4 Team Member:

Kaia Newman

Preferred email: kaian@umich.edu
Business phone
Business address: 48109

1.5 Function with respect to project:

Co-Investigator

1.6 Allow this person to EDIT the application, including any supporting documents/stipulations requested during the review process:

Yes

1.7 Include this person on all correspondences regarding this application: (Note: This will include all committee correspondence, decision outcomes, renewal notices, and adverse event submissions.)

Yes

Credentials: Required for PI, Co-Is and Faculty Advisors

Upload or update your CV, resume, or biographical sketch.

Name	Version
Kaia Newman -- Resume.pdf(0.01)	0.01

Conflict of Interest Detail: Required for all roles except Administrative Staff

Current Disclosure Status in M-Inform: *This study team member has not yet disclosed in M-Inform.*

D1 Do you or your family members **have an** outside activity, relationship, or interest **with a** non-UM entity**, where the non-UM entity:**

- Provides financial or non-financial support for this project;
- Supplies a product used in this project (e.g., an app, device, compound, drug, software, survey, evaluation) either for free or at a cost (e.g., purchased);
- Holds an option or license to intellectual property used in this project (e.g., a device, compound, drug, software, survey, evaluation, code, data, schematics, algorithms) that you or your family member developed;
- Will perform work on this project (e.g., subcontract, service agreement, unfunded agreement); or
- Has a financial stake in the outcome of this research?

D2 If "Yes" to the question above, provide the name of the outside entity or entities and a brief description of the interest/relationship(s):

View: VIEW000072_customAttributes._attribute186_Study Team Detail
Section: 01. General Study Information

Study Team Detail

1.4 Team Member:

Westley Weimer

Preferred email: weimerw@umich.edu
Business phone 734-615-9916
Business address: EECS/CSE 4636 Beyster 48109-2121

1.5 Function with respect to project:

Faculty Advisor

1.6 Allow this person to EDIT the application, including any supporting documents/stipulations requested during the review process:

Yes

Credentials: Required for PI, Co-Is and Faculty Advisors

Upload or update your CV, resume, or biographical sketch.

Name	Version
Westley Weimer Full CV(0.02)	0.02

Conflict of Interest Detail: Required for all roles except Administrative Staff

Current Disclosure Status in M-Inform: *This study team member has indicated in M-inform that they do not have any outside interests to disclose.*

D1 Do you or your family members **have an** outside activity, relationship, or interest **with a** non-UM entity**, where the non-UM entity:**

- Provides financial or non-financial support for this project;
- Supplies a product used in this project (e.g., an app, device, compound, drug, software, survey, evaluation) either for free or at a cost (e.g., purchased);
- Holds an option or license to intellectual property used in this project (e.g., a device, compound, drug, software, survey, evaluation, code, data, schematics, algorithms) that you or your family member developed;
- Will perform work on this project (e.g., subcontract, service agreement, unfunded agreement); or
- Has a financial stake in the outcome of this research?

No

D2 If "Yes" to the question above, provide the name of the outside entity or entities and a brief description of the interest/relationship(s):

View: 01-1. Application Type
Section: 01. General Study Information

01-1. Application Type

1-1.1* Select the appropriate application type.

	Application Type	Description
☑	Human Subjects research **involving interaction or intervention** *(formerly Standard, non-exempt research project - or - Exempt)*	Studies that involve either or both of the following: • Interaction, including communication or interpersonal contact between investigator and subject • Intervention, including both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or subject's environment that are performed for research purposes Interaction/Intervention studies may also have a "secondary research" component.

Does the research involve any of the following:

a. more than minimal risk to participants?
b. use of drugs or medical devices?
c. target prisoners as research subjects?
d. collection of biospecimens from subjects (including blood, saliva, cheek swabs)?

○ Yes ● **No**

Some studies involving interaction or intervention with subjects meet the criteria for exemption. Select the category that best describes your research. Detailed questions to verify eligibility are found on the next page. For some studies, you will be able to issue a self-determination.

If none of these categories apply to your research select NONE. Your application will be routed for comprehensive IRB review.

	Exemption Category
○	**Exemption 1** applies to research that is: • conducted in established **educational settings (typically schools/colleges)**; and • focuses on **normal (accepted) educational practices (e.g. instructional techniques, curricula, classroom management methods** May include use of educational data
●	**Exemption 2 applies to most research that involves collection of information using ONLY one or more of the following:** • **Surveys (with adults only)** • **Interviews (with adults only)** • **focus groups (with adults only)** • **educational tests** • **observation of public behavior** **May involve audio-visual recording but may not involve an intervention (see exemption 3) or linking to additional personally-identifiable data.**
○	**Exemption 3** applies to research with **adults only** that involves: • **benign** (not harmful) **behavioral interventions** Examples: ◦ Playing an online game ◦ Solving puzzles under various noise conditions ◦ Playing an economic game ◦ Being exposed to stimuli such as color, light or sound (at safe levels) ◦ Participating in a nutrition education program • **information collected through verbal or written responses** (including methods described in exemption 2 above) • **no physiological data collection** (e.g. blood pressure monitoring, EEG, FitBit, etc.) • **subjects' prospective agreement to participate** in intervention and

information collection

May not involve deception unless subjects are told that they will be misled

◯ **Exemption 5** applies to **research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads** that are **designed to study, evaluate, improve, or otherwise examine public benefit or service programs**.

◯ **Exemption 6 - Taste and food quality evaluation and consumer acceptance studies**

◯ **NONE** - none of the exemption categories apply to this research.

☐	**Secondary research** uses of private information or biospecimens	"Secondary research" are studies that involve ONLY re-using private information and/or biospecimens that are collected for some other "primary" or "initial" activity, such as other earlier research studies, a biorepository holding specimens obtained with "broad consent," clinical care, or educational records. Includes Exemption 4 and “not regulated” projects. **Do NOT use this application type for:** • Studies that **also** have an interaction/intervention component, such as primary collection of information or biospecimens for the purposes of the study. (Choose instead "Human subjects research involving **interaction or intervention**.") • Projects involving secondary use of information/biospecimens for **only non-research purposes**, such as QA/QI, case studies on one or two individuals, or use in a class to teach research methods. (Choose instead "Activities **not regulated** as human subjects research.")
☐	Activities **Not Regulated** as human subjects research	Not all activities that involve people, their data, or specimens are covered by the regulations governing human subjects research (45 CFR 46 or 21 CFR 50/56). **IRB review is required** for the following activities **ONLY** to assess compliance with **HIPAA** or other regulations or institutional policies: • Research on existing data or specimens that have been coded before the researcher receives them, but identifiers still exist. • Research Involving Deceased Individuals Only • Pre-review of Clinical Data Sets Preparatory to Research • Standard Public Health Surveillance or Prevention Activities **IRB review is not required for the following activities**, but researchers may wish complete this brief application to generate a determination letter for funding or publication purposes, or to request IRB review to confirm the “Not Regulated” determination: • Case Studies • Class Activities • Journalism/Documentary Activities • Oral History • Quality Assurance and Quality Improvement Activities • Research on Organizations • Research using Publicly Available Data Sets
	Projects **lacking immediate**	Activities such as training grants, program projects, center grants, or multi-phase studies not involving human subjects until later years. Before

☐	**plans for involvement of human subjects**, their data, and/or their specimens	release of funding, some agencies may require IRB acknowledgement of the future use of human subjects. These projects are sometimes referred to as "umbrella projects" or "dry applications."
☐	**Single-patient Expanded Access Drug or Biologic (Emergency Use or Non-Emergency/Compassionate Use)**	Use of an investigational drug or biologic, outside of a clinical trial, under a single-patient IND issued by the FDA for a patient faced with a serious or life-threatening disease or condition. • Contact the IRB Chair-on-Call as soon as possible once the decision to use the investigational drug or biologic is made. • Submission for IRB review and approval is required, prior to use if feasible. **If this was an emergency use, submit no later than five days after use of the investigational agent.** • This includes both one-time use and continuing therapy.
☐	**Single-patient Expanded Access Device Use (Emergency Use or Non-Emergency/Compassionate Use)**	Use of an investigational device, outside of a clinical trial, when this is the only option available for a patient faced with a serious or life-threatening disease or condition. • Contact the IRB Chair-on-Call as soon as possible once the decision to use the investigational device is made. • Submission for IRB review and approval is required, prior to device use if feasible. **If this was an emergency use, submit no later than five days after use of the investigational device.** • This includes both one-time use and continuing therapy.
☐	**Humanitarian Use Device** (HUD) under a HDE	Non-research, on-label use of an HUD under a Humanitarian Device Exemption (HDE)
☐	Requesting Review by a **Non-UM IRB**	Use ONLY to request deferral of IRB oversight for UM activities to a non-UM IRB or when UM is a performance site in a multisite research project where UM is the lead site.
☐	**Multi-site Research** where U-M is a Coordinating Center and/or IRB of Record	Do not use Multi-site Research application type when U-M is **only** a performance site - select Standard application type. Select when U-M is any of the following: • Data Coordinating Center; • Clinical Coordinating Center; or • IRB of Record for non-U-M sites (for U-M to be IRB of Record you must contact your IRB for prior acknowledgement). When U-M is **also** a performance site, a separate application is required for local site considerations. Refer to special requirements at the IRB website.

01-2. Standard Study Information

1-2.1* Who initiated this study?

Student investigator or faculty member on behalf of a student

1-2.2* Are you or any students working on this project being paid from a federally funded training grant?

○ Yes ● **No**

1-2.3 This study is currently associated with the following department. To associate this research with a different department, click Select. If the department has defaulted to "student", click select to specify the department through which this application is being submitted.

EECS - CSE

1-2.5* Is the study related to cancer, cancer risk, or cancer care delivery?

○ Yes ● **No**

1-2.7* Has the scientific merit of this study already been peer reviewed (i.e., reviewed by one or more recognized authorities on the subject)?

○ Yes ● **No**

1-2.8* Is this a clinical trial?

○ Yes ● **No**

01-7. Student Research Information

1-7.1* This application is being submitted by a:

Select all that apply:

Student for a dissertation/thesis

1-7.2 Indicate course number here:

View: 02. Sponsor/Support Information
Section: 02. Sponsor/Support Information

02. Sponsor/Support Information

The following sections request details about the current or pending sponsorship/support of this study. Consider all of the choices below and complete the appropriate sections.
*** Note: At least one of the following sections must be answered. Multiple forms of funding or support must be added one at a time.**

2.1 Please select all Proposal Approval Forms (PAFs), Awards (AWDs), and/or Unfunded Agreements (UFAs) associated with this study.

☐ **Click here to indicate that a PAF(s) has not been initiated.**

Related PAFs:

ID	Title	PI	Direct Sponsor	Prime Sponsor	State	Has SUBKs?	Related Awards
There are no items to display							

Related AWDs:

Award ID	Title	PI	Direct Sponsor	Prime Sponsor	State	Has SUBKs?	Project Period	Awarded PAFs
There are no items to display								

Related UFAs:

UFA ID	Title	PI	State	Category	Start Date	End Date
There are no items to display						

2.2 Internal UM Sponsor(s)/Support: [Including department or PI discretionary funding]

	Type	Department Sponsor	Support Type
View	PI Discretionary Funds	EECS - CSE	Financial

2.3 Check here if the proposed study does not require external or internal sponsorship or support:

☐

2.4* Is there any other financial or non-financial sponsorship or support not covered in the sections above?

○ Yes ● **No**

View: VIEW000593_customAttributes._attribute239.customAttributes._attribute3_Internal Sponsor Detail
Section: 02. Sponsor/Support Information

Internal Sponsor Detail

2.2.1* Department Sponsor/Support:

EECS - CSE

2.2.2* Sponsor Type:

PI Discretionary Funds

If other, please specify:

2.2.3* Support Type:

Financial

2.2.4* Is the support confirmed?

● **Yes** ○ No

2.2.5* Please describe the award/support:

Discretionary funds from google. This is a 2019 Google Faculty Research Award. It is an unrestricted gift with no reporting obligations.

There is no obligation to report research results back to google.

2.2.6 Upload Supporting Documentation

Name	Version
There are no items to display	

03. UM Study Functions

3.1* Indicate all functions that will be performed at University of Michigan locations.

Select all that apply:
Recruitment (including screening)
Interaction (e.g., information gathering, survey, interview, focus groups, etc.)
Qualitative research (e.g., 'member checking', open-ended questions, etc.)
Primary or secondary analysis (data/specimen)
Storage (data and/or specimen): Responsible for the management, security and transfer of study data and/or specimens.

If other, please specify.

View: 03-1. Performance Sites
Section: 03. Performance Sites

03-1. Performance Sites

3-1.1* Performance Sites:

Location	Country	"Engaged" in the research?	Performance Site Type	Site Function
University of Michigan	USA	yes		Qualitative research,Storage,Interaction,Analysis,Recruitment

Performance Site Detail

3-1.2* Location or Institution:

University of Michigan

3-1.3 Address:

City
State
Country* USA

3-1.4* Function of this location with respect to this study:

Select all that apply:
Recruitment (including screening)
Interaction (e.g., information gathering, survey, interview, focus groups, etc.)
Qualitative research (e.g., 'member checking', open-ended questions, etc.)
Primary or secondary analysis (data/specimen)
Storage (data and/or specimen): Responsible for the management, security and transfer of study data and/or specimens.

If other, please specify:

3-1.5* Will this site be "engaged" in the conduct of the research?

● **Yes** ○ No

3-1.6 If known, provide the Federalwide Assurance (FWA) number for this location.

FWA00004969

3-1.7 If applicable, indicate what organization, agency or government office has reviewed this research and provided its approval (e.g., IRB, ethics committee, school district office, prison official, nursing home administrator).

3-1.8 Upload any location site approval documentation here:

Name	Version
There are no items to display	

View: Exemption 2
Section: 12. Exemption

Exemption 2

Completion of this section is required based on the Exemption Category selected in question 1-1.1.

Exemption 2 applies to projects that include either:

1. Observation of Public Behavior; or
2. Interactions with human subjects that involves collection of information ONLY using the follow methods:
    - Surveys
    - Interviews (including cognitive interviews)
    - Focus Groups
    - Educational tests (cognitive, diagnostic, aptitude, achievement)
    - Observation of public behavior

Audio and/or video recording of these observations or interactions is permitted.

This exemption does not apply if the research involves:

- Interventions/manipulations that are distinct from the information collection methods
- Collection of biospecimens in conjunction with surveys/interviews/educational tests
- Linking information collected via this exemption to other personally-identifiable data

1* Confirm that your research involves the collection of information ONLY using one or more of the following:

- **Surveys (information collected through questionnaires, in person or online)**
- **Interviews**
- **Focus Groups**
- **Educational Tests (cognitive, diagnostic, aptitude, achievement)**
- **Observation of public behavior**

● **Yes** ○ No

1.1* Does the research involve children?

○ Yes ● **No**

2* Does the research collect information about the subject in such a manner that their identity can be readily ascertained by the study team, directly or through identifiers linked to the subjects?

This means that the information is collected with direct identifiers (name, address, email, phone number, social security number, student ID, medical record number) or indirect identifiers, such as a code that can link back to the subject or data elements that could be combined to readily re-identify an individual (dates, employment history, etc.).

● **Yes** ○ No

2.1* Will the research generate information that, if revealed outside the research, could reasonably place the subjects at risk of criminal or civil liability, or damage their financial standing, employability, educational advancement or reputation?

This means that the research involves the collection of sensitive information, about the subject, such as information about illegal behaviors, mental health issues, sensitive health conditions (HIV, STDs), genetic information, or negative opinions/attitudes about employers or teachers. A disclosure of this information outside of the research (breach of confidentiality) could pose legal risks or risks of social stigmatization to the subjects.

● **Yes** ○ No

3* Will the research involve the access, collection, use, maintenance, or disclosure of protected health information (PHI) to identify eligible subjects? [Require Section 25]

○ Yes ● **No**

4* Provide a brief summary of your research (subject population, study procedures, location of research) or upload protocol below.

Subject Population: We will be studying currently employed software developers and their attitudes toward and usage patterns with psychoactive drugs. To be eligible, potential participants must be software developers who have had direct experience with mind-altering substances in the workplace, whether by using them themselves or having extensive knowledge of others using them in their industry (through managing, colleagues' accounts, etc.). They must also be at least 18 years old and willing to be interviewed about their experiences for 30minutes to an hour.

Recruitment: Some participants will be contacted through a list collected from a previous human study regarding cannabis and programming (HUM00187787). All individuals on this list indicated that they would be interested in being contacted for follow-on studies. For additional participants who were not part of the previous study, we will recruit through social media posts, emails, flyers, and industrial contacts using a preliminary survey. All survey links will be the same (whether clickable or a QR code). We will ask interviewees how they were recruited to our study at the interview time. We have included recruitment emails and posters in the uploaded documents.

Study Procedure:
1. We will first recruit participants from the populations above. This recruitment will point participants to an initial survey hosted on UMich's Google Forms which is approved for use with Human Subjects Research Data. We will either email participants an invitation to participate in the interview or potential interviewees will go to a link provided on a social media post, email, or flyer's QR code to reach a preliminary survey on their experience with mind-altering substances in software engineering workplaces.
2. The initial survey will take approximately 5-10 minutes to complete. The first page of this survey will contain informed consent information, which survey participants agree to by continuing with the survey. After that, the preliminary survey will ask for contact information (names and emails), demographics information (age, gender), a couple of software-specific questions (e.g., how long have you been a software developer?), and if they have had significant first or second-hand experience with mind-altering substances in a software environment. This initial survey will not go into detail about these experiences, only if they exist and are substantial enough to talk about for 30-60 minutes. Participants can stop the survey at any time. As this preliminary survey collects identifying information, we discuss it further in the data management plan uploaded later in this application.
3. From the initial survey responses, we will select up to 30 people from the prescreening survey. Interviewees will be chosen on a first-come-first-serve basis as long as they meet the requirements for participation listed above. Interviews will be scheduled using Umich calendar invites.
4. The interviews are semi-structured and will take up to an hour to complete, or until all interview topics have been covered (if the time elapsed is less than an hour). The interview flow for the semi-structured interviews has been included in the supporting documents uploaded to this application. Interviews will take place over an online UMich Zoom meeting. Participants will first be briefed again on consent information and will give verbal consent, which can be retracted at any point during the interview. The interview will be recorded.
5. For participating, interviewees will have the option to receive $40 via check or visa gift card.

Data Protection:
Due to the sensitivity of the collected data, we have uploaded a detailed data management plan. In brief, however, we will store all data on UMich accounts that are certified for use with Human Subjects Research (UMich Drive, UMich Dropbox, and UMich MiVideo). We will also delete personal identifying information as soon as possible (i.e., names and addresses deleted after payment processed, video recordings deleted immediately, audio recordings deleted once the analysis is completed).

Because your study will collect identifiable, sensitive information, the IRB must review your recruitment materials, consent materials, and data management and security plan. Please upload below.

5* Upload documents (e.g. protocol document, survey/interview/test questions, or other documents relevant to your research).

The submission of an informed consent document is not required for studies that do not collect identifiable, sensitive data. Researchers still have an ethical obligation to ensure that participants are fully informed about the nature of a research project so that they can make an informed decision to participate.

Name	Version
Consent Form.pdf(0.01)	0.01
Data Management Plan (1).pdf(0.02)	0.02
K Research questions, interview questions, and interview flow.pdf(0.01)	0.01
Recruitment posts, emails, and poster text.pdf(0.01)	0.01

6* Will subjects receive payment or other incentives for their participation in the study?

● **Yes** ○ No

6.1* What is the estimated maximum total payment to an individual subject?

$26-$100

6.2* Please indicate what information you will be collecting from subjects that will be paid for their participation:

Select all that apply:

- [x] **Name**
- [ ] None
- [x] **Address**
- [x] **Email**
- [ ] Social Security Number (SSN)

View: 11. Confidentiality/Security/Privacy
Section: 11. Confidentiality, Security and Privacy

11. Confidentiality/Security/Privacy

11.1* Will the study team access any data that is linked to a subject's identity by name or other identifier or code? [Require Section 11-1]

● **Yes** ○ No

11.2* Explain how the subjects' privacy will be protected.

Subjects' privacy will be protected via a combination of destroying identifying information as soon as possible (e.g., after payment or after analysis is over), and storing all data on UMich password-protected accounts that are approved for Human Subjects Research (UMich drive, UMich dropbox, and UMich MiVideo). Access to this data (including access by any external collaborators) will require authentication and permission (e.g., google drive collaboration access). Additionally, external collaborators will be required to access online data using a secure network (e.g., VPN or password protected). Data access permission will be managed by PI Endres. In any publications, all data will be de-identified. Additional information can be found in the uploaded data management plan.

11.3* How will the study team protect research records, data, and/or specimens against inappropriate use or disclosure, or malicious or accidental loss or destruction in order to protect the confidentiality of subject data?

Select all that apply:
Locked office
Locked cabinet or storage unit
Restricted access
Destruction of source data immediately after data collection (e.g., to preserve anonymity of a vulnerable population)
Restrictions on copying study-related materials
Access rights terminated when authorized users leave the project or unit
Secure laptop
Individual ID plus password protection
Network restrictions
No non-UM devices are used to access project data, or any that are used to access project data use secure connections to communicate with U-M services (e.g. VPN – “virtual private network”)
Safe disposition/destruction of data or devices, as appropriate (e.g., shredding paper documents, destroying disks or thumb drives, secure erasure of electronic media)

If other please specify:

11.4* Does either statement apply to this research:

Research has NIH, CDC, or FDA funding, or other federal funding from an agency that automatically issues a Certificate of Confidentiality as part of the terms of the award:

The study will include identifiable sensitive information, identifiable biospecimens, individual human-level genomic data/biospecimens, or any information about an individual for which there is at least a very small risk, as determined by current scientific practices or statistical methods, that some combination of the information, a request for the information, and other available data sources could be used to deduce the identity of an individual.

or

Research does NOT have NIH, CDC, or FDA funding, or other federal funding from an agency that automatically issues a Certificate of Confidentiality as part of the terms of the award:

The study will include identifiable, sensitive information or identifiable biospecimens that, if revealed, might place the subjects at risk for personal safety, criminal or civil liability, or damage to their financial standing, employability, insurability, or reputation.

[Require Section 11-2]

● **Yes** ○ No

11.5* Will data be provided to a repository as part of a data sharing agreement?

○ Yes ● **No**

11.6* What will happen to the data and/or any specimens at the conclusion of this study?

Select all that apply:
Destroy
Retain for future research use - requires Section 11-4

11.6.1* If the data and/or specimens will be destroyed, describe the specific plan that will be employed following the required retention period.

All data except for de-identified textual transcripts of the interview will be destroyed as soon and possible. Names, emails, and addresses will be destroyed once payment is processed (at most 2 months after the interview date). Video recordings from zoom will be deleted immediately after the interview, and audio recordings will be deleted once the analysis is complete (~6 months after the interview). For that data stored on UMich storage platforms (UMich dropbox, MiVideo, drive), they will be deleted by using the platform's built-in delete option. For the video recordings which will be captured on a secure laptop, these will be deleted by dragging them to the trash and emptying the trash. Only the de-identified textual transcripts will be retained after the analysis period.

View: 11-1. Identifiable Data
Section: 11. Confidentiality, Security and Privacy

11-1. Identifiable Data

Completion of this section is required based on the response provided to question 11.1.

11-1.1* Indicate how subjects are identified in the research records.

Select all that apply:

Coded or Indirect Identifiers - data record includes a link to direct identifiers (e.g., name, initials, phone number, SSN, or medical record number linked to data record but stored separately)

No Identifiers (De-identified, Anonymous, or Anonymized) - stored data record is stripped of all identifiers

11-1.2* Explain the necessity for collecting or maintaining data linked to subjects' identities. If the information is covered in the attached protocol, please indicate section.

See the data management plan, sections 1 c-e

In brief, as we are recording interviews, participant voices are contained in the recordings. Additionally, due to the research question (understanding the intersection of mind-altering substance use and professional software development), sensitive information may be collected during the interview.

11-1.3* How long will the identifiers be retained?

This is also contained in the data management plan 1.c and 1.d:

Names, emails, and physical addresses will be destroyed after participant payment is processed (no more than 2 months after the interview day). Zoom recordings collect both video and audio information. Video recordings (with full facial information) will be destroyed within 24 hours of the interview being conducted. Audio recordings will be retained throughout the analysis of the data, and thus will not be destroyed. Text transcripts will be made of the audio recordings. These will be stripped of any latent identifiers (e.g., names, workplace company name, city location).

11-1.4* Will individually identifiable sensitive data be accessed, collected, used, maintained, or disclosed in the study?

● **Yes** ○ No

11-1.4.1* Will a continuous, periodic, or automatic feed of sensitive data be set up to provide data directly from any University information system (e.g., M-Pathways, U-M Data Warehouse, CareWeb)?

○ Yes ● **No**

11-1.4.2* Will sensitive data be accessed by individuals who are not University employees?

● **Yes** ○ No

11-1.4.3* Will sensitive data be stored on or accessed from computer equipment that is not maintained and supported by a University IT services provider (e.g., ITS, MCIT, MSIS) - such as home computers, grant-funded computers, etc.?

● **Yes** ○ No

11-1.4.4* Will sensitive data be stored on portable devices (e.g., laptops, PDAs, flash drives) in unencrypted form?

○ Yes ● **No**

11-2. Certificate of Confidentiality

Completion of this section is required based on the response provided in Section 11

11-2.1* Is there a Certificate of Confidentiality (CoC), or will one be obtained, for this research? (If NIH, CDC, FDA, or other federal funding from an agency that automatically issues a Certificate of Confidentiality as part of the terms of the award, answer "Yes")

○ Yes ● **No**

11-2.2* Describe any measures or procedures that will be employed to prevent others from learning about subjects' participation in this study through forced disclosure (i.e., under subpoena).

To avoid disclosure of participation in this study through forced disclosure, we will be deleting identifiable data as soon as possible:

1. Names, emails, addresses will be deleted as soon as payment is processed (at most 2 months post-interview)
2. Video recordings will be deleted immediately after the interview
3. Audio recordings will be deleted after the analysis is complete (at most 6 months after the interview)

View: 11-4. Retention of Data and/or Specimens Detail
Section: 11. Confidentiality, Security and Privacy

11-4. Retention of Data and/or Specimens Detail

Retention may be for future research by the investigator and/or the creation of a bank or repository.

Completion of this section is required based on the response provided to question 11.6.

11-4.1* What is the intent or purpose of retaining the data and/or specimens?

De-identified textual transcripts of the interviews will be retained. This is primarily such that they can be available as a reference for the researchers to answer reviewer questions when publishing our results and to be used in a potential future extension of the work.

11-4.2* Where will you store the data and/or specimens?

Only at the University of Michigan

If Other Institutions, please specify:

11-4.3* Describe the arrangements for the storage conditions, management, and security of the data and/or specimens. Include the following as applicable:

- ***Personnel access to data and/or specimens***
- ***Whether identifiers will be removed and the key to any code destroyed***
- ***For coded data and/or specimens, indicate who holds key to the code and where it is stored in relation to the data and/or specimens***
- ***Storage plan***
- ***Plan to protect privacy in transfer to other collaborators.***

Only de-identified data will be stored. The key to any codes would be destroyed. This data will be stored on UMich dropbox and/or UMich google drive. Data will not be made publically available. Should it be transferred to other/external collaborators, their google accounts would have to be given explicit access to view the data. Should the de-identified data be shared with other researchers after the analysis is complete, a data-sharing agreement with protections for the confidentiality of the data would have to be signed.

13. Subject Payments Or Other Incentives

Completion of this section is required based on the response provided to question 7-1.1 or 7-3.3.

13.1* Indicate all payments or other incentives provided to subjects for their participation in this study:

Select all that apply:
Cash
HSIP Issued Gift Card
Check

If other, please specify:

13.2* If the subject is a child (under the age of majority), are any of the payments or incentives intended for the parent/guardian of the child?

N/A

13.3* Estimate the maximum total payment (including cash, checks, gift cards, and other cash-equivalent incentives) that an individual subject could receive for participating in this research in a single calendar year.

$26-$100

13.3.1* Please indicate what information you will be collecting from subjects in order to distribute their incentive or compensation.

Select all that apply:
Name
Address
Email

13.4* Describe the frequency of the payments or incentives. If applicable, list any healthcare procedure(s) that will be provided to subjects at no charge.

Payments will happen once

13.5* What is the justification for offering these payments or incentives?

The interview lasts up to an hour, so this payment is compensation for the time the participant spends participating.

13.6* What is the plan to compensate subjects withdrawing from the research prior to completing the entire study.

All participants who attend an interview will be compensated, even if they chose to withdraw from the interview early (e.g., before the 30 minutes to 60 minutes are up)

44. Additional Supporting Documents

44.1 Please upload any additional supporting documents related to your study that have not already been uploaded. Examples include, but are not limited to, data collection sheets, newsletters, subject brochures, and instructional brochures.

Name	Version
There are no items to display	

45. End of Application

The form was successfully submitted. Click 'Exit' or 'Finish' to leave the form.