Guidelines for Research on Psychoactive Drug Use amongst Human Participants

Please note: THESE ARE GUIDELINES ONLY! We hope that the below information will be useful in guiding the planning of your study and prompting appropriate ethical considerations. However, all ethical applications will still need to go through the usual ethical review by the relevant ethical board and will be considered on a case-by-case basis. Decisions are context and committee dependent, however an outcome is more likely to be favourable when consideration of the following points is evidenced (with appropriate tailoring to your research question). These guidelines have been written for research on people who use psychoactive drugs and are **not designed for studies involving drug administration**. Many of the issues discussed in this guideline apply to research on other topics beyond psychoactive drug use, and might be useful considerations in several scenarios.

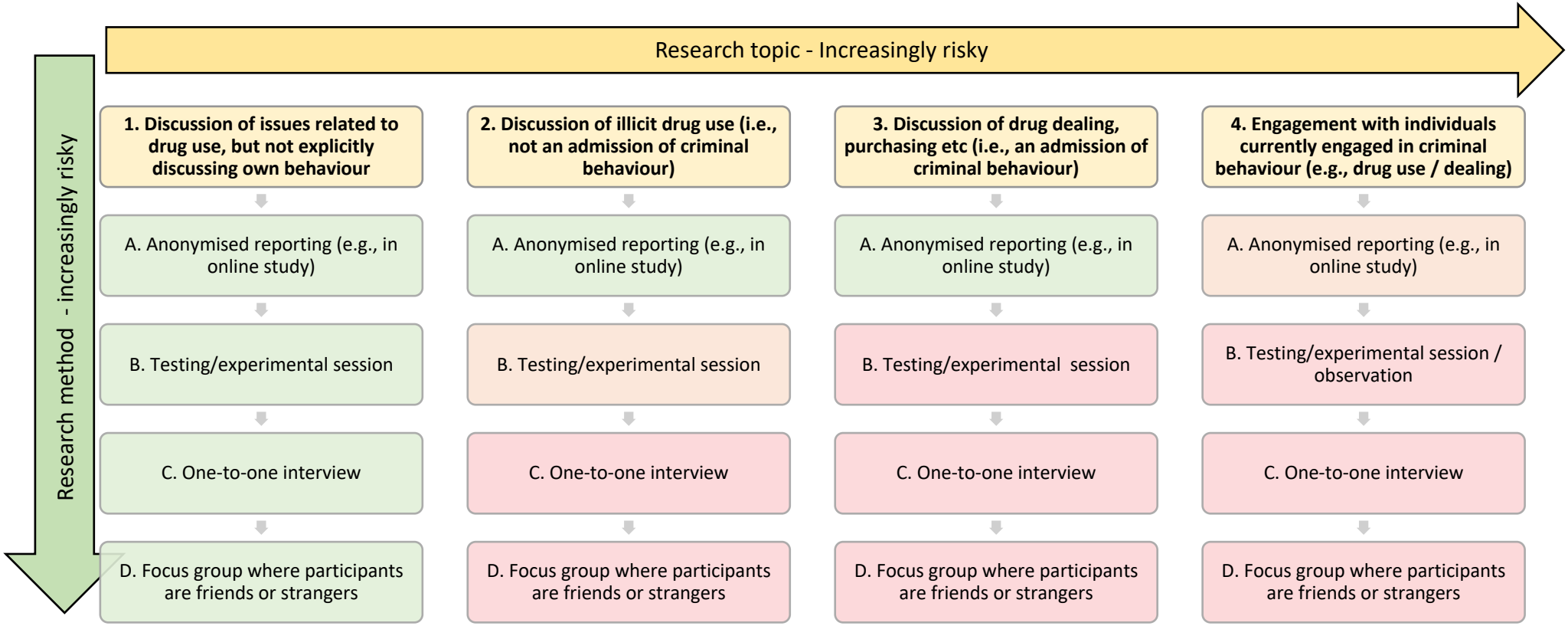
Contents

This guideline has been developed by the School of Psychological Science research ethics board, in collaboration with Dr Olivia Maynard and has been guided by the Transform Drug Policy Foundation Best Practice Guidelines for Research around Drugs Issues which can be read in full here. Given that the guidelines are developed with psychological research in mind, they might not apply directly to research from other schools.

Most recent update: November 2024.

Section 1: Matrix of drug related research and related considerations

Figure 1. Here we present a matrix of types of research involving drugs. This is not an exhaustive list, but we hope that it can provide a useful guide when thinking about what types of research you might wish to conduct, and which require additional considerations in order to obtain ethical approval. Box colour indicates suitability for **undergraduate student projects**: green = most suitable, orange = possibly suitable (with additional support), red = not suitable. Some specific points to consider for each study design are below.



Research Topics

Research Topic 1: Discussion of issues related to drug use, but not explicitly discussing own behaviour

Research which is only discussing issues related to drug use (not discussing participants' own behaviour) is deemed to be less risky, due to no disclosure of illegality and a lower likelihood of participant distress. Ethics applications should include sufficient consideration of how they will reduce the risk of participants disclosing about their own behaviour (transitioning to research topics 2-4). If this is in an interview/focus group setting, researchers should be able to demonstrate training in conducting qualitative research or have a supervisor with sufficient qualitative research experience so that researchers feel able to keep discussions on topic.

Research Topic 2: Discussion of illicit drug use

While the discussion of illicit drug use is not in itself an admission of criminal behaviour in the UK, this information should still be treated sensitively (see Section 2.2.3.). If data collection is entirely anonymous (without open-ended questions), then admissions of drug use can be collected under checklist ethics. However, if data collection is not fully anonymous, then this will trigger full ethics (see section 3). Furthermore, as laid out above in research topic 1, researchers need to carefully guide participants such that more free-form conversations do not move onto the disclosure of illegal activities (e.g. dealing, research topics 3-4) if not relevant to the research question. Research team experience will be important to effectively facilitate such discussions.

Research Topic 3: Discussions of drug dealing, purchasing, and other admissions of criminal behaviour

Admissions of criminal behaviour (e.g. discussions of drug dealing, purchasing etc.) require a full ethics application to demonstrate appropriate handling of this sensitive data (see section 3). See sections 2.2 and 2.4, for further information on how to protect participants and on important considerations to ensure there is not undue harm. Risk assessments and distress protocols must be in place to protect both the participants and the researchers. Disclosures of criminal behaviour do not need to be reported to authorities unless there is a significant risk of harm or safeguarding risk (see section 2.3). If relevant, please provide discussion of how this will be dealt with in your ethics application.

Research Topic 4: Research with individuals currently engaged in criminal behaviour, or under the influence of drugs

Researchers are unlikely to be granted ethical approval to conduct research which involves individuals currently engaged in criminal behaviour (e.g., drug use / dealing) unless the researcher has substantial experience in the field or in previous job roles, or the data is anonymous at data collection (4A). Individuals currently under the influence of drugs may be unable to give informed consent, although this will not always be the case. Please refer to section 2.5 on how to evidence sufficient experience to be able to make appropriate assessment of consent. Risk assessments and distress protocols must be in place to protect both the participants and the researchers.

Study Designs

Study Design A: Anonymous online questionnaires

Overall, anonymous data collection is the least risky research design. Anonymous data collection on research topic 1 is likely to be able to go through checklist ethics (unless other conditions for checklist are not met). If data collection for research topic 2 is completely anonymous and doesn't ask open-ended questions then this will also go through checklist ethics (unless other conditions for checklist are not met). There are a few additional considerations we highlight here. First, ensure that data collection is truly anonymous at all stages (e.g. don't ask participants to email you with their real email address to obtain information). Second, to protect the researcher, do not use your personal email or account to contact participants on forums or social media (unless there are specific reasons to do so, or topic risk is low). Third, consider the geographic region that you are recruiting from. If recruiting more widely than just the UK then consider laws in different countries and ensure research is low risk where necessary. Fourth, despite not being in contact with participants directly, it is still crucial to ensure we do no harm, and so avoid topics that would be difficult to discuss without support and provide links to support lines the participant can access in their region (see Section 2.1 for further guidance on anonymisation). Finally, anonymous data collection is most likely to avoid participant distress or accidental disclosure of GDPR special category information when it is quantitative rather than open-ended. Therefore, this type of data collection is preferred where suitable.

Study Design B: Experiments or testing sessions

In experimental settings, although data will be anonymised, in-person test sessions can never be fully anonymous, as the researcher sees the participant. Therefore, researchers may wish to consider the following to reduce risks to participants: 1) it might be possible to blind the experimenter as to whether the participant is part of a group who use drugs or a group who do not, 2) include a control group so it is not known whether participant uses drugs or not, 3) where suitable, we recommend recruiting participants who are not known to the researcher. Of course for some research designs, those steps will not be possible. Therefore, we emphasise the importance of confidentiality of sensitive information (including study participation). We further recommend including a participant facing study title that does not make it obvious that everyone taking part is a drug user (e.g. implying control group).

Study Design C: One-to-one interview

One-to-one qualitative interviews can become very in-depth and might become distressing for both the researcher and the participant. If the discussion is likely to cover distressing topics, then full ethics will be triggered, and a risk assessment and distress protocol must be in place (see Section 2.4). Researchers should have training in qualitative data collection to be able to conduct interviews on sensitive topics, or have support of a supervisor with such training/experience. In some cases, the research team should include a person who is able to provide emotional support to researchers exploring distressing topics. We suggest that in some situations it might be appropriate to only recruit participants that are not known to the researcher prior to the study (for research topics 2-4) so they are more able to be honest (unless such trust building is required for a certain population or topic of discussion is low risk).

Study Design D: Focus groups

When designing studies using focus groups, sufficient consideration must be given to ensure that the participants are not known to one another, unless they are only discussing research topic 1. There may be occasions where this might not be appropriate (e.g., if all participants in a focus group are one group of friends who already take drugs together, so that new information is not disclosed). Confidentiality and protection of sensitive information should always be the priority, and the best approach should be decided on a case-by-case basis. The importance of confidentiality about other focus group members should be emphasised to participants. Researchers should have training in qualitative data collection to be able to conduct focus groups on sensitive topics, or have support of a supervisor with such training/experience.

Section 2: Overview of important considerations

In section 2, we provide broad guidance on key ethical considerations when planning research related to psychoactive drug use with human participants. Many of these ethical considerations are not specific to research on drug use. The ethical review board will need to see evidence in your ethics application that you have considered each of these topics where appropriate.

2.1. Anonymisation

Projects which involve completely anonymous data collection are more likely to receive favourable ethical approval. We strongly encourage anonymous data collection where it is suitable for your research question (e.g. asking participants to complete and return an anonymous questionnaire). Furthermore, this is the type of research that we would recommend for student projects.

If the study design cannot be anonymous at the point of data collection (e.g. study designs B-D), then the ethics board will need to see additional steps in place for the protection of participant data. Data should be anonymised or pseudo-anonymised as soon as possible. Data must be stored on secure servers (e.g. on the research data storage facility (RDSF), or on University password-protected OneDrive) and non-anonymised data files or linkers must be deleted as soon as they are no longer needed. Access to linker files should be limited and password protected. These steps need to be clearly outlined in the ethics application and the participant information sheet.

For qualitative interviews and focus groups, the data cannot be anonymised at the point of data collection, but it must be anonymised at the point of transcription, removing any names and identifiable information. As soon as the data is transcribed and checked, the recordings should be deleted. This needs to be described clearly in the participant information sheet so that participants can give fully informed consent. Where appropriate, participants could be advised to not disclose potentially identifiable information. In the majority of circumstances, it is not necessary to record video, only audio. This needs to be made explicit in the application and if video is being recorded then this needs to be fully justified.

2.2. Sensitive topics

In this section, we cover research topics that are considered sensitive, and give guidance on how to handle them. Some sensitive topics have special category status under GDPR (triggering full ethics). Disclosures of illegality will also now trigger full ethics. Other topics (such as drug use) will need to be treated sensitively (with evidence to demonstrate this).

2.2.1. Special category sensitive topics under GDPR

Sensitive topics which have special category status under GDPR include: personal data revealing racial or ethnic origin; personal data revealing political opinions; personal data revealing religious or philosophical beliefs; personal data revealing trade union membership; genetic data; biometric data (where used for identification purposes); data concerning health; data concerning a person's sex life; and data concerning a

person's sexual orientation. Research addressing any of these topics will require full ethics.

2.2.2. Disclosure of illegality

Researchers have a professional duty to refrain from doing anything that could bring the University into disrepute. Given that drug use is highly stigmatised and the news media tend to have a sensationalist approach to topics related to drug use, it is possible that research related to drug use could be misrepresented by the media. Researchers should therefore clearly communicate the value and importance of their research in both the ethics application and in participant facing documents.

Drug possession, supply and production are all illegal in the UK. Research projects in which participants could disclose these activities will need to submit a full ethics application. Although drug use itself is not illegal, this data is also sensitive. Therefore, if participants are disclosing drug use that is not fully anonymised at the point of data collection, this will also require a full ethics application (see section 3). When submitting a full ethics application, pleased show due consideration of the guideline considerations in your ethics application.

2.2.3. Disclosures of drug use should be treated sensitively

As well as these GDPR sensitive topics and disclosures of illegality, disclosures of drug use should also be treated sensitively by researchers. Although drug use is not illegal, it is still a heavily stigmatised behaviour in many settings. In all cases it is therefore still highly sensitive information that could have repercussions for the participant if this data was not appropriately stored or anonymised. Researchers have a moral duty to protect the sensitive data of participants (both special category sensitive data under GDPR and other data which should be treated sensitively).

There are some participants for whom the repercussions of admitting to drug use could be severe, including some people from certain cultures or religions, or for students on professional courses. As such, due consideration needs to be given to the vulnerability of certain participants. Even outside of these constraints, the researcher should be aware that participants may feel uncomfortable discussing drug use with a researcher who they may not trust.

Researchers should be aware that certain questions related to drug use (either asked using qualitative or quantitative data collection methods) may be more / less sensitive. For example, asking about what drugs someone uses (particularly if asked in an online fixed-response survey) may not be seen as particularly sensitive for some participants, but asking about the context of their use (e.g. motivations for use, harms from use etc) may be more sensitive and in some contexts may be distressing for some participants (see section 2.4 on distress). Researchers should carefully consider which questions are necessary to answer their research questions and consider what is the best way to ask these questions.

2.2.4. Considerations for collecting and handling sensitive information

The researcher should make it clear to the participant how their sensitive data will be handled, including confidentiality, anonymisation and storage of data. This should be taken seriously by the research team, and it may not be appropriate for undergraduate students to collect sensitive data. The researcher should also be aware that even when researching topics are not deemed to be sensitive (e.g., student's attitudes to drugs harm reduction education at university), it is possible that in qualitative work, the focus of the discussions could move onto more sensitive topics (e.g., participants' concerns when using drugs, including concerns around sexual violence, or discussions around social supply of drugs which would be an admission of criminal activity). Sufficient training of the research team will be required to appropriately facilitate these discussions.

The following are suggestions to researchers on the handling of all sensitive data:

- Clearly explain how data will be kept confidential.
- Clearly outline in the participant information sheet the extent of the confidentiality participants can expect. You may wish to refer to the BPS ethical guidance document which has information on the limits to confidentiality and to section 2.3 on safeguarding.
- Where possible for the research design, data should be completely anonymous at collection. If not, data must be anonymised as soon as possible (see section above on anonymisation).
- Demonstrate that appropriate and secure data storage will be used (i.e. RDSF).
- The research methods must be appropriate and well justified so that participants are not disclosing sensitive information unnecessarily.
- Centre research questions on drug use, production, the impacts of supply on livelihoods, economies and experiences, rather than on criminality.
- We recommend considering if geographic limits should be put in place when recruiting online. For example, it may be appropriate for some research studies to limit online recruitment to those living in the UK, as laws and repercussions in other countries might be much more severe, increasing the risk to participants.
- If sensitive topics are being discussed, then support resources should be signposted (see section 2.4) and these resources need to be suitable/accessible to the countries you are recruiting from.
- Even within the UK, there are certain groups of individuals who might be more vulnerable if data about their illegal activities or drug use was leaked. For example, they may be a citizen of another country where laws/repercussions are more severe and applicable to them even whilst not in the country, or they might be part of a cultural or religious group where drug use is more stigmatised and consequently there could be severe social consequences if their use was disclosed, or those working in specific professions. Due consideration of these potential harms will need to be demonstrated if important for the study design (see section 2.4).

2.3. Vulnerability of participants

An ethics application must go through full ethics if the participants are particularly vulnerable or unable to give informed consent. Examples of vulnerable participants are: children, people with learning difficulties, patients, people experiencing emotional distress or mental illness, people living in care or nursing homes, people recruited through self-help groups, participants in a dependent or unequal relationship with the researcher(s) or research supervisor. Additionally, being currently intoxicated can increase participant vulnerability. Specific considerations for research with people currently under the influence of drugs can be found in section 2.5.

With regards determining vulnerability, Transform highlight that perceived risks of drug use can often be exaggerated, informed by media and prohibitionist laws that may distort judgement of actual risks. Do not assume that people who use, sell, or produce drugs are a homogenous group, are all vulnerable, or all pose a risk to the researcher. Vulnerability should be determined on a case-by-case basis with guidance, where appropriate (e.g. from service staff). In scenarios where researchers are working with vulnerable participants, we emphasise that researchers must be even more aware of the considerations posed across the other sections. Every effort should be made to reduce potential risks to the participants.

As well as a duty of care to participants, if there is a disclosure that involves a risk of harm to the individual or to someone else who is vulnerable (i.e., a safeguarding concern), then this may need to be reported to appropriate authorities. Staff at the University have a responsibility to safeguard vulnerable individuals (as defined above) including those under the age of 18. Therefore, researchers should have a plan in place for reporting safeguarding issues (e.g. to supervisor/clinician), and this should be detailed in the ethics application if such safeguarding issues are likely to arise. See the University's safeguarding policy for more information.

2.4. Protecting participants and researchers from distress

It is of upmost importance to minimise distress to both participants and researchers. An ethics application must go through full ethics if the research risks causing psychological stress/anxiety/other harm/negative consequences beyond that normally encountered by the participants in their life outside research. For example, negative consequences could come from the disclosure of illegality in research settings where there could be negative implications. Furthermore, discussing distressing topics might cause psychological stress or anxiety beyond that usually experienced in everyday life.

In the ethics application, you will be asked to complete a risk assessment which details all potential risks (physical, psychological, legal, social) to research participants and the researchers arising from the research. We provide an example risk assessment for drug research in Section 5. If participant/researcher distress is probable, you will need to: 1) complete the section titled: 'Participant and Researcher Safety', where you must detail the steps in place to mitigate distress to participants and researchers (we provide an example response in Section 6). 2) You must complete a distress protocol, which outlines the process to be followed if the participant or researcher becomes upset or

distressed during participation in your research project (in Section 7, we provide an example of a distress protocol for drug related research).

2.4.1. Considerations for protecting participants

If a participant in a qualitative interview indicates they are experiencing a high level of emotional distress, or appears to be distressed, the researcher should encourage the participant to take a break from the interview. The researcher will encourage the participant to discuss any concerns that they may be having and assess whether they are able to continue, either with the researcher or a member of service staff. If they are not able to continue, the participant will be signposted to /encouraged to speak to local support services, their GP and/or mental health provider. Researchers will need to be able to justify that they are able to make these judgements and provide the appropriate support. If the researcher themselves is not able to evidence this, then collaborators/team members will need to be involved (e.g. service staff, clinical psychologists, senior researchers) who are available to support participants in distress.

2.4.2. Considerations for protecting researchers

Beyond distress to the participant, some research topics might lead to the disclosure of sensitive information that is distressing for the researcher to hear. Therefore, it is also important to reflect upon how harm can be minimised to the researcher. It may be important to have regular supervision set-up (with an individual able to advise on the sensitive issues and / or safeguarding concerns raised), or avenues available through which the researcher can access support. If working with participants one-to-one off University premises or outside of University hours, you must adhere to the University's lone working guidance.

2.5. Providing informed consent

If participants are not currently under the influence of drugs, or are not in acute withdrawal from drugs, then informed consent can be obtained as usual. As always, ensure the consent form includes all information necessary for participants to give their informed consent.

If participants are under the influence of drugs, or in acute withdrawal, then this could affect their ability to give informed consent, as it may impede comprehension and decision making. It is not possible to set an exact threshold or limit in these guidelines, as this will differ depending on many factors (e.g., the dose of a drug taken, an individual's familiarity with the drug, the setting in which the drug has been taken). Therefore, professional judgement of the researcher conducting the study will be required to decide whether the individual is able to give informed consent. All researchers wishing to conduct research of this type must **submit evidence of the researcher's practical related experience.** For example, a strong track record of being involved in similar research designs, previous work in services, or clinical training. If the research team at Bristol does not have this expertise, then it is recommended to involve a service (e.g. Bristol Drugs project) or a clinician to support the recruitment and consenting process. This individual with the appropriate training should be present for the participant facing work. As a general rule, undergraduate or Masters level students will not be granted ethical approval to make these judgements unless they can evidence

the above. Researchers should also provide details to the ethics committee of the factors they will consider when assessing whether an individual can give informed consent (e.g., participants' experience with the drug, dose taken, the setting it's been taken in, time since it's been taken, outwardly physical signs of intoxication).

Consent should be iterative - before each encounter ensure that the participant wants to contribute. If your research question permits, consider just getting participants to register interest whilst intoxicated, and recontact for informed consent and participation on the following day.

2.6. Language

Stigmatising language related to drug use and people who use drugs is common and reinforces negative stereotypes. Researchers should ensure that they use humanising, person-first language (e.g. person who uses drugs not drug user). Transform also recommend it may be suitable to ask participants what language they prefer or conduct patient and public involvement (PPI) to ensure terms are up to date with community views. This is important both when conducting the research, but also when disseminating it to the media, where sensationalist stigmatising language is frequently used. Researchers should take steps (e.g., in press releases) to increase the likelihood that appropriate language is used by news outlets.

2.7. Payment of participants

Participants who use drugs should not be reimbursed differently from any other participants. Researchers should decide on a study-by-study basis which reimbursement method is most appropriate.

Section 3: Determining whether the application should be full or checklist ethics
When completing your ethics application in the School of Psychological Science, there are a series of questions used to decide whether your application will require checklist or full ethics. Here we focus on four questions that might be more likely to require a full ethics application for drug research:

Question 1. Participants who are particularly vulnerable or unable to give informed consent
Examples of vulnerable participants are children, people with learning difficulties, patients, people experiencing emotional distress or mental illness, people living in care or nursing homes, and people recruited through self-help groups, participants in a dependent or unequal relationship with the researcher(s) or research supervisor.

As discussed in section 2.5, participants who are currently under the influence of drugs or in acute withdrawal *might* be unable to give informed consent. Vulnerability should be determined on a case-by-case basis with guidance, where appropriate (e.g. from service staff). We can't give hard and fast rules, clinical expertise may be required. If you are going to be conducting research with individuals under the influence of drugs then please tick this box, and evidence in your application how you will determine whether the participant is able to consent.

Question 2. Does your research involve disclosures of illegal activity or use of illegal substances?
Please tick this box if you are collecting participant disclosures of illegal activity, regardless of whether data collection is anonymous or not. Drug possession, supply and production are all illegal in the UK. Drug use is not illegal in the UK, but is ethically-sensitive data. Please also tick this box if collecting disclosures of drug use (**with the exception of anonymous fixed-choice questionnaire responses**).
As discussed in section 2.2, drug possession, supply and production are all illegal in the UK. If your study is directly asking about these topics, or participants are likely to disclose this information then please tick this box and complete full ethics.

Question 3. The risk of causing psychological stress or anxiety or other harm or negative consequences beyond that normally encountered by the participants and/or researchers in their life outside research

When your research has the potential to cause distress or harm to either researcher or participants beyond day-to-day life then please tick this box and complete the additional questions on mitigating harms. When considering what participants might be experiencing in their day-to-day lives, ensure to consider a broad range of possible participants. What has the potential to cause distress will vary across groups.

Question 4. Funds received from politically or culturally sensitive funding sources
Examples include the defence sector, projects with potential environmental effects and other internationally regulated or protected industries. For more information, please follow the link to the 'Research Governance and Integrity Policy'

If you are receiving funding from a potentially politically or culturally sensitive source then please tick this box and disclose the funding source for ethical review.

Section 4: Research appropriate for undergraduate student projects

All of the above guidance applies to student projects as well as ethics applications being submitted to the main ethics board. However, there are certain types of research or study design that are less likely to receive ethical approval for an undergraduate student project (and to a lesser extent for a Masters project). Most suitable for undergraduate student projects are study designs 1A, 1B, 1C, 1D, 2A, & 3A (see green boxes in Figure 1). If the student wishes to conduct a different study type from the matrix, then we will need to see additional supporting documentation outlining why they have the research skills to handle highly sensitive data and demonstrating that they have the supervisory team and support network in place to maintain both participant and researcher safety. These types of research will always need to be in collaboration with more senior researchers who can detail their relevant expertise in this area, and who can provide the necessary support. There are also situations where it might be harder for students to demonstrate that participation will be anonymous (e.g., when recruiting from the student body via experimental hours). Ways to mitigate this risk need to be evidenced where appropriate.

If you have questions or concerns please contact the Chair of the relevant Psychology Ethics Committee for further guidance or the Faculty Ethics Team at: research-governance@bristol.ac.uk

Section 5: Example Risk Assessment

All research projects must include a risk assessment. If this summary assessment of the risk proves insignificant: i.e. answer no to all questions, no further action is necessary. However, if you identify risks, you must identify the precautions you will put in place to control these.

Please answer the following questions:

1a. What is the title of the project?

Barriers and facilitators to successful treatment for people who inject drugs.

1b. Please provide a brief description of your experiment (please provide an overview of the experiment design/methodology)

The following safety plan is designed for data collection at a service provider external to the University called "xxx" for people who inject drugs (PWIDs). The aim is to understand barriers and facilitators to successful treatment. The safety plan will be followed by the researchers during data collection at all times.

2. Is the project purely literature based or secondary data analysis (i.e., there will be no new data collection or need for contact with participants)? **YES / NO**

If YES, please go to the bottom of the assessment and sign where indicated. If NO, complete question 3

3. Identifying the Risks – *Please circle YES or NO. If YES, please add proposed precautions.*

Risk	**If YES, consider the following and discuss with your supervisor**	**If YES, please list the precautions you will take.**
Will you be using any equipment other than IT equipment? **NO**	**Consider:** · Is equipment regularly checked and maintained as per manufacturer's instructions? · Will researchers receive adequate training prior to use? · Will participants receive adequate training prior to use? ***Please note*** Researchers should check that own electrical equipment (e.g. laptops) are maintained in good working order.	

Will you be using hazardous or biological substances? **NO**	**Consider:** · If researcher is using any chemicals e.g. solvents, acids, flammable materials, gas cylinders, please see www.bristol.ac.uk/safety/chemical-safety/. · If researcher is using any biological substances such as blood or salvia, please see www.bristol.ac.uk/safety/biosafety/. · **If working with either type of substances, a risk assessment must be in place prior to the work commencing**. Please contact Anthony.Crawford@bristol.ac.uk for further guidance.	
Will you or the participant be performing any manual handling activities? (e.g. lifting / moving awkward or heavy equipment). **NO**	**Consider:** · How to adapt the task to reduce or eliminate risk from manual handling activities. · Researcher and participants must understand how to complete task safely and be capable of the manual handling task prior to testing. · Should the participant complete a health questionnaire to determine their fitness at the recruitment stage?	
Are you or your participant required to have a certain level of fitness for the experiment? (e.g. walking long distances for off-site working, testing with sports equipment such as exercise bike or treadmill). **NO**	**Consider:** · Exposure to levels of exertion unsuitable for an individual's level of fitness. · Exposing vulnerable participants to health risk. Participants should make researcher aware of any health issues prior to any testing session. · Researchers should ensure they are in good health prior to any testing session. · Researchers should be aware of locations of all first aiders within the building and ensure they are aware of the University's accident and incident policy. See http://www.bristol.ac.uk/safety/guidance/ and click "accident" tab.	

Will you be working anywhere off campus? (excludes your own home). **YES /**	**Consider:** · Researchers should have at least one external contact who is aware of exact movements during the working day. Contact must know location and times of testing and must be telephoned once researcher is back at a safe location. Contact must know what action to take if they don't receive a telephone call. · Researcher to provide details of how they may be contacted whilst working off-site. Must also have phone numbers for UoB security and school office with them at all times. · How will the researcher get to and from the locations? · If you are working from home you must complete the working from home checklist at the end of the guidance document, available here: http://www.bristol.ac.uk/safety/media/gn/homeworking-gn.pdf · Researcher must have emergency procedures in place i.e. phone contacts, know nearest hospital/medical centre and ensure that accidents/incidents are reported. · Researchers should consider their physical safety and if they will be using equipment when off-site. For example manual handling risks, operation of machinery, tools, use of specialist equipment etc. School equipment must have passed safety check prior to use, e.g. eye-trackers.	All interviews will be conducted on xxx premises, with a member of xxx staff onsite who will be able to support the researcher if needed. Prior to every interview, the researcher must identify where the xxx staff member will be and how they can be contacted rapidly in an emergency. If a member of staff is not present in the room, a member of staff in the service will be informed that the interview is taking place, where the interview is taking place, and how long the interview is expected to last. The researcher must have a mobile phone on them at all times with safety numbers (xxx helpdesk and key xxx staff contact) stored. In accordance with the lone working policy, the researcher will inform a designated person where and when each interview is scheduled to take place. The interviewer will contact the designated person after each interview at an agreed time. If the designated person does not receive the call within 5 minutes of the agreed time they will initiate the emergency response plan as below: • Attempt to contact the interviewer via mobile phone. • If no response, attempt to contact the interviewer via xxx help desk which is manned during the times

		the research is being conducted.

<u>Testing Participants</u> - Adults

Will you be recruiting participants (including in online studies)? Psychology students (Low risk) **YES / NO** Other University personnel (Medium risk) **YES / NO** Unknown Non-University personnel (High risk**)** **YES**	**Consider:** · How will contact with participants be made? I.e. do not give out personal mobile no., home number or home email, etc. · Is the experiment and location suitable for the elderly/infirm/disabled? Do you need any extra provisions or procedures? · Will the participant need a chaperone or translator if they have limited English or are from a different culture?	All participant recruitment will be handled by the staff at xxx.
Will you or your participant be exposed to data or information which may cause upset or distress? **YES**	**Consider:** · What precautions will be taken to prevent this from happening? · What/who will be used to counsel distressed participants or researchers? · What will you do if you uncover information regarding an illegal act?	The researcher must at all times be vigilant for any signs of distress displayed by the participant. If a participant indicates they are experiencing a high level of stress or emotional distress, or appears to be distressed, the researcher must encourage the participant to take a break from the interview. The researcher must then encourage the participant to discuss any concerns that they may be having and assess whether they are able to continue, either with the researcher or a member of service staff. If they are not able to continue, the participant is to be

		signposted to /encouraged to speak to the support services run by the service, their GPand/or mental health provider. The researcher must monitor the participant for any signs of stress, distress or aggression and take breaks/terminate the interview at any point if needed. In order to further reduce risk, the researchers will keep doors open, and will sit between the door and the participant at all times. We do not expect to participants to disclose information about illegal activities. However, if they do, as researchers we are not obliged to report this information. However, if this is related to a Safeguarding concern, then this would be treated accordingly.

<u>Testing Participants</u> – Children

Will you be testing young participants under 16? **NO**	· If yes, please complete the "**Working with Children**" risk assessment form.	
Any additional comments:		

<u>Face-to Face testing</u>

Will you be testing participants face-to-face? **YES**	**Consider:** · Will testing take place in a safe environment, e.g., University building, work place? How will participants get there? · What support will be available (i.e., will be anybody be available to assist if you call for help)? · How will you deal with violent / aggressive behaviour? What precautions will be taken to prevent this from happening?	All testing will occur in a room at xxx. The door to the room will always be left open and the researcher will be sat next to the door in case a swift exit is necessary. As explained above, the researcher will be able to quickly contact a member of staff at xxx should there be any issues or concerns during the testing session. To help ensure the questions being asked are received well by participants, the interview guide has been carefully developed including with staff members at xxx and with service users.

Data collection start date: **End date:**

Data collection location:

Full name..... Signature.....
Date .....

Once completed, please email this form to psych-tech@bristol.ac.uk

Section 6: Example of steps taken to minimise harm

The following is taken from a student research project conducting one-to-one interviews about challenging psychedelic experiences. This is an example only, and will need to be adapted to suit your study design and research question.

If your research risks causing psychological stress or anxiety or other harm or negative consequences beyond that normally encountered by the participants in their life outside research, what safeguards have been put in place to minimise any harm?

There is a chance that participants may experience distress due to the sensitive information surrounding challenging psychedelic experiences. The resurfacing of any negative memories about challenging psychedelic experiences may be a risk for some participants.

To mitigate these risks:

• Participants will be made aware of the sensitive topics of the study before participation.

• The questions used in the interview have been carefully considered. No leading language will be used, and questions will be kept open to allow participants to only report whatever they feel comfortable with.

• Participants will be given a debrief form at the end of the study to give further information surrounding the topic. The debrief will also include linked resources for further relevant help.

Researchers contact details will also be provided for any further questions. Additionally, a distress protocol (see Section 7) will be put in place for conducting the interviews. This will include:

• Reminding participants they can withdraw at any point of the interview at the beginning of the study before the interview commences to reiterate the point that the participant has complete control throughout the interview.

• Informing participants they do not have to answer any questions they do not want to without having to provide any explanation.

• If the participant appears to be distressed during the interview, researcher will remain empathetic and emphasise that the participant can take a break from the interview or stop the interview completely.

• If the participant wishes to leave the interview, the interview will be immediately terminated, and the participant will be guided towards relevant support materials.

• In the unlikely event the participant shows signs of significant emotional distress (defined as high levels of emotional distress that includes behaviours such as crying or shouting) the recording will be immediately stopped, and the interview terminated. The participant will be directed towards support resources (see the attached information and debrief sheet). Furthermore, afterwards the research projects supervisor will be contacted for instruction and guidance regarding the future running of the study.

Section 7: Example of a Distress protocol

The following is taken from a student research project conducting one-to-one interviews about challenging psychedelic experiences. This is an example only, and will need to be adapted to suit your study design and research question.

The distress protocol serves as a document that reassures the committee and the researcher that if either participants or the researcher become distressed there is a suitable procedure in place.

Distress to the Participant

Due to the nature of the research, it is possible that participants may experience difficult thoughts and feelings. This however has been carefully considered in the framing of questions.

Signposting will also be clearly and heavily used throughout the study. Participants will be directed to a variety of well-being services before signing the consent form (in the information sheet) and after completing the study (in the debrief sheet). These UK-based, specialised services can help support participants.

As the participants will have my email address from the informed consent procedure, it is possible that they might contact me seeking support in the very unlikely event that they are distressed by the study. However, I am aware that I am not a healthcare professional and will not take on any responsibilities beyond my remit as a student. This could place the participants or myself at risk of harm. If participants do contact me seeking support, I will signpost them to the well-being services provided in the debrief and information sheet. Further details surrounding email risk mitigation can be found below.

The following measures will be taken whilst conducting interviews to ensure that participant distress is minimised:

1. Participants will be reminded that they can withdraw at any point of the interview before the interview commences, to reiterate the point that the participant has complete control throughout the interview.
2. Participants will also be informed they do not have to answer any questions they do not want to, and do not have to provide any explanation for not answering a question.
3. If the participant appears to be distressed during the interview, the researcher will remain empathetic and emphasise that the participant can take a break from the interview or stop the interview completely.
4. If the participant wishes to leave the interview, the interview will be immediately terminated, and the participant will be guided towards relevant support materials.
5. Participants will be reminded frequently that they can pause or stop the interview at any time, without having to provide reason. This will be said in the interview schedule before starting to ask questions, and also brought up at any point during the interview if the participant shows any signs of distress.

6. In the highly unlikely event that the participant shows signs of significant emotional distress (defined as high levels of emotional distress that includes behaviours such as crying or shouting) the recording will be immediately stopped, and the interview terminated. The participant will be directed towards support resources (below). Furthermore, afterwards the research project's supervisor will be contacted for instruction and guidance regarding the future running of the study.

Distress to myself as a researcher.

I have experience running qualitative interviews on a similar topic, as last year I conducted my dissertation on the potentially distressing phenomenon known as psychedelic ego-dissolution. This experience has guided my expectations on the kind of content I expect to see and helped me develop my qualitative research skills. I believe that this prior experience will help me manage any distress I encounter whilst running the project.

In the event that I am exposed to content that is distressing to myself, I intend to do the following:

1. I will keep a journal throughout the process of data collection. This will serve as a good medium to process and recognise any patterns of thoughts or feelings that may be cause for concern to my own well-being.
2. Should I notice a pattern of deteriorating well-being, either through the journal or my own self-reflection, I will talk to my supervisor who can signpost to University wellbeing services, senior tutors, and student administration services. I will also seek help from the university's Wellbeing and Mental Health Services and speak to my tutor (who has regular pastoral meetings with me where they check-in with me as to how my experience with the project is going).
3. In the extremely unlikely event that I require more immediate care and support, I am aware of 24/7 talklines (the same as mentioned in the study for participant support). Should I require emergency medical help, I will have no hesitation to contact the emergency medical services. However, I would like to reiterate the unlikelihood of this occurring.
4. I will also draw support from my project-group peers, who are also studying sensitive topics.

Email risk.

1. Should a participant email my anonymous university email address with an innocuous question that is beyond the scope or relevance to the study or my knowledge, I have prepared an email (see below) that I can readily use that will inform the participant of the fact that I am unable to help their query.
2. Should a participant email my anonymous university email address with content or Information that I find distressing, I will follow and assess my level of distress in accordance with the measures listed above.

Illicit material

In the extremely unlikely event of receiving illicit material to my email, my weekly meeting with my supervisor provides the opportunity to discuss any emails that I find

troubling and distressing. My supervisor can then advise me on the appropriate level of escalation which will be dependent on the content I've received and the distress that I feel. It is also worth noting that my university email is an anonymous email that will not be able to be traced back to my own identity. Furthermore, in July 2024, this email address will expire, leaving a limitation on the participant's ability to contact myself.

Additional Materials

Template for email response to participant questions.

Hello,

Thank you for your email regarding the aforementioned topics, I'm really appreciative of your time to enquire further about aspects of the study.

Unfortunately, I do not feel like I am able to reply in a way that can be of any help regarding your email. I am currently a student and while I have comprehensively investigated the literature surrounding the research topic, I am by no means in the position to advise you on your query. Below I have listed well-being services as well as adverse psychedelic reaction and drug use support resources. I hope you find these useful.

Thank you very much for the email and all the best.

Adverse psychedelic reaction/ drug use online resources:

The fireside project

https://firesideproject.org/

The fireside project is a free app that has been developed to help manage adverse psychedelic reactions. This includes a support line for people currently experiencing an adverse reaction, as well as information to help promote safe use, as well as forums where people can discuss their shared experiences. This is available worldwide.

Talk to Frank

https://www.talktofrank.com/drugs-a-z

"Talk to Frank" is a public awareness campaign in the United Kingdom aimed at providing information and education about drugs. The campaign, which includes a website and various resources, is operated by the National Health Service (NHS) and is designed to offer factual and unbiased information about drugs, their effects, and related issues. This website is useful to help educate and learn any risks associated with psychedelics, and to avoid adverse reactions. This is available worldwide.

The British National health service

https://www.nhs.uk/live-well/addiction-support/drug-addiction-getting-help/

The British national health service website has a variety of useful resources. The specifically attached web page provides a variety of useful pieces of information for people struggling with drug use and addiction and can guide you in the right direction if you need help. Whilst this is available worldwide, it may be more useful for participants living in Britain.

Wellbeing resources:

Mind Infoline

(to help find local specialist resources)

Mind website: www.mind.org.uk

Samaritans

(a 24/7 phone-based listening service)

Samaritans website: www.samaritans.org

Both websites offer call services that can be accessed worldwide.