Basic Study Information

1. * **Title of study:**
Partnering with Pregnant and Postpartum People to Co-Create a Novel Intervention to Reduce Tobacco and Cannabis Use

2. * **Short title:**
PICTURe Aim 3

3. * **Brief description:**
We will conduct a single group, proof-of-concept feasibility trial of a new intervention designed with guidance from the PICTURe community collaborative to address prenatal depressive symptoms to encourage tobacco and cannabis cessation.

4. * **What kind of study is this?**
Single-site study

5. * **Will an external IRB act as the IRB of record for this study?**
○ Yes ● **No**

6. * **Local principal investigator:**
Natacha DeGenna
* **Is this your first submission, as PI, to the Pitt IRB?**
○ Yes ● **No**

7. * **Does the local principal investigator have a financial interest related to this research?**
○ Yes ● **No**

8. **Attach the protocol:**
   - Sponsor/Multicenter/Investigator-initiated protocol
   - Coordinating Center supplement
   - Emergency Use Consent/ Protocol/ FDA Form 3926
   - Exempt Application form

Document Category Date Modified Document History
There are no items to display

Funding Sources

1. * **Indicate all sources of support:**
   External funding

2. * **Identify each organization supplying funding for the study:**

Funding Source	Sponsor's Funding ID	Grants Office ID	Attachments	Pitt Awardee	Grant Recipient
National Institute on Drug Abuse	1R01DA057946-01A1		Original Grant Application 1R01DA057946-01A1_ModifiedScopeREV.pdf	yes	Dr. Natacha De Genna

Study Team Members

1. * **Identify each person involved in the design, conduct, or reporting of the research:**

Name	Roles	Department/School	Affiliation	Involved in Consent	Qualifications	Financial Interest
Judy Chang	Co-investigator	U of Pgh | School of Medicine | OB-Gyn and Reproductive Science	Pitt faculty	no	Judy Chang, MD, is aProfessor of Obstetrics, Gynecology and Reproductive Sciences and Internal Medicine at the University of Pittsburgh. Dr Chang is... view all	no
Natacha DeGenna	Principal Investigator	U of Pgh | School of Medicine | Psychiatry	Pitt faculty	no	Natacha De Genna, PhD, is Associate Professor of Psychiatry, Epidemiology and Clinical and Translational Science at the University of Pittsburgh. Dr... view all	no
Jennifer Grace	Key Personnel / Support Staff	UPMC | Hospital Divisions | WPIC	Non-Pitt student (Pitt/UPMC employee)	yes	Ms. Grace, MS, has extensive training and experience in cognitive behavioral interventions with pregnant and postpartum people. She has provided evid... view all	no
Michele Levine	Co-investigator	U of Pgh | School of Medicine | Psychiatry	Pitt faculty	no	Michele D. Levine, Ph.D., is a Professor of Psychiatry and	no

Name	Roles	Department/School	Affiliation	Involved in Consent	Qualifications	Financial Interest
					Psychology at the University of Pittsburgh School of Medicine. Dr. Levine is a clinical an... view all	
Maya Ragavan	Co-investigator	U of Pgh | School of Medicine | Pediatrics	Pitt faculty	no	Maya Ragavan, MD, MPH, MS, is an Associate Professor of Pediatrics at the University of Pittsburgh and Associate Vice Chair of Diversity, Equity, and... view all	no
Alison Sanfacon	Primary Study Coordinator	Other	Non-Pitt student (Pitt/UPMC employee)	yes	Ms. Sanfacon, MEd, is a Research Project Coordinator who has worked for the PI as part of the YoungMoms study for years and more recently as the coor... view all	no

2. External team member information: (Address all study team members in item 1. above and leave this section blank)

Name	Description
There are no items to display	

3. Have you, Natacha DeGenna**, verified that all members of the research team have the appropriate expertise, credentials, training, and if applicable, child clearances and/or hospital privileges to perform those research procedures that are their responsibility as outlined in the IRB application?**

* ● **Yes** ○ No

Study Scope

Check all that apply

1. * Will this study actively recruit any of the following populations?

- [ ] Adults with impaired decision-making capacity
- [ ] Children (under the applicable law of the jurisdiction in which the research will be conducted (<18 years for PA))
- [ ] Children who are Wards of the State
- [ ] Employees of the University of Pittsburgh/UPMC
- [ ] Medical Students of University of Pittsburgh as primary research group
- [ ] Nursing School Students of University of Pittsburgh as primary research group
- [ ] Students of the University of Pittsburgh
- [ ] Neonates of uncertain viability
- [ ] Non-viable neonates
- [ ] Non-English speakers
- [ ] Nursing home patients in the state of Pennsylvania
- [x] Pregnant women
- [ ] Prisoners
- [ ] N/A

2. * Will any Waivers be requested?

- [ ] Waiver/Alteration of Consent
- [ ] Waiver to Document Consent
- [ ] Waiver/Alteration of HIPAA
- [ ] Exception from consent for emergency research
- [x] N/A

3. * Will this study involve any of the following?

- [x] Specimens
- [ ] Honest Broker to provide data/specimens
- [ ] Return of Results to Subjects or Others
- [ ] Fetal tissue
- [ ] N/A

4. * Will Protected Health Information be collected?

- [ ] Pitt medical records
- [ ] UPMC medical records
- [ ] Other Institutions' medical records
- [x] N/A

5. * Other Requests?

- [ ] Deception (if not Exempt, also requires Waiver/Alteration of Consent)

- [ ] Emergency Use / Single Patient Expanded Access (using FDA Form 3926)
- [ ] Placebo Arm
- [ ] Withdraw from usual care
- [x] N/A

6. * **Determining Scientific Review:**
Received External funding where scientific merit was established as a condition of funding

7. * **Has this study (or substantially similar study) been previously disapproved by the Pitt IRB or, to your knowledge, by any other IRB?**
○ Yes ● **No**

Review the HRPO policy, if participating in research at the VA Pittsburgh Healthcare System or using funding from the VA

8. * **Does the study use an approved drug or biologic, use an unapproved drug or biologic, or use a food or dietary supplement to prevent, diagnose, cure, treat, or mitigate a disease or condition?**
○ Yes ● **No**

9. * **Does the study evaluate the safety or effectiveness of a device (includes in-vitro laboratory assays)?**
○ Yes ● **No**

10. * **Is this application being submitted to convert an approved study from OSIRIS to PittPRO?** (Tip Sheet)
○ Yes ● **No**

11. * **Does your research protocol involve the evaluation or use of procedures that emit ionizing radiation and, after reviewing this** HUSC guidance**, does your research protocol require HUSC review? (If yes, upload the** HUSC form **in the Local Supporting Documents section). If you are unsure of review requirement, select yes.**
○ Yes ● **No**

Research Sites

1. **Choose all sites that apply:**
   University of Pittsburgh
   UPMC

   * **Select the University of Pittsburgh sites where research will be conducted:**
   Main Campus – Pittsburgh

   List university owned off-campus research sites if applicable:

   * **Select the UPMC sites where research will be conducted:**
   Magee Women's Hospital
   Western Psychiatric Institute & Clinic

2. **Describe the availability of resources and the adequacy of the facilities to conduct this study:**
   Department of Psychiatry. The Co-PIs are well-supported by a robust research infrastructure within the Department of Psychiatry and the University of Pittsburgh (Pitt). A dual entity, Western Psychiatric Institute and Clinic (WPIC) is the academic Department of Psychiatry within the University of Pittsburgh School of Medicine, but also a psychiatric hospital within the University of Pittsburgh Medical Center (UPMC). This dual status allows for optimal integration between the academic and clinical domains. WPIC is recognized nationally and internationally as one of the premier research and treatment centers in the United States. The Department has over 200 primary faculty trained in a mix of disciplines, including medicine, psychology, basic sciences, and social work, who are dedicated to the pursuit of excellence in research, training and provision of clinical care. Their efforts are supported by numerous emeritus, secondary, adjunct, and volunteer faculty. The intellectual resources at WPIC are enriched by close collaborative ties with numerous other Departments within the University of Pittsburgh, including Psychology, Pediatrics, Public Health, Statistics, Neuroscience, Medicine, Neurology, and Radiology. The Department also maintains active collaborations with many other departments and research institutions in the U.S. and around the world. The Department of Psychiatry has been ranked in the top 10 among all Departments of Psychiatry in the U.S. with regard to research funding from the National Institutes of Health (NIH) since the mid-1980's.

   The Division of General Academic Pediatrics (GAP) is located in the Children's Hospital Office Building, adjacent to the University of Pittsburgh Medical Center and the University of Pittsburgh main campuses. GAP has a long history of leadership in pediatric research. Infrastructure includes experienced project managers, study nurses, research assistants, and biostatisticians. The division maintains faculty offices, centralized research space, and administrative support. GAP trains post-doctoral scholars through an interdisciplinary HRSA NRSA T32 and supports monthly works-in-progress sessions for post-doctoral scholars and junior faculty. Additionally, GAP (along with the Division of Adolescent and Youth Adult Medicine) hosts a monthly seminar for junior faculty engaged in pediatric health services research (the Child Health Access, Outcomes, and Equity Research Seminar). GAP is also forming a Parent and Caregiver Collaborative, for parents to play an integral

role in co-creating clinical and research materials relevant to the division.

Office Space. Adequate space for project faculty is available at the University of Pittsburgh Medical Center, in the Oakland neighborhood of Pittsburgh, PA. Each faculty member has an individual office equipped with a computer and printer. Drs. De Genna and Levine have dedicated research space on the University of Pittsburgh campus with adequate space for project staff. The Co-PIs have laboratory space located on the same floor providing opprotunities for frequent contact across staff. Staff offices have ample locked file cabinets for storage of research data. Shared areas for common use include individual clinician offices, large meeting areas, several conference rooms of varying sizes, and a kitchen. There is nearby parking available for research participants, if needed. Shared space for intervention and assessment is available near the obstetric clinics from which women will be recruited. Dr. Ragavan (co-I)'s primary office is located in the Children's Hospital Office Building, which houses offices for the Division of General Academic Pediatrics. It is located on the main campus of the University of Pittsburgh, in close proximity to those of Co-PIs De Genna and Levine (10 minute walk). The Division of General Academic Pediatrics will provide Dr. Ragavan with administrative support, printing, copying, mail service, and networked conference rooms with multimedia capabilities. The Division of General Academic Pediatrics maintains faculty offices, centralizing research spaces, and administrative support, and has multiple workstations outfitted with the hardware and software needed for this proposal. Dr. Chang's primary office is located at UPMC Magee-Womens Hospital in Oakland within walking distance from the Co-PIs's office space at Bellefield Towers (20 minute walk). This proximity of office space will provide easy access for collaboration across the scientific team.

Computing. The Office of Academic Computing (OAC) manages the desktop, database, file and print services for federally and privately funded research programs in the Department of Psychiatry, Western Psychiatric Hosptial, University of Pittsburgh Medical Center. All desktops and servers, with the exception of the public web server, are secured behind the UPMC firewall. All data files and databases are stored on servers inside the UPMC firewall. Only fully authenticated and authorized accounts are permitted to open files and tables. Permissions are granted on a strictly "as needed" basis as specified by the Principal Investigator. The servers are backed up to tape each night. Backup tapes are duplicated each week and stored in locked cabinets in locked offices in two different buildings within the campus. Access to the data center holding the servers is limited to the OAC System Administrators and all entries are automatically logged because the UPMC staff ID is used to gain entrance. Direct Internet connections to the servers are impossible from outside the UPMC domain. Connections are possible to a select number of OAC servers, but only through a proxy server, and only via a 128-bit encrypted Secure Socket Layer (SSL) port (https or sftp). The proxy server filters all transactions and all connections are logged. These connections require a UPMC account and password and access is permitted only to appropriate data files and datasets. Servers available through these encrypted portals hold only de-identified research information.

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Recruitment Methods

*** Will you be recruiting individuals for participation in this study?**

● **Yes** ○ No

1. *** Describe who will be recruiting individuals for participation for this study:**

   A research staff member with experience and who is trained by the investigative team will recruit individuals who are pregnant from clinics associated with local obstetric and midwifery care centers and the Primary Care Center, who respond to recruitment flyer, Pitt+Me listing, lab websites, or who contact research staff directly.

2. *** Select all methods to be used for recruitment:**

   Email/Listserv/Electronic Mailing List
   Flyers/Posters or Brochures
   Pitt+Me
   Telephone scripts
   Website/Social Media

3. *** Provide details on your recruitment methods:**

   Recruitment for the study will occur from multiple sources: 1) Clinics associated with local obstetric and midwifery care centers and the Primary Care Center; 2) flyers distributed with administrator permission at local OB clinics, offices or programs affiliated with or recommended by PIs; 3) Pitt+Me; 4) DeGenna and PHAB Lab current studies webpages, and 5) word of mouth from community collaborative members. A trained research team member will contact potential participants by telephone and/or email. We will use the relevant telephone and email scripts to describe the study and gauge interest. For individuals recruited through flyers, Pitt+Me listing or word of mouth, a screening survey will be used to determine eligibility. The screening survey will be programmed on REDCap and made available through Pitt+Me or a link sent to individuals who contact research staff directly. Once screened eligible, interested individuals will be contacted by the research assistant who will review and obtain consent for participation. The REDCap screening survey will be programmed so that contact information including name, phone number, and email will only be collected from those who screen eligible. Ineligible individuals will be identified only by a Record ID generated by REDCap.

4. *** Describe all compensation/incentives offered to participants and timing of these offers:**

   Participants will be compensated for completing assessments at T1 (baseline) $30, T2 (end of intervention) $50; T3 (1 month postpartum) $70, T4 (3 months postpartum) $100.

   In addition to the incentive for completing assessments, we have budgeted up to $50 for a clean (i.e., no evidence of tobacco and cannabis use) sample as a contingency management incentive at the final postpartum assessment (T4).

Participants will be paid using Vincent, the University's approved payment system. There will be no compensation for partial completion of T1, T2, or T3. At T4, participants will be paid separately for completing all questionnaires ($75) and interviews ($25).

5. **Recruitment materials:** (attach all material to be seen or heard by subjects, including advertisements and scripts)

	Document	Category	Date Modified	Document History
View	Recruitment Scripts(1)	Recruitment Materials	2/3/2026	History
View	Intervention Screening Survey(2)	Recruitment Materials	1/30/2026	History
View	Recruitment flyer(1)	Recruitment Materials	1/6/2026	History

Study Aims

1. * **Describe the purpose, specific aims, or objectives and state the hypotheses to be tested:**
Guided by the PICTURe community collaborative, we will conduct a single group, proof-of-concept feasibility trial of a new intervention designed to address prenatal depressive symptoms to encourage tobacco and cannabis cessation. We will examine the initial feasibility and acceptability of the intervention using standard measures in addition to measures suggested by the collaborative. We hypothesize that 1) the intervention will be feasible to participants and 2) the intervention will be acceptable to participants.

   The primary outcomes of the trial are the feasibility and acceptability of the novel intervention and abstinence from tobacco and cannabis use. Feasibility and acceptability of the intervention will be assessed using attendance, completion of intervention-related procedures, and the Acceptability of Intervention Measure (AIM). Abstinence will be measured by proportion of the participants who self-report no use of either substance and by calculating the proportion of participants with negative urine screens for THC and COT. Secondary outcomes include changes in depressive symptoms, tobacco, and cannabis use from the baseline assessment in pregnancy to 3 months postpartum.

   The intervention will be considered feasible and acceptable if participants attend more than 70% (i.e., >4) of sessions. Differences in feasibility also will be compared according to demographic variables and use history variables. Acceptability will be assessed by completion of self-monitoring forms, attendance during pregnancy, and the Acceptability of Intervention (AIM) measure. Retention also will be documented and will be defined as the proportion who provide data at 12-16 weeks postpartum relative to the total number enrolled. We will present these measures of feasibility and acceptability to the collaborative to solicit their input and may add other measures of feasibility and acceptability based on their recommendations.

2. * **Describe the relevant prior experience and gaps in current knowledge including preliminary data. Provide for the scientific or scholarly background for, rationale for, and significance of the research based on existing literature and how it will add to existing knowledge:**
B. SIGNIFICANCE
B1. People from marginalized communities are more likely to use tobacco during pregnancy (Agrawal et al., 2019) and are under-represented in tobacco treatment research (Weinberger et al., 2022). Rates of prenatal tobacco use have not decreased among Black people (Agrawal et al., 2019; Li et al., 2018) and are higher for sexual minority people (Beck et al., 2021; Gonzalez et al., 2019). At least 40% of individuals who quit smoking during pregnancy will resume smoking in the postpartum (Fingerhut et al., 1990; Rockhill et al., 2016), most of them within 100 days of delivery (De Genna et al., 2022). Younger, less educated, Black people are more likely to relapse to smoking postpartum (Orton et al., 2018; Rockhill et al., 2016) and, on average, Black people smoke for more years prior to quitting (Jones

et al., 2018). Bisexual women are also more likely than heterosexual women to be unemployed, have lower incomes, and smoke cigarettes (Beck et al., 2021; Cunningham et al., 2018). Higher rates of tobacco use may be related to exposure to traumatic experiences (Estey et al., 2021) including those driven by racism and heterosexism. Discrimination has been linked to dual use of tobacco and cannabis and joint Tobacco Use Disorder (TUD) and Cannabis Use Disorder (CUD) among non-Hispanic Black people (Mattingly et al., 2023) as well as TUD among those who are sexual minority (Kcomt et al., 2021; McCabe et al., 2019). In addition to facing more discrimination, individuals from Black (Chen-Sankey et al., 2021; Giovenco et al., 2019; Lee et al., 2015) and LGBT communities (Dilley et al., 2008; Soneji et al., 2019; Spivey et al., 2018) are targeted by tobacco companies with point-of-sale marketing, free samples, promotional items and activities, and online campaigns.

B2. Black (Mukerhjee et al., 2016) and sexual minority (Marsland et al., 2021; Ross et al., 2007) people experience more prenatal depressive symptoms, and depressive symptoms are associated with cigarette use and response to smoking treatment. There are bidirectional associations between depression and smoking in non-pregnant people (Bakhshaie et al., 2015; Breslau et al., 1998; Leventhal & Zvolensky, 2015; Needham, 2007; Pedersen & van Soest, 2009; Weinberger et al., 2017; Wilkinson et al., 2016). In rodent models, nicotine appears to be more reinforcing for depression-prone animals (Smethells et al., 2021; Tizabi et al., 1999) and in humans, depressed individuals experience nicotine as more reinforcing than do not depressed individuals (Perkins et al., 2010; Whitton et al., 2021). Former cigarette users with clinically significant depressive symptoms are more likely to remain abstinent when they receive cognitive-behavioral mood management intervention compared to former smokers with low levels of depressive symptoms (Haas et al., 2004; Kapson & Haaga, 2010). In contrast, cognitive-behavioral mood-management has been less efficacious for smokers who are not at high risk for depression (Brown et al., 2001; Haas et al., 2004; Kapson & Haaga, 2010). Thus, depressive symptoms are important targets in tailoring smoking cessation treatment in general. Similarly, among pregnant people, those with depressive symptoms (De Wilde et al., 2013, Hoffman & Hatch, 2000) and clinical depression (Goodwin et al., 2017b, Oh et al., 2017) are more likely to smoke cigarettes than are those without depressive symptoms. Depressive symptomatology prior to pregnancy is a robust predictor of persistent smoking during pregnancy (Tong et al., 2016). Depressive symptoms are common at the end of pregnancy (Bennett et al., 2004) with between 18% (Josefsson et al., 2001; Marcus et al., 2003) and 31% (Da Costa et al., 2000) of pregnant people reporting clinically significant symptoms of depression. Importantly, individuals with depression and depressive symptoms are motivated to quit smoking, and tobacco cessation does not increase depressive symptoms (Morozova et al., 2015). In fact, successful tobacco cessation during pregnancy is associated with better mood (De Wilde et al., 2013). Thus, prenatal depressive symptoms are common and an ideal target for smoking cessation interventions.

B3. Prenatal depressive symptoms predict postpartum depressive symptoms and smoking relapse, perpetuating tobacco-related disparities into the postpartum. Depressive symptoms during pregnancy predict postpartum depressive symptoms (Heron et al., 2004; Milgrom et al., 2008) and postpartum relapse (Allen et al., 2009). Evidence from our group (Kolko et al., 2017; Levine et al. 2020) and others

(Correa et al., 2015; Orton et al., 2018) has linked prenatal depression to postpartum smoking. For example, we found that women with elevated depressive symptoms late in pregnancy were more successful maintaining abstinence if they received an intervention that was tailored to psychosocial factors like depressive symptoms than if they received a relapse prevention intervention that did not include intervention designed to address psychosocial factors (Levine et al., 2020). Racial discrimination is also associated with prenatal depressive symptoms and tobacco use (Bennett et al., 2010; Giurgescu et al., 2020; Nguyen et al., 2012) as well as trauma (Kirkinis et al., 2021) enhancing risk for prenatal substance use among those experiencing discrimination. Pregnant people with trauma are more likely to be nicotine dependent (Blalock et al., 2011) and trauma may moderate their response to psychotherapy for depression and smoking cessation - pregnant people with more trauma respond better to treatment (Blalock et al., 2013). Structural inequities also contribute to higher rates of perinatal substance use (Marbin et al., 2021), and Black people are more likely to relapse in the postpartum compared to white people (Orton et al., 2018; Rockhill et al., 2016). Targeting depressive symptoms during pregnancy is likely to result in better long-term smoking cessation outcomes, reducing inequities in long-term health among those disproportionately affected by prenatal depressive symptoms and postpartum relapse.

B4. Depressive symptoms are also linked to cannabis use, especially among women (Danielsson et al., 2016; Leadbeater et al., 2019; Weinberger et al., 2020). History of depression predicts current cannabis use in women (Ewing et al., 2020). The link between cannabis use (CUD) and psychological distress/depressive symptoms is stronger for women compared to men (Danielsson et al., 2016; Khan et al., 2013; Leadbeater et al., 2019; Tomko et al., 2020; Weinberger et al., 2020). This association has grown more robust in recent years, perhaps due to the increasing potency of THC in recreational cannabis (Halladay et al., 2020; Rabiee et al., 2020). The effect is likely bidirectional with some studies reporting depressive symptoms prior to initiation of cannabis (Bolanis et al., 2020; Wilkinson et al., 2016b) or increasing cannabis use (Tomko et al., 2020) while others report that cannabis affects mood. Cannabis use, especially frequent and/or heavy cannabis use, increases the likelihood of depressive symptoms and depression (Bahorik et al., 2017; Davis et al., 2023; Degenhardt et al., 2003; Gobbi et al., 2019; Gunn et al., 2020; Hayatbakhsh et al., 2007; Horwood et al., 2012; Marmorstein et al., 2010; Patton et al., 2002; Smolkina et al., 2017; Womack et al., 2016) and reductions in cannabis use result in decreased depression scores (Hser et al., 2017; Moitra et al., 2016). More information is needed about prenatal cannabis use and other behaviors related to depressive symptoms and perinatal smoking cessation (e.g., sleep, discrimination) and how they interact to derail cessation efforts (Patterson et al., 2019).

B5. People with depressive symptoms are also more likely to use cannabis while pregnant (Goodwin et al., 2020; Mark et al., 2021; Short et al., 2020). Pregnant people use cannabis to provide relief from stress, depression, and anxiety (Ko et al., 2020). For example, one study found a dose-response relationship between depression and cannabis use-even mild symptoms were linked to a positive cannabis screen (Young-Wolff et al., 2020). Trauma-related diagnoses also predicted prenatal cannabis use in this study, which did not report on tobacco use.

Thus, it is unclear if there is a stronger link between depressive symptoms, trauma, and prenatal dual use of cannabis with tobacco. Dual use of cannabis with cigarettes is concerning because it is associated with greater risk of low birthweight infants compared to prenatal tobacco use in isolation, controlling for maternal age, race/ethnicity, marital status, education, pre–pregnancy BMI, insurance, parity, and timing of prenatal care (Haight et al., 2021). The relationship between trauma and prenatal tobacco and cannabis use may be particularly relevant to the inequities in prenatal care experienced by minoritized populations (Lindquist et al., 2017). Indeed, trauma has been uniquely related to perinatal depressive symptoms (Meltzer-Brody et al., 2013; Wosu et al., 2015). We have also shown that chronic cigarette use and depressive symptoms were associated with a chronic maternal cannabis use trajectory spanning the prenatal period up to 16 years postpartum, illustrating the long-term nature of these associations (De Genna et al., 2015).

B6. Prenatal cannabis use is prevalent among Black (Young-Wolff et al., 2020) and sexual minority people (King et al., 2020) and may hinder tobacco cessation efforts in these populations, contributing to tobacco-related health disparities. Dual use of cannabis with tobacco during pregnancy is three times more prevalent than prenatal cannabis use and is more common among Black people (Coleman-Cowger et al., 2017; 2018). To our knowledge, there are no published data on dual use in pregnant sexual minority people but pregnant sexual minority people are more likely than those who are heterosexual to smoke cigarettes daily (Gonzales et al., 2019). We have found a history of cannabis use to be associated with cigarette use during pregnancy and at 6 months postpartum (De Genna, Germeroth, et al., 2021), and documented long-term associations between prenatal cannabis use with continued cigarette use 16 years postpartum (De Genna et al., 2017). Non-pregnant people who use cannabis are more likely to persist cigarette use or relapse if they have previously quit smoking (LeSueuer et al., 2018; Weinberger et al., 2018; 2020). There is also evidence among treatment-seeking samples, that cannabis affects smoking cessation outcomes (Goodwin et al., 2022; McClure et al., 2020; Rogers et al., 2020). However, no studies have examined this association in pregnant populations nor focused on populations that are the most likely to use cannabis and tobacco during pregnancy. Thus, the potential negative effect of prenatal cannabis on perinatal smoking cessation is unknown. As shown in Figure 1, we conceptualize bidirectional associations among prenatal depressive symptoms, perinatal tobacco use, and perinatal cannabis use that contribute to difficulties maintaining tobacco abstinence during and after pregnancy. Given that public health research needs to be informed by health disparities in social and historical context (Mannor & Malcoe, 2021), our model includes experiences of racism, sexism, homophobia, transphobia, stigma and trauma. This model is consistent with minority stress theory (Hatzenbuehler et al., 2009; Meyer, 2003) and informed by intersectionality theory and a Public Health Critical Race (PHCR) praxis (see section B10).

B7. Few perinatal tobacco or cannabis smoking and relapse prevention interventions target depressive symptoms, and none have been co-developed in partnership with individuals who have experienced prenatal depressive symptoms, tobacco, and cannabis use. Compared to other types of interventions designed for prenatal cannabis use, those using CBT appear to be the most effective at reducing use (Groff et al, 2023). Previous interventions on maternal substance use range

from those with substance use experts housed in obstetric practices (Goler at al., 2008) to electronic screening, brief intervention, and tailored text-messaging (Ondersma et al., 2019) although, to date there are no data on reductions in cannabis use from these approaches. For CUD in non-pregnant people, the most effective approach appears to be a combination of CBT, motivational enhancement, and abstinence-based incentives (Chatters et al., 2016; Gates et al., 2016). Given that perinatal cannabis use is associated with depressive symptoms and increases risk for tobacco relapse, we posit addressing perinatal depressive symptoms may promote sustained postpartum tobacco abstinence in populations with higher risk of prenatal depressive symptoms, tobacco, and cannabis use. Pregnant individuals with high depressive symptoms benefit more from a depression-focused treatment for smoking cessation than pregnant women with low depressive symptoms (Cinciripini et al., 2010) and financial incentives can promote tobacco abstinence in depression-prone pregnant and parenting people (Lopez et al, 2015). However, there is a paucity of evidence on non-pharmacologic interventions to address tobacco use among individuals with mental health conditions (Steinberg et al., 2019) and none that have addressed perinatal depressive symptoms among people who use both tobacco and cannabis. Ample evidence suggests that addressing depressive symptoms improves rates of abstinence (Gierish, 2012) and there is strong support for the use of psychosocial counseling to promote perinatal smoking cessation (Chamberlain et al., 12017). Addressing prenatal depression symptoms among dual tobacco and cannabis users may promote tobacco abstinence during and after pregnancy.

B8. Intervention development should be guided by non-pharmacological interventions with demonstrated efficacy to address depressive symptoms and psychological distress. Smoking cessation interventions address depressive symptoms using components from cognitive behavior therapy (Brown et al., 2001; Hall et al., 1994; 1996). Given the robust efficacy of CBT strategies for perinatal smoking (Cincirpini et al., 2010; Levine et al, 2019), its initial efficacy for cannabis cessation (Babor, 2014; Chatters et al., 2016), its use to treat perinatal depression (Sockol, 2015), and relevance for trauma-informed care generally (e.g., Jackson et al., 2020), we will begin development efforts using the cognitive behavior therapy (CBT) framework. For example, intervention techniques and participant materials we have used in our prior tobacco-only focused work (Levine, 2016) can serve as starting points for discussion with the collaborative. We then will consider elements of mindfulness-based CBT (MBCT) as several recent trials adapted for use in a perinatal population have demonstrated that it is effective in preventing or mitigating symptoms of depression and anxiety among pregnant and postpartum people (Dimidjian et al., 2015; 2016). Perinatal adaptations of MBCT include emphasis on informal meditation of shorter duration, added focus on practicing loving kindness towards the self, and learning to set boundaries and build social support. Self-reported satisfaction with and engagement in MBCT have been high despite the unique demands of the perinatal period (Dmidjian et al., 2015; 2016). Further, initial evidence suggests that the benefits of MBCT delivered in pregnancy persist up to six months postpartum (Dmidjian et al., 2015; 2016; Dunn et al., 2012; Woolhouse et al., 2014). We will also consider other evidence-based tools that have been used to promote perinatal substance use, such as contingency management (Heil et al., 2008, Donatelle et al., 2004), which may be particularly useful in adapting our prior

materials to the co-use outcomes we seek to address. Contingency management is based on principles of operant conditioning (replacing positive association of smoking with that of the financial incentive) and delay discounting (a more immediate reward such as a voucher may be more valuable in the moment than long-term goals such as infant health) (Higgins et al., 2012). Psychoeducation may include evidence that reductions in cannabis use improves mood (Hser et al., 2017; Moitra et al., 2016) and, conversely, using cannabis to manage tobacco withdrawal symptoms may actually increase depressive symptoms (Bahorik et al., 2017).

B9. Core to our proposal is leveraging the expertise of people with lived experience as scientific partners in this work. Intervention tools will be reviewed by a collaborative using intervention mapping and human centered design activities to co-develop a novel intervention. Intervention mapping (IM) is a systematic approach to developing theory-based health promotion interventions. During collaborative meetings, a human-centered design activity will be paired with an IM step to help collaborative members visualize the material and develop the intervention in real time. In addition to evidence-based interventions, theory and content mentioned in section B.8, we will be responsive to a recent action plan (the Allegheny BIRTH plan for Black Babies and Families, 2022) that centers the voices, experiences, and leadership of Black mothers and community members in Pittsburgh. This plan calls for expanded mental health training and the use of "… culturally relevant materials that are linguistically appropriate and rooted in an anti-racist framework; bedside manner, reflective practices, active listening." To effectively address depressive symptoms and reduce co-use in a culturally relevant manner, we will leverage people's lived experiences and the existing evidence base to collaboratively develop a novel intervention that addresses perinatal depressive symptoms. Although we will begin by discussion of Aim 1 results, prior intervention strategies, and the Allegheny BIRTH plan, the collaborative will develop the novel intervention. Final decisions about content will be decided by the collaborative. Importantly, none of the prior interventions address the roles of cannabis use, discrimination, stigma, trauma, or structural barriers to tobacco or cannabis cessation. No prior interventions have been developed by a collaborative of people with lived experiences of tobacco and cannabis use and prenatal depressive symptoms, including those who are Black and/or bisexual, who can provide invaluable insight into their needs, challenges, and strengths.

B10. This project is guided by the Public Health Critical Race (PHCR) praxis, an adaptation of Critical Race Theory for public health and an iterative methodology to help researchers remain attentive to equity. PHCR highlights how race is a social construct, racism is embedded in the social fabric of society, aims need to be situated in a specific context and place, and systems of power preserve the interests of dominant group members (Ford & Airhihenbuwa, 2010). This project recognizes the pervasiveness of racism and seeks to better understand how experiences of racism and structural inequities contribute to prenatal depressive symptoms, tobacco, and cannabis use by partnering with people most affected by these experiences and learning from them. We acknowledge the racist and homophobic practices of Big Tobacco that have perpetuated tobacco-related health disparities and the role that tobacco scientists have also played a role by, among other practices, not measuring racial discrimination, sexual and gender minority status,

nor examining the impact of interventions as a function of different, intersecting statuses (Weinberger et al., 2022). It is important to acknowledge that cannabis use has been weaponized against Black people as part of the War on Drugs and that pregnant Black people are more likely to be drug tested (Ellsworth et al., 2010; Winchester et al., 2022). Research guided by the praxis seeks to “center in the margins” or amplify the voice, experiences, and strengths of marginalized communities (Ford & Airhihenbuwa, 2010). Successful intervention development should include members of communities disproportionately affected by discrimination as a core part of the scientific process. Thus, we seek to collaborate with individuals with lived experiences of prenatal depressive symptoms and substance use to reduce power imbalances in the research process and conduct qualitative research within an intersectional framework (Abrams et al., 2020; Tan et al., 2023). Central to PHCR is intersectionality, a Black feminist critique (Crenshaw, 1989) that explains how race and other social categories (i.e., gender, sexual orientation) intersect to impact behaviors and experiences (i.e., tobacco use, cannabis use, depression), which reflect multiple interlocking systems of oppression and privilege at the macro level (i.e., racism, sexism, homophobia, toxic masculinity). A recent analysis documented how race/ethnicity and sexual orientation may intersect to promote prenatal smoking in higher-risk subgroups (Hartnett et al., 2021). Accordingly, we propose to conduct formative research with people who have lived experiences of depressive symptoms, prenatal tobacco and cannabis use, to more closely examine this triad, and to learn about the unique barriers faced by pregnant Black and sexual minority people to better understand their needs and address structural and other barriers to tobacco and cannabis cessation.

C. Innovation

This project is theoretically innovative because it conceptualizes prenatal depressive symptoms and cannabis use as key factors for tobacco use during pregnancy and in the postpartum. Moreover, it frames that research question in the context of intersecting identities and experiences that may promote tobacco use before, during, and after pregnancy and hamper cessation efforts, contributing to lapse and relapse. It is methodologically innovative to elevate the voices of those with lived experiences of depressive symptoms, tobacco, and cannabis use to co-develop an intervention for prenatal tobacco cessation with real world impact. Human centered design (HCD) and IM are powerful methods to translate community perspectives into workable solutions for pregnant people who smoke. Demonstrating the importance of addressing depressive symptoms and cannabis use for success in prenatal smoking cessation also has significant implications for clinical practice. Collaboratively developing an intervention will enable us to design an intervention that incorporates minoritized people’s views and lived experiences of depression, stress, discrimination, stigma, trauma and other contexts in a way that is distinct from previous “one-size fits most” approaches in other prenatal substance use interventions. Members from minoritized groups will adapt intervention parameters that address their needs, contexts that should be emphasized, and which elements are less relevant to their circumstances.

D2. Preliminary results

The investigative team has conducted prior research examining health disparities in

prenatal substance use as well as relations among prenatal depressive symptoms, cannabis use and tobacco use. Most participants in the YoungMoms project are Black or Biracial (78%) and one-third identify as something other than strictly heterosexual (21% are bisexual). As seen in Figure 2, sexual minority (SM) participants in the YoungMoms study are more likely to smoke during pregnancy compared to those who identified as heterosexual (De Genna et al., under review). In qualitative interviews, some SM participants linked their experiences as a SM and related mental health with prenatal tobacco use. The results of this and other research (e.g., Beck et al., 2021; Gonzalez et al., 2019; King et al., 2020) demonstrate that pregnant SM people need to be included in research related to prenatal tobacco and cannabis use.

Our research has also shown that there are long-term associations between cannabis and tobacco use before, during, and after pregnancy. For example, cannabis was associated with combustible cigarette use in adolescent parents and those who used cannabis were significantly less likely to quit smoking cigarettes 10 years postpartum (De Genna et al., 2009). In another study, a history of any cannabis use was associated with cigarette use during pregnancy and 6 months postpartum, suggesting that assessing history of cannabis use early in pregnancy might be useful in determining risk for prenatal and postpartum tobacco use (De Genna, Germeroth, et al., 2021). In trajectory analyses, we have shown that prenatal cannabis use was related to cigarette use spanning the prenatal period to 16 years postpartum (De Genna et al., 2017). Thus, it is crucial to address prenatal cannabis use in interventions promoting tobacco cessation and prevention of relapse to smoking in the postpartum.

Using a latent class analysis of YoungMoms data, we found that the class with highest probability of clinically significant depressive symptoms also had the highest probabilities of prenatal tobacco and cannabis use, as verified by urine screening (Hill et al., 2022). This class was more likely to be non-Hispanic Black, Biracial, or Hispanic and reported more prenatal stress, morning sickness, and unintended pregnancy (Hill et al., 2022). We have found self-reported and/or positive screen for prenatal tobacco and cannabis use, and emotional distress scores to be significantly related to prenatal dual use, even after controlling for household nicotine and cannabis use and sexual minority status. These results underscore the role of depressive symptoms in prenatal dual use of tobacco and cannabis (De Genna, Richardson et al., 2021).

Relatedly, we examined the effectiveness of two postpartum smoking relapse preventions as a function of prenatal depressive symptoms (Levine et al., 2020). People with clinically significant depressive symptoms late in pregnancy did not maintain smoking abstinence in the postpartum if they received a standard intervention with behavioral techniques to manage cigarette cravings (SUPPORT). However, as seen in Figure 3, those who were depressed late in pregnancy were more successful maintaining abstinence if they received a smoking abstinence intervention that was tailored to psychosocial factors such as mood (STARTS). These results highlight the importance of depressive symptomatology in postpartum tobacco abstinence and the significance of addressing prenatal depressive symptoms for long-term impact on maternal and child health. Thus, we propose to

invite people who use tobacco and cannabis and experienced elevated depressive symptoms during pregnancy to partner with us in an intervention development project to reduce tobacco-related health inequities.

Study Design

1. **Total number of subjects to be enrolled at this site (enter -1 for chart reviews, banking, registries):**
   25

2. **Describe and explain the study design:**
   This study is an experimental, single-arm feasibility trial.

3. **Describe the primary and secondary study endpoints:**
   The primary outcomes of the trial is the feasibility and acceptability of the novel intervention and abstinence from tobacco and cannabis use. Feasibility and acceptability of the intervention will be assessed using attendance, completion of intervention-related procedures, and the Acceptability of Intervention Measure (AIM). Abstinence will be measured by proportion of the participants who self-report no use of either substance and by calculating the proportion of participants with negative urine screens for THC and COT. Secondary outcomes include changes in depressive symptoms, tobacco, and cannabis use from the baseline assessment in pregnancy to 3 months postpartum.

4. **Provide a description of the following study timelines:**

   Duration of an individual subject's active participation:
   Depending on gestation age at enrollment, subjects will actively participate in the study for approximately 6 to 12 months.
   Duration anticipated to enroll all subjects:
   9/30/2026
   Estimated date for the investigator to complete this study (complete primary analyses):
   10/1/2027

5. **List the inclusion criteria:**
   (1) <26 weeks of gestation
   (2) English speaking
   (3) confirmed pregnant
   (4) plan to remain pregnant
   (5) use of combustible tobacco at least once a week during pregnancy, or at least once a week in the 3 months before pregnancy if stopped
   (6) use of cannabis at any frequency during pregnancy or in the 3 months before pregnancy if stopped

   English speaking is a requirement since study materials are in English and intervention sessions will be conducted in English.

6. List the exclusion criteria:

(1) current opioid use or active treatment for Opioid Use Disorder
(2) unable to provide informed consent in English
(3) under 18 years old

7. Will children or any gender, racial or ethnic subgroups be explicitly excluded from participation?

● **Yes** ○ No

*** Identify the subgroups and provide a justification:**

We exclude individuals under age 18 from this work because the perinatal concerns and treatments for depression of individuals younger than age 18 are likely to differ from those of individuals 18 years of age or older and would require developmentally appropriate assessments and interventions.

8. Describe the power analysis used and cite your method of statistical analysis. If a power analysis is not possible, thoroughly justify the sample size required for the study, including appropriate literature citation (alternatively provide page reference in attached protocol):

Chi-square tests will be used to calculate differences in feasibility as a function of key intersecting identities (e.g., age, race, ethnicity, SM status) and use history variables. If feasibility is found to be significantly different by race or SM status, the analyses will be weighted to account for differences in attrition. We will assess the preliminary efficacy of the novel intervention to promote self-reported abstinence from tobacco and cannabis at the end of pregnancy (Time 3) and 12-16 weeks postpartum (Time 4). The proportion of self-reported abstinence among participants in the INT and EUC groups at Times 3 and 4 will be compared using chi-square tests of difference. We will stratify by race and sexual orientation to test for intersectional effects. Secondary analysis will examine differences in biochemically verified abstinence (urine dip test for presence of cotinine or THC) and depressive symptoms between INT and EUC using chi square tests and compare depressive symptoms (EPDS) scores in the two groups using two-sample t-tests. The Cochran Q test will be applied to self-reported tobacco and cannabis use across the 4 time points within the INT group to test whether there has been a change in the ratings over time. Next, a generalized linear mixed effects model (GLMM) with a logit link will be used to test the treatment effect (INT vs. EUC) and treatment by time interaction to test whether the rate of abstinence over time was steeper among the INT group compared to the EUC group. We have 70% power to detect a 15% difference in quit rates between INT and EUC, assuming a 25% intervention arm quit rate and 10% control arm quit rate.

Pregnant Women

1. * **Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses. [45 CFR 46.204 (a)] [Include references]:**
Many qualitative interview studies on these subjects have been conducted, including studies lead by the investigative team. We have provided references for some examples.

Bennett HA, Boon HS, Romans SE, Grootendorst P. Becoming the best mom that I can: women's experiences of managing depression during pregnancy–a qualitative study. BMC women's health. 2007 Dec;7:1-4.

Chang JC, Tarr JA, Holland CL, De Genna NM, Richardson GA, Rodriguez KL, Sheeder J, Kraemer KL, Day NL, Rubio D, Jarlenski M. Beliefs and attitudes regarding prenatal marijuana use: perspectives of pregnant women who report use. Drug and alcohol dependence. 2019 Mar 1;196:14-20.

De Genna NM, Boss N, Hossain F, Frankeberger J, Mark E, Coulter RW. A qualitative investigation of nicotine and tobacco use in young pregnant and birthing sexual minority people. Nicotine and Tobacco Research. 2024 Jul 26:ntae189.

De Genna NM, Hossain F, Dwarakanath M, Ms Balascio P, Ms Moore M, Hill AV. Pandemic stressors and vaccine hesitancy among young, pregnant Black people: A qualitative study of health disparities during a global pandemic. Birth Defects Research. 2023 Dec 1;115(20):1912-22.

Graham H, Flemming K, Fox D, Heirs M, Sowden A. Cutting down: insights from qualitative studies of smoking in pregnancy. Health & social care in the community. 2014 May;22(3):259-67.

Jarlenski M, Tarr JA, Holland CL, Farrell D, Chang JC. Pregnant women's access to information about perinatal marijuana use: a qualitative study. Women's Health Issues. 2016 Jul 1;26(4):452-9.

Staneva AA, Bogossian F, Wittkowski A. The experience of psychological distress, depression, and anxiety during pregnancy: A meta-synthesis of qualitative research. Midwifery. 2015 Jun 1;31(6):563-73.

2. * **The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the women or the fetus; or, if there is not such prospect of direct benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means. [45 CFR 46.204 (b)]:**

There is no risk to the fetus expected as a result of participation in this pilot intervention.

3. * **Any risk is the least possible for achieving the objectives of the research. [45 CFR 46.204 (c)]:**
   This is the least possible risk for achieving the study aims.

4. * **No inducements, monetary or otherwise, will be offered to terminate the pregnancy. [45 CFR 46.204 (h)]:**
   No inducements will be offered to terminate the pregnancy.

5. * **Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy. [45 CFR 46.204 (i)]:**
   The investigative team, including research assistants, will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy. any decisions as to the timing, method, or procedures used to terminate a pregnancy.

6. * **Individuals engaged in the research will have no part in determining the viability of a neonate. [45 CFR 46.204 (j)]:**
   The investigative team, including research assistants, will have no part in determining the viability of a neonate.

Research Activities

1. * **Provide a detailed description of all research activities (including screening and follow-up procedures) that will be performed for the purpose of this research study. This description of activities should be complete and of sufficient detail to permit an assessment of associated risks.**
Recruitment for the study will occur from multiple sources: 1) Clinics associated with local obstetric and midwifery care centers and the Primary Care Center; 2) flyers distributed with administrator permission at local OB clinics, offices or programs affiliated with or recommended by PIs; 3) Pitt+Me; 4) DeGenna and PHAB Lab current studies webpages, and 5) word of mouth from community collaborative members.

   A trained research team member will contact potential participants by telephone and/or email. We will use the relevant telephone and email scripts to describe the study and gauge interest. A screening survey will be used to determine eligibility. The screening survey will be programmed on REDCap and made available through Pitt+Me, the recruitment flyer, lab websites, and as a link sent to individuals who contact research staff directly. Once screened eligible, interested individuals will be contacted by the research assistant who will review and obtain consent for participation. After obtaining consent, the research team member will schedule the participant for their first prenatal session. The participant will then be texted or emailed a link to their baseline assessment questionnaires on REDCap.

   Baseline Assessment (T1):
   Participants will complete the following questionnaires as part of the baseline assessment: Demographics, EPDS, Smoking and Alcohol Use Questionnaire, Cannabis Use Questionnaire, Perceived Stress Scale-4, Major Experiences of Discrimination. Participants will be paid $30 using the Pitt Vincent payment system when questionnaires are completed. The baseline assessment is estimated to take 30-60 minutes.

   Prenatal Sessions
   Participants will meet virtually with a study interventionist over the course of 6 prenatal sessions. Sessions will include education and discussions on the topics and strategies listed below. The scheduling timeline of prenatal sessions will depend on the gestational age of the pregnancy at time of enrollment and so will be determined on a case-by-case basis. Sessions will last up to 30 minutes.

   1: Self-monitoring targets/ problem identification. This may include recognition of depressive symptoms, urges for tobacco and cannabis, how one might be used to manage withdrawal from the other.

   2: Psychoeducation. This may include the teaching of rationale for addressing psychological distress/mood, relationship of trauma to mood and behaviors, model of cessation and relapse prevention/ learn how cannabis may hinder tobacco cessation and increase depressive symptoms.

3: Behavioral Activation. This may include identifying reinforcing activities and activities incompatible with tobacco and cannabis use.

4: Cognitive restructuring. This may include understanding/addressing dysfunctional thoughts about mood/stress and dysfunctional thoughts about tobacco and cannabis use.

5: Mindfulness skills. This may include teaching of nonjudgmental emotional awareness, nonjudgmental awareness of management of urges, and trauma-informed adaptations to mindfulness practice.

End of Intervention Assessment (T2):
This assessement will occur when participants are 32-36 weeks gestation. Participants will complete the following questionnaires on REDCap as part of the end-of-intervention assessment: Demographics, EPDS, Smoking and Alcohol Use Questionnaire, Cannabis Use Questionnaire, Perceived Stress Scale-4, and Everyday Discrimination Scale. Participants will be paid $50 using the Pitt Vincent payment system when questionnaires are completed.

1-month Postpartum Assessment (T3):
Participants will complete the following questionnaires on REDCap as part of the 1-month postpartum assessment: Demographics, EPDS, Smoking and Alcohol Use Questionnaire, Cannabis Use Questionnaire, Perceived Stress Scale -4, and Everyday Discrimination Scale. Participants will be paid $70 using the Pitt Vincent payment system when questionnaires are completed.

3-month Postpartum Assessment (T4):
This assessment will be scheduled to occur in person at Bellefield Towers or at an agreed upon location convenient to the participant. Participants will complete the following questionnaires and interviews: Demographics, EPDS, Smoking and Alcohol Use Questionnaire, Cannabis Use Questionnaire, Perceived Stress Scale-4, Everyday Discrimination Scale, Acceptability of Intervention (AIM), Additional Treatments, Timeline Follow-back and OB/Neonatal outcomes. Following completion of the questionnaires and interviews, participants will be paid $100 using the Pitt Vincent payment system. Participants will be asked to provide a urine sample as contingency management, which will be tested for the presence of cotinine (COT) and THC. Participants will receive an additional $50 if their sample tests negative for both substances.

Urine collection:
Participant will be provided with a sterile urine collection cup and directed to a nearby bathroom where they can collect their sample independently. Participants will be offered an opaque bag to transport urine sample cup back to the assessment location. Research staff will follow testing procedures for the THC and COT dip tests and then dispose of all testing and collection equipment in a hazardous waste bin or bag.

2. Upload a copy of all materials used to collect data about subjects: (Attach all surveys, interview/focus group scripts, and data collection forms except for case report forms, SCID or KSADS):

	Document	Category	Date Modified	Document History
View	TLFB Interview(1)	Data Collection	12/29/2025	History
View	Self-Reported Medical Record Info Interview(1)	Data Collection	12/29/2025	History
View	Smoking and Alcohol Questionnaire(1)	Data Collection	12/19/2025	History
View	Perceived Stress Scale(1)	Data Collection	12/19/2025	History
View	Major Experiences and Everyday Discrimination(1)	Data Collection	12/19/2025	History
View	EPDS(1)	Data Collection	12/19/2025	History
View	Demographics T3 and T4(1)	Data Collection	12/19/2025	History
View	Demographics T1 and T2(1)	Data Collection	12/19/2025	History
View	Cannabis Questionnaire T2, T3, T4(1)	Data Collection	12/19/2025	History
View	Cannabis Questionnaire T1(1)	Data Collection	12/19/2025	History
View	Additional Treatments(1)	Data Collection	12/19/2025	History
View	Acceptability of Intervention (AIM)(1)	Data Collection	12/19/2025	History

3. * Will blood samples be obtained for research purposes?

○ Yes ● **No**

Consent Process

Enter N/A in response to the following questions if a Waiver of Consent is requested for all research activities or if no subjects are being enrolled.

1. * **Indicate where the consent process will take place and at what point consent will be obtained:**
Trained research staff will reach out to consent potential participants following their eligible screening through the RedCap screening survey. The consent process will primarily take place by telephone but may also be completed in person if coordinated to accommodate participant preference or schedule.

2. * **Describe the steps that will be taken to minimize coercion and undue influence, including assurance that there is sufficient time for subjects to make an informed decision:**
Each individual who expresses an interest in participating in the study will receive a consent document with a thorough explanation from a research study staff member about the study, procedures, risks, benefits, and participant rights prior to participating in the study. Participants will also be informed that they can withdraw from the study at any time. No coercion or social pressure will be exerted to participate.

3. **For studies that involve multiple visits, describe the process to ensure ongoing consent:**
Before beginning each visit, study participants will be reminded of the intervention elements and will be given time to ask questions. They will be reminded of their right to withdraw from the study if they choose and that they can speak with a senior member of the team or PI if they have any concerns or questions while participating.

4. * **Steps to be taken to ensure the subjects' understanding:**
Research assistants will email the consent document to all participants. Questions are provided in the consent script for each section of the consent document, to ensure that participants understand these sections before moving on to the following section. Research assistants will allow plenty of time to allow for participants to reflect on the information in the consent document, answer questions to demonstrate that they understand the material, and ask any questions they might have about the study.

5. * **Are you requesting an exception to the IRB policy related to the informed consent process:**
● **Yes** ○ No

* **Provide a justification and describe the qualifications of the individuals who will obtain consent:**
Jennifer Grace, MS, has extensive training and experience in cognitive behavioral interventions with pregnant and postpartum people. She has provided evidence-based behavioral medicine interventions for smoking cessation, postpartum relapse, and worked on obesity, eating disorders, and smoking cessation trials. She also has

served as a trainer, providing training with manual-based research interventions for trainees and other interventionists. Ms. Grace will serve as primary interventionist and maintain responsibility for ensuring intervention materials and practices retain integrity over the course of the trial.

Alison Sanfacon, MEd, is a Research Project Coordinator who has worked for the PI as part of the YoungMoms study for years and more recently as the coordinator for the PICTURe Study Collaborative. She has over a decade of experience working with pregnant and parenting people providing coaching, training, and behavioral intervention. Ms. Sanfacon has recruited, consented, and conducted assessments for the YoungMoms study, including TimeLineFollowBack (TLFB) interviews and infant assessments. She is also familiar with IRB protocols and modifications.

Consent Forms

1. **Consent Forms:**

	Document	Category	Date Modified	Document History
View	PICTURe Intervention Consent Form(2)	Consent Form	2/3/2026	History

Refer to the following templates and instructional documents:

- Guidance - Consent Wording
- Template - Consent Document - Short Form
- HRP-090 - SOP - Informed Consent Process for Research
- HRP-091 - SOP - Written Documentation of Consent

Electronic Data Management

1. * **Will only anonymous data be collected (select NO if identifiers will be recorded at anytime during the conduct of the study)?**

○ Yes ● **No**

Select all identifiers to be collected during any phase of the research including screening:

Name:	☑	**Internet Protocol (IP) Address:**	☐
E-mail address:	☑	**Web Universal Resource Locators (URLs):**	☐
Social security #:	☐	**Social security # (for Vincent payment only):**	☑
Phone/Fax #:	☑	**Full face photo images or comparable images:**	☐
Account #:	☐	**Health plan beneficiary #:**	☐
Medical record #:	☐	**Device identifiers/serial numbers:**	☐
Certificate/license #:	☐	**Vehicle identifiers/serial #/license plate #:**	☐
		Biometric identifiers, finger and voice prints:	☐

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* **a: Will you be collecting any of the following location data: geographic subdivisions smaller than a State such as street address, city, county, precinct, zip, geocodes, etc.?** ● **Yes** ○ **No**

* **b: Will you be collecting any date information such as birth date, death, admission, discharge, date of surgery/service?** ● **Yes** ○ **No**

c: List any other unique identifying numbers, characteristics or codes related to an individual that are to be collected:

d: Will you be collecting any data subject to the General Data Protection Regulation (GDPR)? ○ **Yes** ● **No**

* **e: Provide a justification for recording Social Security numbers including why it's required, where it's stored, how it's protected and who will have access:**

Social security numbers will be requested for Vincent payment and recorded in that database. Research assistants trained to maintain confidentiality will record the numbers prior to making payments and they are the only ones who will have access to the system.

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* **For ALL identifiable data collected, will you be coding the data by removing the identifiers and assigning a unique study ID/code to protect the identity of the participant?** ● **Yes** ○ **No**

* **Will the data be HIPAA de-identified?** ○ Yes ● No

* **Briefly describe your plan to store coded data separately from the identifiable data:**

To maintain the confidentiality of participants' responses, all data forms will be coded with a subject identification number only. A separate file including participants' personal information (e.g., name and phone numbers) will be maintained. Raw data will be stored on a secure password-protected server to which only the Investigators and authorized project and HRPO staff will have access. Drs Levine, De Genna, and Chang have decades of experience recruiting pregnant people who use substances into clinical research studies while preserving confidentiality.

2. **During this study, will restricted data as defined by the University's Data Risk Classification matrix (https://www.technology.pitt.edu/security/data-risk-classification-and-compliance) be processed, stored, or transmitted?**
○ Yes ● **No**

3. * **During this study, will sensitive data (https://www.hrpo.pitt.edu/electronic-data-security) be collected where disclosure of identifying information could have adverse consequences for subjects or damage their financial standing, employability, insurability, educational advancement, reputation or place them at risk for criminal or civil liability?**
○ Yes ● **No**

4. * **Select all locations where data will be stored or archived(including e.g., personal / employer laptop or desktop): If you have access to University owned or controlled resources, facilities, or repositories, such as computer servers, please choose that option to comply with the Research Data Management Interim Policy R1 14.**

Please note that to address Research Security Requirements, University data must be stored in University owned, controlled, or approved repositories, such as Pitt OneDrive. If UPMC or external electronic repositories must be used, they must be approved by Pitt IT.

	Storage Device	Description	Identifiable Data	Sensitive Data	De-Identified/Anonymous Data
View	UPMC: Departmental or Hospital Server	The Office of Academic Computing (OAC) manages the desktop, database, file and print services for federally and privately funded research programs in the Department of Psychiatry, Western Psychiatric Hosptial, University of	yes	no	yes

Storage Device	Description	Identifiable Data	Sensitive Data	De-Identified/Anonymous Data
	Pittsburgh Medical Center. All desktops and servers, with the exception of the public web server, are secured behind the UPMC firewall. All data files and databases are stored on servers inside the UPMC firewall. Only fully authenticated and authorized accounts are permitted to open files and tables. Permissions are granted on a strictly “as needed” basis as specified by the Principal Investigator. The servers are backed up to tape each night. Backup tapes are duplicated each week and stored in locked cabinets in locked offices in two different buildings within the campus. Access to the data center holding the servers is limited to the OAC System Administrators and all entries are automatically logged because the UPMC staff ID is used to gain entrance. Direct Internet connections to the servers are impossible from outside the UPMC domain. Connections are possible to a select number of OAC servers, but only through a proxy server, and only via a 128-bit encrypted Secure Socket Layer (SSL) port (https or sftp). The proxy server filters all transactions and all connections are logged. These connections require a UPMC account and password and access is permitted only to appropriate data files			

Storage Device	Description	Identifiable Data	Sensitive Data	De-Identified/Anonymous Data
	and datasets. Servers available through these encrypted portals hold only de-identified research information.			

5. * **Select all technologies used to collect data, interact with subjects, or store subject data. Technologies selected in this section may require a Vendor Security Risk Assessment, which can be requested here.**

Text messaging
Electronic audio, photographic, or video recording or conferencing
Web-based site, survey, or other tool

6. * **Text Messaging - Identify all uses of SMS / cellular text messaging:**

name	Identifiable
Text Message	no

7. * **Video, Audio, Images – identify all uses of video, audio, photography, etc. to be used to collect data during any phase of the research:**

	name	Identifiable
View	Pitt HIPAA Zoom	no

8. * **Web Based Technologies – identify all web based technologies to be used to collect data during any phase of the research:**

	name	Identifiable
View	Pitt Redcap Version	

Data Safety and Monitoring

1. * **Describe your plan to periodically evaluate the data collected regarding both harms and benefits to determine whether subjects remain safe. The plan might include establishing a data monitoring committee and a plan for reporting data monitoring committee findings to the IRB and the sponsor:**
Drs. Michele Levine and Natacha De Genna (MPIs) will be responsible for the oversight of Data Safety and Monitoring for this project. Drs. Michele Levine and Natacha De Genna (MPIs) will continually evaluate the progress of the study. Data safety monitoring for the collaborative and the intervention in AIM 3 will be regularly reviewed at weekly meetings with Co-I Ragavan and the study staff. Staff, PI and Co-Is all have the opportunity to bring up and discuss any issues that may have occurred since the previous lab meeting and at prior meetings of the collaborative. Dr. De Genna, the contact PI, will report the following to the University of Pittsburgh Human Research Protection Office: Reportable New Information such as breach of confidentiality, adverse events, and protocol noncompliance and deviations.

   Study procedures addressed at these staff meetings also will include: (1) participant safety and confidentiality issues, (2) participant recruitment, accrual, and retention, and (3) data quality and integrity issues. To safeguard against the risk of confidentiality, all participant data records will be encoded with identification numbers. Access to subject data records will be given only to the PI and study staff supervised by Drs Levine and De Genna.

2. * **Describe your plan for sharing data and/or specimens:**
De-identified data from the project will be saved in a database prepared for the study. The database will be password protected. The MPIs will make deidentified data collected from research participants available to other researchers and community partners after the study is completed and the final report has been generated. Data will be provided in the form of Excel files containing only ID codes as subject identifiers. No identifying information, including names, telephone numbers, or addresses, will be made available. Researchers requesting use of data must submit their request in writing to the MPIs, including the purpose for which they are requesting use of the data. These requests will be reviewed by the Investigators and will require engaging in a Data Use Agreement (DUA), in cooperation with the University of Pittsburgh. Data will be of sufficient quality to allow other investigators to validate and replicate research findings, consistent with NOT-OD-21-013. Updates on data sharing activities will be provided in annual progress reports to the funding organization.

3. **If any research data is collected, stored, or shared in a paper format, address what precautions will be used to maintain the confidentiality of the data:**
Paper documents are kept in locked filing cabinets in an office of the Western Psychiatric Hospital at the University of Pittsburgh. Access to subject data records will be given only to the PI and study staff supervised by Drs Levine and De Genna.

Specimens and Related Data

1. * **Data and Specimens will be stored:**
   Limited time (i.e., only until the study is completed)

2. * **Indicate the type of specimen, describe where stored, and for how long:**
   Participants will be asked to provide one urine sample during their final assessment. The sample will be tested for cotinine and THC and then disposed of immediately after this testing.

3. * **How the specimens will be accessed and who will have access to the specimens:**
   The urine sample will be collected by the participant and accessed only by the research staff testing the sample.

4. * **List the data to be stored or associated with each specimen:**
   The results of the THC and cotinine dip tests, date and time of the test, participant ID number, and documentation of payment for negative results will be recorded in a secure study database.

5. * **Describe the procedures to release data or specimens, including the process to request a release, who can obtain data or specimens, the data to be provided with the specimens:**
   Urine samples and related data will not be available to others outside of the study team.

Risk and Benefits

1. * **Enter all reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related to subjects' participation in the research:**

View

Research Activity	**Urine sample collection**
Common Risks	***No Value Entered***
Infrequent Risks	**There is potential for study participants to be uncomfortable providing a urine sample to research staff.**
Other Risks	***No Value Entered***

View

Research Activity	**AIM 3 Intervention**
Common Risks	***No Value Entered***
Infrequent Risks	**As with any study, there is potential for breach of confidentiality. In terms of emotional risks, the proposal is about depressive symptoms and prenatal substance use, and therefore some people may be uncomfortable discussing these topics or find them upsetting.**
Other Risks	***No Value Entered***

View

Research Activity	**Text Messages and Email**
Common Risks	***No Value Entered***
Infrequent Risks	**Text messages and emails may not be encrypted or secure during their transmission or storage, and it is possible they could be intercepted and used by others not associated with the study.**
Other Risks	***No Value Entered***

2. * **Describe the steps that will be taken to prevent or to minimize risks:**

Breach of confidentiality: Information security is a top priority. Assessments and prenatal sessions will be conducted confidentially, in a private room or through the secure University of Pittsburgh Zoom account. Therefore, we believe it is highly unlikely that a security breech will occur. We acknowledge however, that if a security breech were to happen, several serious consequences could occur for the family, including identity theft and loss of privacy.

Emotional distress: Assessments and sessions will be conducted by highly trained interventionist with experience discussing depressive symptoms and prenatal substance use. Participation in the study is voluntary; prior to the visits, participants will be reminded that they can stop participating at any point. Similarly, participants may skip elements of the intervention or stop the session at any point. If a participant finds an element of the assessment or intervention upsetting, they can discuss it with the interventionist and will be given the opportunity to discuss it Dr. Levine, a licensed clinical psychologist.

3. **Financial risks - will the subject or insurer be charged for any research required procedures?**

○ Yes ● **No**

4. **Describe the steps that will be taken to protect subjects' privacy:**

Intervention sessions will be conducted in a private room or on a HIPAA-compliant version of Zoom. Before beginning the intervention session, the interventionist will remind the participant that sensitive topics related to substance use and mental health may be discussed and that they may prefer to be in a private location while discussing these topics. If someone other than the study participant is present, the interventionist will ask the participant if they are comfortable continuing with others present before beginning the session.

Participants providing a urine sample will obtain the sample independently in a private restroom stall. The participant will be offered an opaque bag in which to place the urine sample cup to further protect their privacy as they return to the location of the intervention session.

5. **What steps will be taken in the event that a clinically significant, unexpected disease or condition is identified during the conduct of the study:**

If a participant finds a part of the assessment or intervention upsetting, they can skip the question or that part and/or discuss it further with the interviewer or PI Levine, a clinical psychologist. Research assistants will consult Dr. Levine about participants who report significant depressive symptoms and/or suicidal ideation or plans. Participants who self-report levels of depressive symptoms that warrant immediate treatment will be referred to the Adult Outpatient Clinic at Western Psychiatric Hospital for further evaluation and treatment, if indicated. Emergent cases with acute problems such as suicidal intent will be discussed immediately with Dr. Levine and referred to the Psychiatric Emergency Room of Western Psychiatric Hospital for immediate evaluation.

6. **Describe the potential benefit that individual subjects may experience from taking part in the research or indicate if there is no direct benefit. Do not include benefits to society or others:**

There are no direct benefits, but some participants may benefit from participation in this study by having an opportunity to talk with trained staff about perinatal experiences, structural racism and discrimination, stress, or psychosocial functioning during study meetings, and from receiving referral information provided by study personnel.

7. **Do you anticipate any circumstances under which subjects might be withdrawn from the research without their consent?**

○ Yes ● **No**

8. **Describe procedures that will be followed when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection and data already collected:**

Participants may withdraw consent for participation in this research study at any time. Any identifiable research information that was provided prior to the date that they formally withdraw your consent may continue to be used by the investigators. To formally withdraw consent for participation in this research study, participants need to provide a written and dated notice of this decision to one of the Principal Investigators of this study at the address listed on the first page of the consent form that is provided to all participants.

Conflict of Interest

Institutional Financial Interests

1. * **To the best of your knowledge, has the University of Pittsburgh optioned or licensed technology that will be tested or evaluated in this research?**

   ○ Yes ● **No**

Ancillary Reviews

1. **Ancillary reviews or notifications selected below are required based on previous answers to questions. If a selection is incorrect, return to the appropriate page and adjust the answers to questions on that page:**

- [ ] Conflict of Interest (**COI**)
- [ ] Clinical and Translational Research Center (**CTRC**)
- [ ] Data Security
- [ ] Honest Broker
- [ ] UPMC Investigational Drug Service
- [ ] Pitt Medical School Review
- [ ] Pitt Nursing School Review
- [x] Pitt+Me
- [ ] IND & IDE SUPPORT (**IIS**)
- [ ] Radioactive Drug Research Committee (**RDRC**)(study involves the evaluation or use of procedures that emit ionizing radiation)
- [ ] RCCO Business **Manager** (required for industry sponsored studies)
- [ ] Religious Directives
- [ ] Scientific Review
- [ ] Health Record Research Request (**R3**) (required if using UPMC clinical data and authorization for other UPMC data sources for research)
- [x] UPMC Office of Sponsored Programs and Research **Support** (using UPMC facilities and/or UPMC patients during the conduct of the study)

2. **Additional ancillary reviews the PI may choose to include as needed for the research:**

- [ ] Human Stem Cell Oversight (**hSCRO**)
- [ ] Institutional Biosafety Committee (**IBC**)(study involves deliberate transfer of recombinant or synthetic nucleic acid molecules)

Good Clinical Practice (GCP) Training

1. * **Regardless of funding source, is this study a clinical trial (**as defined by the NIH**)?**
   - (●) **Yes** ( ) No

ClinicalTrials.gov Information

Visit the University of Pittsburgh Office for ClinicalTrials.gov website or contact ctgov@pitt.edu for further information.

1. * **Was this study registered, or will it be registered, on ClinicalTrials.gov?**
   - (●) **Yes** ( ) No

2. * **Is the University of Pittsburgh or UPMC the Sponsor Organization for this study record?**
   - (●) **Yes** ( ) No

   * **Who will be the Responsible Party for this study record?**

   Principal Investigator of this IRB application

Supporting Documents

1. **Attach any additional supporting documents not previously uploaded. Name the documents as you want them to appear in the approval letter:**

	Document	Category	Date Modified	Document History
View	10623 Levine & De Genna - Approval Letter _Version_0.01(1).pdf(0.01)	Other	2/10/2026	History

Add Storage Information

1. * **Select a Storage Type:**
   UPMC: Departmental or Hospital Server

2. **Description:**
   The Office of Academic Computing (OAC) manages the desktop, database, file and print services for federally and privately funded research programs in the Department of Psychiatry, Western Psychiatric Hosptial, University of Pittsburgh Medical Center. All desktops and servers, with the exception of the public web server, are secured behind the UPMC firewall. All data files and databases are stored on servers inside the UPMC firewall. Only fully authenticated and authorized accounts are permitted to open files and tables. Permissions are granted on a strictly “as needed” basis as specified by the Principal Investigator. The servers are backed up to tape each night. Backup tapes are duplicated each week and stored in locked cabinets in locked offices in two different buildings within the campus. Access to the data center holding the servers is limited to the OAC System Administrators and all entries are automatically logged because the UPMC staff ID is used to gain entrance. Direct Internet connections to the servers are impossible from outside the UPMC domain. Connections are possible to a select number of OAC servers, but only through a proxy server, and only via a 128-bit encrypted Secure Socket Layer (SSL) port (https or sftp). The proxy server filters all transactions and all connections are logged. These connections require a UPMC account and password and access is permitted only to appropriate data files and datasets. Servers available through these encrypted portals hold only de-identified research information.

3. * **Will identifiable data be stored in this location?**
   ● **Yes** ○ No

4. * **Will sensitive data be stored in this location?**
   ○ Yes ● **No**

5. **Will de-Identified or anonymous data be stored in this location?**
   ● **Yes** ○ No

6. **Provide additional information as needed:**
   Identifiable data (tracking information) are stored separately from the de-identified recordings and transcripts (data for analysis).

Risk

1. * **Research Activity:**
   Urine sample collection

2. **Common Risks:**

3. **Infrequent Risks:**
   There is potential for study participants to be uncomfortable providing a urine sample to research staff.

4. **Other Risks:**

Risk

1. * **Research Activity:**
   AIM 3 Intervention

2. **Common Risks:**

3. **Infrequent Risks:**
   As with any study, there is potential for breach of confidentiality. In terms of emotional risks, the proposal is about depressive symptoms and prenatal substance use, and therefore some people may be uncomfortable discussing these topics or find them upsetting.

4. **Other Risks:**

Risk

1. * **Research Activity:**
   Text Messages and Email

2. **Common Risks:**

3. **Infrequent Risks:**
   Text messages and emails may not be encrypted or secure during their transmission or storage, and it is possible they could be intercepted and used by others not associated with the study.

4. **Other Risks:**