**PROTOCOL**

**FULL TITLE: GOVERNING PARENTAL OPIOID USE: A RELATIONAL ETHNOGRAPHY**

**SHORT TITLE: THE RELATIONS STUDY**

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**CHIEF INVESTIGATOR:** Professor Anne Whittaker, NMAHP Research Unit, University of Stirling. [Anne.Whittaker@stir.ac.uk](mailto:Anne.Whittaker@stir.ac.uk)

**CO-INVESTIGATORS (UK):** Dr Polly Radcliffe (Kings College London), Dr Emily Finch (South London and Maudsley NHS Foundation Trust), Dr Emma Wincup (Independent Researcher), Dr Alison Munro (University of Dundee), Dr Amy Chandler (University of Edinburgh), Emeritus Professor Avril Taylor (University of the West of Scotland), Professor Jane Callaghan (University of Stirling), Dr. Hannah Carver (University of Stirling).

**CO-INVESTIGATORS (INTERNATIONAL):** Professor Thomas McMahon (Yale University, USA), Professor Miriam Boeri (Bentley University, USA); Dr Amy Salmon (University of British Columbia, Canada); Dr Fiona Martin (Dalhousie University, Canada); Dr Anna Olsen (Australian National University, Australia).

**PROTOCOL AUTHORS:** Anne Whittaker, and the UK Co-Investigators named above.

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**INTRODUCTION**

Improving the lives of children and families affected by parental drug use is key policy priority in the UK. However, policy and practice governing parental drug use is politically, ideologically and morally controversial [1]. Debates centre on competing policy domains and practice orientations [2]: ‘public health’ vs ‘criminal justice’, ‘harm reduction’ vs ‘abstinence’, ‘child protection’ vs ‘family support’, ‘maternal rights’ vs ‘foetal rights’. Over the past decade, ‘recovery’ has become a dominant policy paradigm, explicitly targeting drug users maintained on opioid replacement therapy [3]. However, ‘recovery’ is an ambiguous concept, which is understood and enacted in multiple and contradictory ways [4]. Simultaneously, there has been a shift towards assertive child protection interventions until parental recovery has been ‘proven’, but these too remain contentious [5, 6]. For instance, mandatory reporting of parents (primarily women), the routine practice of placing ‘drug-exposed’ newborn babies in out-of-home placements, the rise of ‘family drug courts’, compulsory drug testing, and a general call for ‘adoption or addiction’, are contested but widespread strategies. Importantly, there a lack of robust evidence that such initiatives improve outcomes for children and families [7] or the provision of effective family support [8].

More recently, attention has turned towards the negative effects of policies and practices which impact on drug dependent parents, such as repeat child removals [9] and austerity measures affecting public funding for welfare, housing, education, child care, mental health and addiction treatment, and integrated services which are crucial for marginalised families who have multiple and complex needs [10]. Notwithstanding recent fluctuations in the numbers of people in the UK accessing drug treatment, the majority remain opioid users [11], and many are parents, or have some parenting role and responsibility [12]. In 2003, an estimated 350,000 children were affected by parental drug use in the UK [13], and more recent estimates show no decline [14]. Sharp rises in drug-related deaths [15] and the growing ‘opioid crisis’ [16], brings the issue of parental opioid use and its impact on children and families into sharp focus [17].

There is growing consensus that in order to understand, and respond to, parental opioid use, research must account for the wider social ecology in which families are embedded, rather than take parental opioid use as the starting point [5]. A social ecology model includes factors such as the relationships between family members; stressors such as inadequate housing and financial strain; access to, and engagement with services; cultural and gendered norms; and the laws and policies that govern and regulate family life [18]. While the latter has been well-documented in studies of parents who use drugs [19], few look specifically at the impact of health and social care policies, discourses, and practices on this population and field as a whole. Given that parents who use drugs are an intensely governed population [6], highly stigmatised and marginalised [20, 21], but subject to competing policy agendas and opposing practice orientations [22], such research is vital in order to understand how to respond better to the needs of parents who use drugs and their families.

This study aims to tackle this challenging research agenda. By examining the field through a social ecological lens [23, 24], we will critically analyse the lived experience of family trajectories through the health and social care system and the nexus of relations between families, agencies and the state. Our study will give a voice to parents who use drugs, their families, service providers, and other stakeholders that are often unheard in the development and evaluation of governmental approaches to caring for marginalised families [25]. It aims to generate high quality evidence and outputs to inform, and transform, responses to parental opioid use with the ultimate aim of improving the lives of parents who use drugs and their families. In collaboration with our team of clinical academics and social scientists from the USA, Canada and Australia, this project is the first phase of an international programme of comparative ethnographic studies on the governing of parents who use opioids.

**STUDY AIMS**

1. To advance theoretical and real-life understandings of how parents who use opioids and their families are governed in the UK.
2. To build capacity and capability for transformational change in this field of policy and practice.
3. To prepare for an international comparative analysis of ethnographic research on the governing of parental drug use across the USA, Canada, Australia and the UK.

**STUDY DESIGN**

This is a multi-method comparative study, conducted over 36 months. It integrates three complementary approaches: Learning Alliance methodology, relational ethnography, and post-structural policy analysis.

The study comprises three phases and four interconnected workstreams, across two contrasting research areas in Scotland and England, including: 1. NHS Lothian and other local authority areas across Scotland, and 2. South London and Maudsley NHS Foundation Trust (SLaM), Homerton NHS Trust, Lewisham and Greenwich NHS Trust, and other local authority areas across Greater London. Both geographical areas have a large population of drug users and consequently parents who use opioids, yet differ significantly in terms of their policy and legal context, service delivery models, illicit drug markets, geography (urban/rural mix) and population characteristics (including ethnic mix). Incorporating two distinct fields of policy and practice enables comparative analysis of wider influences on the governance of families and how these contrast in terms of processes and outcomes. Understanding how these wider contextual factors collectively constitute the governance of parental opioid use is a key focus of this study.

**THEORETICAL APPROACH**

Our theoretical approach draws on a range of post-structural social science theories that have the capacity to transform normative thinking about the treatment and care of parental drug use. The aim is to not only observe how something is done or described, but to ask who did it, for what purpose, and to what effect, and describe and analyse it in that way. Rather than relying on normative explanations of causality to examine the impacts of parental drug use, this project will explore and critique relational, social and cultural factors that produce the problem, form the basis of health and social care interventions, and define the experiences of parents, families and other actors within the field.

**KEY RESEARCH QUESTIONS**

1. How is ‘the problem’ of parental opioid use constituted?
2. What are the policies and practices governing the problem?
3. How are these enacted locally?
4. What are the impacts on parents/families and professionals/services, do they differ between locations, and in what ways?
5. Are there alternative ways of responding to parental opioid use?

**STUDY OBJECTIVES**

1. Collaborate with key stakeholders (using Learning Alliance methodology) over the lifetime of the project to exchange ideas and experiences, discuss and review study findings, and co-produce study outputs (Patient and Public Involvement and Engagement [PPIE] Strategy).
2. Conduct a relational ethnography across contrasting sites in England and Scotland, to systematically observe and critically examine policies and practices which govern parents who use opioids and their families.
3. Identify national and local policies instrumental in governing parental drug use and employed in everyday practice, to interrogate representations of, and responses to, parental drug use.
4. Analyse, compare, and synthesise data from within and across the two study sites, to contextualise and theorise on the governance of parental drug use.
5. Identify alternative and innovative responses to parental drug use, and develop and implement a knowledge exchange and translation strategy that maximises impact on policy and practice in the UK and internationally (Impact Strategy).

**PHASE ONE**

**PUBLIC ENGAGEMENT AND CO-PRODUCTION**

This phase (approx. six months) will address **Objective #1** and involves: **public engagement in science** - establishing a Learning Alliance (see workstream #1); convening research team meetings to discuss and plan the fieldwork, analytic strategy and collaboration with stakeholders for the project duration; and policy analysis of national strategies relevant to parents who use drugs and their families (see workstream #4). It includes applying for NHS REC and R&D approvals to conduct the study within health and social care services.

NOTE: **The project began on 1st January 2020** but progress was curtailed in March and April because of the COVID-19 pandemic and the grant was **suspended from 1st May – 31st August**. In light of COVID-19, the data collection methods were revised to include remote and digital (online) communication with participants. The funder, ESRC, then agreed to **restart the project on 1st Sept 2020**, with a **revised end date of 30th April 2023**.

**WORKSTREAM #1: LEARNING ALLIANCE (Public Engagement in Science)**

Learning alliance methodology [26] is a form of patient/public engagement and knowledge production that can address inequalities and innovation within policy and practice. It engages multiple stakeholders in the objectives of the study as well as the translation and diffusion of findings in order to maximise impact.

Drawing on our team’s extensive networks, we will invite key stakeholders to join our study **Learning Alliance (LA)** for the duration of the project. Stakeholders will include parents who have lived experience of opioid dependence and other affected family members, including young people 16-25yrs; front-line practitioners; senior managers; commissioners and policymakers from health and social care services who are typically involved with this population of families. We aim to include approximately 30-50 members in the Learning Alliance (from England and Scotland).

The **purpose of the LA** is to involve and engage **members of the public** in all aspects of the study, review progress, discuss preliminary findings, and to build consensus and capacity around the translation of evidence. Whilst COVID-19 restrictions are in place, **LA meetings will be convened online (using MS ‘Teams’).** To begin with, small group meetings of different stakeholders will be arranged at a convenient time for members once every 6-8 weeks, with meetings lasting approximately one hour. Different LA members will have the opportunity to mix and share ideas with each other over time. The LAs will be organised by the research group and will include presentations from research group members, round table discussions and action plans. LA members will be asked to read and agree a ‘**Terms of Reference’** (ToR) for the LA, which will operate under ‘Chatham House Rules’. LA meetings will be facilitated by different members of the research team and with the permission of members, will be **audio-recorded** (via MS Teams) so that accurate notes of each meeting can be produced. **Pseudonymised and anonymised summary notes** from each meeting will be made available to all LA members and there will be a **dedicated web page on the study website** for LA members (password protected). LA discussions will inform the focus and conduct of the study and its outputs.

With the **written consent** of LA members, the research team will establish and maintain a **LA membership database** with the names and contact details of all members. The membership list will be used for communicating meetings, recording attendance, sending out minutes and papers and inviting members to dissemination events. The database will be stored on a **secure SharePoint folder** (password protected) at the University of Stirling, only accessible by research team members at the University of Stirling and Kings College London. The database will be updated as required, to ensure it remains current and accurate. The database will be **deleted 12 months after the completion of the project** to allow for members to be invited to dissemination events. **Use of personal data** held in the LA membership database will only be used for the purposes of the project and we will follow all privacy rules (GDPR) – see Data Management Plan (enclosed). Members can chose to withdraw from the LA at any time and their personal details will be removed from the database. Lastly, **service users (parents/affected family members/young people)** who take part in the LA will be given expenses/payment for their input and a member of the research team will act as a **‘point of contact’** to ensure service users are supported to fully engage in the process.

Where possible (COVID-19 permitting), the research team will convene some LA meetings face-to-face in 2022/2023 and convene an ‘expert event’ with a wider group of stakeholders in year 3, one in Scotland and one in England (see Dissemination section).

**PHASE TWO**

**RELATIONAL ETHNOGRAPHY**

This phase (approx. 21 months) will address **Objectives #2 & #3** and will answer Research Questions 1-4. It involves:

* Ethnographic fieldwork with parents who use opioids and their children, as well as affected family members (AFMs) who are either related or not related to parents participating in the study (workstream #2);
* Ethnographic fieldwork within health and social care services who provide treatment and care to individuals and families affected by drug use (workstream #3) and;
* A critical policy analysis to contextualise the ethnographic fieldwork (workstream #4).

In each site (Scotland and England), one full-time researcher will work primarily with **parents/families** and one will work primarily with **practitioners/services**. Four experienced research fellows have been employed on the project (see Research team details section).

**WORKSTREAM #2: RELATIONAL ETHNOGRAPHY WITH PARENTS/FAMILIES**

**Ethnography** offers a unique way of investigating social worlds and utilises multiple methods to comprehend complex patterns of relations, interventions, structures and other factors that shape people’s lives and the phenomena of interest – in this case, the governing of parental opioid use. Our ethnographic approach draws on Desmond’s ‘relational ethnography’ [27], which adopts as its basic object of inquiry, not groups of people or places, but ‘processes involving configurations of relations among different actors or institutions within a field’. The relational ethnographer explores the production of knowledge and action through relational processes and mechanisms, for instance, by tracing the networks and trajectories of different actors (e.g. practitioners and parents) to increase understanding of the social production of certain ways of thinking, behaving and responding (e.g. within the context of ‘drug treatment’ and ‘child protection’). We will study the way parents who use opioids are governed by attending to, and observing, relations between parents, family members, health and social care professionals and other actors/institutions in the field (e.g. housing, education, welfare agencies, family law and the police). This involves exploring the day-to-day lives of families and practitioners, their relational processes, social context and trajectories over time.

**STUDY PARTICIPANTS**

We will recruit 30 parents and their families into the study (15 per site), ideally working with each family for an extended period of time to map life events and trajectories, conduct interviews with family members, investigate relations with services, and generate detailed family case studies. Families may include mothers, fathers, their children, and wider family members involved in the care of either the parents or children (e.g. kinship carers, siblings). In addition, we will recruit Affected Family Members (AFMs) or ‘Significant Others’ who are not related to the parents recruited to the study but who have experience of parental opioid use in the family – for example, AFMs who provide kinship care or are relatives/partners of parents who use opioids (siblings, parents, non-substance using partners). Together these families and AFMs will constitute our study population for the ethnographic fieldwork (including participant observation and qualitative interviews).

**SAMPLING STRATEGY**: In line with Desmond’s approach to ethnography, where the emphasis is on relations between actors within the field, we will adopt a fairly open and ‘unbounded’ sampling strategy to maximize diversity within the sample of families who take part in the study.

**INCLUSION CRITERIA (Parents/Families):**

1. Families with at least one parent in drug treatment and prescribed Opioid Replacement Therapy (ORT) at the time of recruitment.
2. Parents who have at least one child aged 0-16 years (or 18 years if ‘looked after’). The parent can be a biological/non-biological parent/carer. The child/children may be living in the family home, or with the partner/other parent, or in kinship care, foster care, or in residential care.
3. Or, the mother and/or father is on Opioid Replacement Therapy (ORT) and is expecting a baby (recruitment around 20+ weeks’ gestation).
4. The parent/s are aged 18+ years.
5. Significant others (AFMs) of a parent who meets the criteria above, whether or not the parent is participating in the study.

**EXCLUSION CRITERIA**:

1. The parent is unable to provide informed written consent, for example, if they are actively psychotic or have severe cognitive impairment.
2. The parent’s children have all been adopted or have been freed for adoption.
3. If there is a court order or child protection order preventing the parent from contact with their child/children.
4. The parent cannot speak English.

NOTE: The research team appreciates that parents’ circumstances change over time, and parents do drop in and out of drug treatment (and other services). Thus, we do not expect parents on ORT to necessarily remain in drug treatment for the duration of the study. Rather, we are interested in following their service use trajectories. Recruiting parents who are currently in ORT/drug treatment programmes is a pragmatic decision because drug dependent individuals are easier to identify when they are engaged in drug treatment.

**SAMPLING METHOD:** We will utilise a sampling ‘matrix’ to guide recruitment with the aim of including a purposive sample of families into the study. We will seek to enrol a diverse population, for example, where both one or both parents are on ORT (concordant and discordant couples), single and co-habiting mothers and fathers, younger/older parents, biological/non-biological parents, resident/non-resident parents, large families and families with only one child, families with young as well as older children, and families involved with the child protection system and those who are not. In terms of drug use, we assume that many, if not most, will be ‘polydrug’ users: i.e., using other psychoactive drugs such as cannabis, alcohol, benzodiazepines, stimulants (e.g. cocaine/crack, amphetamines), gabapentinoids, and new psychoactive substances in addition to illicit and/or prescribed opioids (e.g. heroin, methadone, buprenorphine, fentanyl, tramadol). We also anticipate that some parents may be injecting drug users, or have a history of injecting drug use, and may be HIV and/or Hepatitis C positive.

**CHARACTERISTICS OF THE SAMPLE**: We anticipate that the majority of parents enrolled in the study will reflect the wider population of parents who normally attend ORT treatment services and are subject to governing policies and practices. Therefore, the majority will be aged between 18-55 years old, on a low income/unemployed and in receipt of welfare benefits, living in areas of deprivation in social housing or temporary/homeless accommodation, and have a history of polydrug use and offending. We anticipate that most will have multiple morbidities and complex needs such as poor physical health, mental health issues (e.g. anxiety and depression), a history of childhood adversity and trauma (childhood abuse/neglect, victimisation, loss and bereavement, parental separation) as well as a history of aggression/impulsivity and/or domestic abuse. In London, we also expect that the ethnic mix of participants will be diverse. In Scotland, we expect the population to be the norm of ~95% white. Children in the families are also likely to present with a range of additional needs related to child poverty, poor child development and/or child welfare concerns. Infants born to mothers on ORT may present with Neonatal Abstinence Syndrome. Parents are likely to be involved in the child protection system, or have children in local authority care, or kinship care, or attending special educational services, youth services, and CAMHS. Parents recruited into the study may or may not have parental responsibilities and rights for their children, and/or their legal parental status may change during the course of the study. The above characteristics of the sample will be recorded by the research team in order to provide a profile of the families who take part (see data collection below).

**SAMPLE SIZE JUSTIFICATION:** Our target of **30 families (15 per site)** is primarily related to the requirements of our ethnographic fieldwork – for example, the amount of time spent with families, the nature of the activities involved, and the amount of qualitative data collection and analysis. This number is large enough to include a purposive sample of families with differing characteristics to reflect diversity within the population, yet small enough to enable an in-depth analysis of the data (within the time frame of the study) to answer our research questions. Our chosen sample size also allows for an attrition rate of approx. 1/3 of families without jeopardising the rigour of the study (see data collection methods below). We will however, aim to recruit more families into the study to replace families who withdraw or drop out (up to 1 year after recruitment has begun) or who only wish to engage in the study for a limited period of time.

Likewise, our **target sample size of 12 agencies/teams (6 per site)** for the study was chosen in order to: include a wide range of different types of services involved with the study population (Third Sector, NHS and Social Services); enable the researcher to embed themselves in each service for a reasonable length of time to engage with staff, observe on-going practice with families who are receiving the services (approx. 3 months full-time or 6 months part-time); and to follow an iterative approach with data collection and analysis developing over time with successive ‘placements’. The sample size for the service ethnography also incorporates diverse professional stakeholder groups to take part (e.g. front-line practitioners, managers, commissioners, policymakers) as well as comparative analysis between a sizeable number of services and staff in each site and across the Scottish and English sites. In addition to the services/teams who engage in the service ethnography, we will also include individual practitioners in Health, Social Care and Third Sector services who wish to take part in one or more interviews and/or focus groups, whether or not their service/team are involved in the study. For example, this may include practitioners who have a specific role to work with parents who use drugs, or who have a special interest in the topic, or more wide-ranging experience.

Our sample size for parents/families and services also allows the research team to contextualise the data within a broader policy context (see workstream #4) in order to develop our theoretical work around the social ecology of the field as a whole.

**RECRUITMENT PROCESS**

We will recruit parents and families via practitioners across a network of agencies who provide treatment and care to parents and families affected by drug use. This will include: NHS drug treatment services; partner drug agencies who provide care for people on Opioid Replacement Therapy (ORT) programmes; maternal/parental and child health/welfare services, including specialist services for pregnant women drug users; Children and Families Social Services, and Third Sector family support and drug treatment services. We will also recruit via self-referral using **poster adverts/easy read flyer** (see enclosed) and through **snowballing methods** (i.e. by asking enrolled families to introduce the research team to other parents on ORT). We expect that most agencies will be able to identify and approach a small number of eligible parents over the study recruitment period (up to and including October 2022).

A **Participant Information Sheet** (PIS) for parents will describe the study in detail (see enclosed). Direct care staff in agencies will be asked to identify eligible parents when they attend for routine appointments and invite them into the study. An **invitation letter** (see enclosed) will be sent to staff with details on the study and eligibility criteria. The **‘easy read’ study flyer** will be provided for staff to give to eligible parents. If parents are interested, staff will pass on the parent’s contact details to the research team via telephone or letter. This will only be done with the parent’s consent.

Following referral into the study, the research team will telephone the parent/parents to discuss the study in more detail. All members of the research team will use **study mobile phones** to contact participants. No personal mobile phones will be used. After speaking to the researcher, if the parent is interested in taking part, the researcher will arrange a further telephone or online video call or home visit to meet the parent/parents. Each potential parent will be given a **copy of the PIS and Consent Form to read** (via post). When the researcher meets with the parent/s online or at home, they will **read through the PIS** to ensure the parent understands what is involved in the study and has an opportunity to ask questions and have them answered satisfactorily. The parent will be advised that they can talk to others about the study if they wish and can take time to consider all the information before they make a decision.

**CONSENT PROCESS - PARENTS**

If the parent/parents agree to take part in the study, a **consent form** (see enclosed) will be used to obtain both verbal and **informed written consent**. If the researcher obtains informed consent via an online meeting or telephone call (i.e. verbal consent), this will be noted for auditing purposes. In addition, the parent will be asked to return their **signed consent form in the post** (using a pre-paid envelope). The researcher will countersign the consent form and ensure that the original is stored securely and a copy is given to the study participant.

All parents who live in the same home will be consented into the study in the same way. This would normally include the **parent’s spouse/co-habiting partner**, who may or may not be a drug user. Couples who live together can be seen together to discuss the PIS, but they will be consented into the study **separately** and in private (to avoid risk of undue influence/coercion from the partner).

The consent form includes optional agreement for: audio-recorded interviews and professional transcribing; long term storage of data; and GP/key worker notification (see **GP notification letter** enclosed).

NOTE: Drug users can present in varying degrees of intoxication and drug withdrawals, depending on their fluctuating drug consumption, which may affect their ability to provide informed consent. If the parent shows signs of intoxication (e.g. drowsiness, slurred speech) or drug withdrawal (e.g. agitation, sweating) then another appointment to obtain consent can be arranged. If there are doubts about the parent’s capacity to consent, the researcher can discuss with their line manager, who will make a decision about enrolment. In addition, because of the longitudinal nature of the study, on-going consent should be reaffirmed on a regular basis (by verbal assent).

CONFIDENTIALITY and CHILD/ADULT PROTECTION: Consent to take part in the study will be on the understanding that confidentiality cannot be 100% guaranteed because of **public protection** responsibilities and procedures which must be followed if there is an actual or potential risk of **significant harm to a child or vulnerable adult**. In these circumstances, the researcher may need to breach confidentiality in order to implement safeguarding procedures. However, in most cases, this would be done with the knowledge of the participant/s concerned. Before consent is obtained, the researcher will clearly explain this to potential participants and will provide examples to aid understanding of the limits to confidentiality if they decide to take part in the study.

LEGAL RISKS/CRIMINAL DISCLOSURES: Likewise, drug users can be engaged in offending behaviour and by nature, drug use often involves the procurement of illegal drugs (as defined under the Misuse of Drugs Act). Detailed disclosure of any serious criminal behaviour or unsolved crime could compromise the legal position of the researcher if they are party to this knowledge. As part of the consent process therefore, the researcher will explain the limitations of confidentiality should detailed descriptions of offending behaviour be disclosed and examples will be given to aid understanding before informed consent is obtained.

**CONSENT FOR CHILDREN FROM A PERSON WITH PARENTAL RESPONSIBILITY**

The enrolment and consent process with drug dependent parents in this study includes obtaining details of any **children** living in the family home for whom they have **legal parental responsibilities and rights**, and any children living elsewhere, for whom they still retain legal parental responsibilities and rights. **Parental consent will be obtained for these children to take part in the study** (see Consent Form for Parents). The names, dates of birth, gender and address of each child will be recorded when the parent is enrolled in the study. The research team will explain to parent/s that informed consent to take part in the study from young people aged 12-16 years is required, if the young person has the capacity to provide informed consent.

**Guardians** (e.g. kinship carers) and **corporate parents** (the Local Authority) who have legal parental responsibilities and rights for the children of drug users who are enrolled in the study will be contacted by the research team to obtain consent for the child to take part in the study (see **Consent Form for Guardians** enclosed). For example, a parent participant might have regular 'contact visits' with a 'looked after' child living elsewhere and the researcher may request to accompany the parent on a contact visit (to observe the parent-child relationship and the way the contact visit is managed and the parent 'supervised'). If the parent agrees, and if the child is under 12 years of age, the Social Worker would need to seek agreement (assent) from the child, before the researcher could attend the contact visit with the study participant. Likewise, if the parent participant was planning a visit to a kinship carer who is the legal Guardian for their child, the researcher would need to seek consent from the Guardian to accompany the parent on the visit and the Guardian would need to seek agreement (assent) from the child, before the researcher could attend the contact visit with the study participant. In all cases, **where the child has the capacity to consent** for themselves, and is aged 12-16 years (or 18 years if 'looked after'), the researcher will obtain informed written consent from the young person themselves.

**ASSENT/INFORMED CONSENT OF CHILDREN:** The study includes children from newborn to the age of 16 years (or 18 years if a 'looked after' child) and the parents enrolled in the study may have some children living in the home, some living elsewhere ('looked after' or 'non-looked after' children), and some adopted. In all cases, the **rights and wishes of the child** in relation to their involvement in the research need to be taken into account, and their agreement needs to be established where possible, or their consent needs to be obtained where they have **capacity to consent** themselves (i.e. if they are **'Gillick competent'** and able to fully appreciate the nature and consequences of what is involved in the proposed research). Age-appropriate information which addresses different levels of understanding will be provided to enable children to learn about the study, and to express their wishes and/or to make an informed decision to take part, where they have the capacity to do so – see below.

**INFORMED CONSENT - YOUNG PEOPLE**

For children aged 12-16 years (or 18 years if 'looked after'), who have the capacity to consent, a **'Participant Information Sheet (PIS) for Children 12+ years'** (see enclosed) explains the purpose of the study, what is involved for them, risks and benefits if they decide to take part, information on confidentiality and limits to confidentiality in respect of child/adult safeguarding, anonymity and information management, and contact details of the study team. The **PIS** and **Consent Form** (see enclosed) cover general aspects of the ethnographic study as well as an invitation for the young person to take part in a one-to-one interview with the researcher where appropriate (see data collection section below). The PIS and Consent Form for young people aged 12+ years will be **read out loud** by the researcher to check the young person's level of understanding and to provide an opportunity for the young person to ask questions. The young person will be encouraged to talk to another trusted adult about the research if they wish, before they decide. The researcher will also stress that their involvement in the research is voluntary and they are free to withdraw at any time. A copy of the PIS for Children aged 12+ years will be given to the **Parent with parental responsibilities and right/Guardian/Corporate Parent**. Obtaining informed written consent with young people will be done in private (face-to-face, via telephone, or online video call) to ensure that the young person is free from any undue influence from the person with parental responsibility. **The PI at each site will take part in the consent process, along with the researcher**. If the child/young person does not demonstrate sufficient understanding of the nature and consequences of their involvement in the proposed study (i.e. sufficient competence to provide informed consent), assent will be established instead. This decision will be made jointly by the PI and the researcher at each site. The wishes of the child/young person will be recorded and the parent with parental responsibility will be informed. In cases where a young person (aged 12-16 years, or 18 years if ‘looked after’) is **invited to take part in a qualitative interview with the researcher**, they must be able to provide informed consent.

**ASSENT - PRIMARY SCHOOL-AGED CHILDREN**

An **information leaflet** (see enclosed) for younger primary school-aged children (6-11 years) will be provided in order to explain the study in simpler terms in order to establish assent from the children. A copy of the information sheet will be given to parents with parental responsibility for the child/children. The information sheet explains why the study is being done, provides examples of what the researcher will do with the family and what it will involve for them, including potential risks and benefits. It explains how the researcher will safeguard their welfare; tells the child how they can choose to take part or not, and provides contact details of the study team. If the child demonstrates an understanding of the proposed research they will be encouraged to form a view about whether they would like to take part in the study and this will be recorded by the researcher. Where appropriate, the child will be asked to sign the **assent form** (see enclosed) which the researcher will read out for them.

**ASSENT - PRESCHOOL CHILDREN**

We understand that **very young children** (newborns/infants/pre-school aged children) may not be able to understand even simple written or verbal information about the study so seeking their **written assent** would not be appropriate. However, some young children will be able to express a view on whether they agree or not to taking part in some of the research activities (for example, informal conversations with the researcher when visiting the family at home). Their assent may be assumed if they comply and do not demonstrate resistance, upset or uncooperative behaviour. The parent may also indicate whether the child is willing or unwilling to engage with the researcher, or a specific research activity (e.g. going to the park or an appointment). As with older children, this may change from one contact to the next, so the researcher will remain mindful of seeking **verbal assent** from children where possible and when appropriate, at each contact. For example, the researcher might say 'Would it be okay for you if I walk with you and mummy to the nursery today?'.

For all children, **consent from the parent with responsibilities and rights for the child** will be obtained along with the child's assent where possible, if the researcher intends to observe the parent participant and their child together in another home/out-of-home placement - for example, when the parent participant visits a kinship carer or another parent (if separated) who has custody of the child.

**INFORMED CONSENT FROM AFFECTED FAMILY MEMBERS/SIGNIFICANT OTHERS**

In addition, some **wider family members/significant others** involved in the care of either the parents or the children (e.g. grandparents/kinship carers, siblings, close friends) may be invited to take part in the study. Significant others would be identified by parent participants **as part of the ethnographic fieldwork**, and they would introduce the significant other to the researcher (with their assent). To widen the scope, we will recruit 'Significant Others' (AFMs) also via agencies that offer support to AFMs in their own right (i.e. AFMs whose relatives do not take part in the study). Relevant agencies will be provided with a recruitment flyer/poster to distribute to eligible AFMs (see enclosed), who can contact the researcher if they are interested in taking part, or the agency worker can refer them into the study. The researcher would invite the family member/significant other to take part in a qualitative interview (audio-recorded) and they would be provided with a **Participant Information Sheet** (see **PIS for Significant Others**). If they agree, informed written consent would be obtained (see **Consent Form for Significant Others**). We aim to recruit a total of 30 family member/significant others from families participating in the study and via agencies that offer support to AFMs.

At all times, the researchers will remain sensitive to the wishes of family members, and will discuss their involvement in the ethnographic fieldwork with the parent/legal guardian. Recruitment and consent will be obtained by remote and online methods if face-to-face meetings are not possible on account of COVID-19.

**ASSENT FROM THE GENERAL PUBLIC/CASUAL CONTACTS**

In the course of the ethnographic fieldwork with families, **the researcher will come into contact with a wide range of individuals who parents meet/converse with or do joint activities with**. These may be planned or unplanned encounters as part of everyday life. **Where planned**, the researcher will make their identity known and will seek the assent of other individuals involved so they can continue their participatory observational fieldwork. **Assent** will be important to establish, for example, where the parent may want to introduce the researcher to a friend, neighbour, other family member, or professional (e.g. when they attend appointments with health and social care agencies). **If assent is not provided, the researcher will not attend or observe the planned meeting.** At other times, these encounters will be **unplanned** and likely spontaneous (e.g. chance meeting with a friend when walking to school), so the participant and researcher will not be able to seek agreement/assent in advance and it might not be appropriate for the researcher to intervene to seek assent. However, **where possible the researcher will make themselves known and will maintain confidentiality** of any casual contacts/the general public who are observed as part of the participatory research. That is, personal identifiable data (e.g. names, other identifiers) will NOT be recorded by the researchers (e.g. in field notes). This **protocol for establishing assent for planned and unplanned contacts with the public** during the ethnographic fieldwork will be explained clearly to parent participants.

**RETENTION IN THE STUDY:** We will aim to retain as many families as possible for the duration of the ethnographic fieldwork (i.e., up to 21 months/end of October 2022), although we anticipate that some families will drop out for various reasons – for example, moving out of the area, imprisonment or residential rehab placement, or failure to respond to calls and home visits (although we will adopt an ‘open door’ policy to allow for periods of no contact if withdrawal from the study has not been communicated). **Accordingly, we will recruit families on a rolling programme - up to five families every 2-3 months – over a 9-month period, to a maximum of 30 families at any one time.** This will allow the researcher to work intensively with each family to begin with (contacting them 2-3 times each week for the first few weeks), to ensure they develop a good rapport, familiarise themselves with each family’s home environment and social networks and immerse themselves in the parents’ everyday lives. This initial intensive involvement phase with families will maximise opportunities to establish trust and an alliance with the researcher and will lessen the chances of disengagement (see **‘risks’ section for further retention strategies**). As the ethnographer-family relationship becomes established, time spent with each family will reduce and become more focused, for instance, meetings or home visits once a fortnight to accompany parents to attend appointments with services, or to interview family members around the time of important events e.g. safeguarding meetings, becoming homeless, imprisonment of partner, re-starting methadone etc. After a period of approx. 9 months, the researcher in each site should have a ‘caseload’ of around 15 families who they can spend substantial amounts of time with (e.g. 1-3 hours) per week/fortnight, depending on each family’s circumstances. In addition, if parents would like to engage in the research project in less intensive ways, for example by taking part in one off interviews, or a series of interviews, rather than taking part in observational or other ethnographic activities, then the researcher will accommodate their wishes. Telephone, video call, or in person interviews can be arranged, and with the parent’s consent, these interviews would be audio-recorded and transcribed verbatim.

In order to **maximise retention**, each parent will be asked to complete an ‘**alternative contacts form’** (see enclosed) when they enrol in the study in order to identify individuals who the researcher could contact should they be unable to contact the study participant themselves (for example, if they move address or change their phone number). Individuals identified could be anyone who the participant thinks would know of their whereabouts – e.g. the parent’s GP, Health Visitor, Drug Worker, Social Worker, as well as family members and neighbours. As many contacts will be recorded as possible to maximise the chances of re-contacting the study participant should they become unobtainable. Each participant will be asked to provide **written consent** for the research team to approach people who they name on their **alternative contacts form** (see **Consent Form for Parents**) and completed ‘alternative contacts’ forms will be stored securely for the duration of the fieldwork and updated regularly.

**Implicit withdrawal from the study**: if consenting parent/s do not make any contact with the research team for a period of at least four months, it will be assumed that the family no longer wish to take part in the study and they will be classed as a study withdrawal with no further follow-up.

The **ethnographic fieldwork** will involve multiple methods of engaging with parents enrolled in the study, as well as their children and wider family/significant others, as they go about their daily lives and engage with different health and social care services. This will include **remote and online meetings, home visits and face-to-face outdoor meetings, participatory observation in different environments, observation of meetings with family, friends and professionals,** as well as more **structured interviews with parents** (utilising stimulus materials to facilitate in-depth exploration of particular topics and significant family events).The type and amount of data collected and generated over the time period of the ethnography will vary according to each parent/family, their particular set of circumstances and their trajectories over time. However, similar data collection methods will be employed across the sample as a whole, and across both sites in Scotland and England, in order to provide comparable data sets for the analysis (see Data Collection section below).

**WORKSTREAM #3: RELATIONAL ETHNOGRAPHY WITH PRACTITIONERS/SERVICES**

In parallel, another researcher in each site will conduct **ethnographic fieldwork** for up to 21 months with 12 selected community teams/services (6 in Scotland, 6 in London). They will situate themselves within participating teams (in consecutive ‘placements’), for a period of approximately 12 weeks (full-time) or 24 weeks (part-time) each, depending on what arrangements suit the agency and what capacity they have for accommodating the researcher at any point in time. The main aim of the ‘in-situ’ service ethnography will be for the researcher to **document everyday practices in relation to the governing of parental drug use** through immersive participant observation, conversations with staff members and focus groups with practitioners. A key focus of the observational field work will be on relations between **staff and parents/families** and relations between **staff in the service and other professionals and agencies**, including senior managers, policymakers and commissioners.

In each site (Scotland and London), we will aim to include **two NHS community drug teams, two Local Authority children and families’ social work teams and two Third Sector agencies** who provide drug treatment and/or family support services to parents who use opioids. These services will be located in different geographical areas (e.g. different Local Authorities), and managed/funded by different organisations. This will ensure institutional, professional and sociodemographic diversity. **NHS services** will be located in NHS Lothian (Scotland) and South London and Maudsley NHS Foundation Trust (SLaM, London), Homerton NHS Trust, Lewisham and Greenwich NHS Trust, and NHS R&D Office approvals will be obtained. Other sites will be negotiated with the respective **Local Authorities** and **Third Sector agencies** and R&D approvals will be obtained as required from these agencies before the start of the ethnographic fieldwork.

**RECRUITMENT STRATEGY AND CONSENT FOR AGENCIES:**

Operational managers of eligible services will be contacted via email by the research team to invite them to take part in the research as a **service site** for the ethnography (see **Invitation letter**). If they express an interest in taking part, the researcher will send them a **PIS and consent form** (see enclosed) and will arrange a telephone call, online or face-to-face meeting to discuss the study in more detail so the manager has the opportunity to ask questions. If the manager agrees, the researcher would then arrange to meet with the **staff team** to discuss the purpose of the research, what it involves, and answer any questions from staff. The researcher will ask the manager to circulate the PIS in advance of the staff meeting so all **team members have an opportunity to read the information sheet**. At the staff team meeting, the researcher will also discuss how the fieldwork could be conducted on site and remotely to ensure the fieldwork is feasible and the staff team as a whole can agree the methods to be employed and who might be directly involved with the researcher – for example, there may be some staff in the team who work with a number of drug-dependent parents and their families who the researcher could ‘shadow’ (with the appropriate permissions in place). **The research team will seek staff agreement (assent) for the ethnographic fieldwork and the manager will be asked to provide informed written consent on behalf of the service** (see Consent Form for Site Managers). Signed consent forms from managers will be returned by post or via email (eConsent).

We will work closely with the **service/team manager** to plan the study and a feasible time for the fieldwork placement to begin, taking into account pressures on the service and any operational issues (e.g. severe staff shortages or service redesign). We will also negotiate fieldwork activities relevant to the each service and their role/remit with drug-using parents and their families.

**CONSENT TO TAKE PART IN AUDIO-RECORDED FOCUS GROUPS (AGENCY STAFF):**

As part of the service ethnography, agency staff will be invited to attend focus groups, one convened at the beginning of the ethnographic placement and one convened towards the end of the placement. Invitations to take part in the focus groups will be sent to staff members via email (see **Invitation letter**), with the permission of the manager. Staff will be provided with a **PIS and Consent Form** (see enclosed). The PIS will clearly state that participation in the focus groups is voluntary and the researcher will offer an online meeting with individual staff members to answer any questions that they might have in order to make a decision. **If staff agree to take part in the focus groups, they will be asked to provide informed written consent, returning via post or email.** We anticipate that a maximum of 10 members of staff will attend each focus group, which will be convened at a convenient time and place (e.g. over lunchtime, with refreshments provided by the research team, or via online video-conferencing e.g. MS Teams).

A total of **12 focus groups** will be conducted in **each site** (Scotland and London) and the focus group discussion, lasting approx. one hour, will be facilitated by the researchers. With the permission of the participants, the focus groups will be audio-recorded and transcribed verbatim. The consent form will include agreement for professional transcribing and long term storage of the data for future ethically approved studies.

**CONSENT TO TAKE PART IN AUDIO-RECORDED INTERVIEWS (FRONTLINE PRACTITIONERS, SENIOR MANAGERS, COMMISSIONERS AND POLICYMAKERS)**

Likewise, eligible participants in the above categories will be identified via the service ethnography and/or via established networks. They will be invited to take part in the study via email (see **Invitation letter**) and will be sent a **PIS and Consent form** (see enclosed). Taking part in the study will be entirely voluntary and the researcher will offer a telephone call, or online or face-to-face meeting with potential participants to discuss the PIS and to answer any questions. If the professional would like to take part, the researcher will obtain **written informed consent**. We will conduct **six interviews** with senior managers, local policymakers and commissioners (per site) and we will conduct **interviews with frontline practitioners** (across Scotland and England) where this is more feasible or appropriate than as part of a service ethnography site. We will schedule interviews at a suitable time and place for participants. Interviews will last around one hour and with the participants’ permission, they will be audio-recorded and transcribed. Again, online interviews will be arranged if this is preferred.

**ONGOING ASSENT FROM THE STAFF IN AGENCY SETTINGS:** We assume that during the period of fieldwork, **new staff members** may join the fieldwork site on a temporary (e.g. agency staff, students) or permanent basis (e.g. new team members), in which case the researcher will inform them about the study when on site and provide them with a copy of the PIS for staff/agencies.

**ASSENT FROM SERVICE USERS IN AGENCY SETTINGS:** Service users and other members of the pubic who attend the service sites will be informed about the research in two ways. A prominent **‘Notice’** (see enclosed) will be displayed in agency waiting rooms and other public spaces to notify clients/patients and/or the public that a researcher from the University may be present (‘in attendance’) and may be observing (for example, in waiting rooms). The **notice** will provide details on how members of the public can identify the researcher and obtain more information about the study. It will also provide reassurance about **confidentiality and anonymity** if anyone is observed as part of the study. If the researcher is shadowing staff, the staff member will ask service users if they consent to the researcher sitting in on the consultation. At all times, the researcher will establish **assent** before joining a staff-patient consultation and will respect the wishes of service users who do not want the researcher to observe their interactions with agency staff. At all times, the researchers will wear their **University staff badge on a lanyard whilst on site**.

The researchers will talk to agency staff about the **observation** of everyday clinical practice and service activity. For planned appointments with patients/clients, **assent** can be established in advance but for **unplanned meetings**, where assent cannot be established in advance (e.g. a drop-in service), the staff member will introduce the researcher at the point of meeting the patient/client and will seek assent for the conversation to continue with the researcher present. If assent is not given, the researcher will remove themselves from the area/room. This **protocol for establishing assent** of patients/the public during the ethnographic fieldwork will be explained clearly to staff teams/services who agree to be ethnographic sites for the study.

**DATA COLLECTION METHODS (ETHNOGRAPHY)**

We will adopt an **iterative but structured approach** to fieldwork data collection in order to gradually build up a comprehensive picture of each family and service, and relations between and among families and services, in order to inform explanatory theories on the wider social ecology of this field of policy and practice. We will utilise a range of participatory, observational and qualitative methods to engage with parents/families and practitioners/services and will review and refine emerging findings (analytic summaries) in regular team meetings. Types and methods of data collection are detailed below.

**PARENTS/FAMILIES**

***Socio-demographic data***: After enrolment in the study, the researcher will obtain socio-demographic information about each parent/s and family using the **‘Participant Details Sheet’** (see enclosed) in order to provide a descriptive profile of the sample of parents/families who take part in the study. The socio-demographic questions include: items on the parent’s social circumstances (e.g. housing, employment, education, financial and legal situation), children (living at home/elsewhere), relationships (with partner/s), drug use and drug treatment history, general physical and mental health, and involvement with family (e.g. parents/siblings) and services. **Non-identifiable data** from the ‘Participant Details Sheet’ will be entered onto a database (e.g. Access or SPSS) to allow descriptive statistics of the sample to be reported. Selected socio-demographic data (e.g. gender, age) will be entered onto NVivo v12 to aid comparative analysis of the pseudo-anonymised qualitative data. Completed participant details sheets will be stored securely in a secure **unlinked** folder to the participants’ pseudo-anonymised research data. Updates on changes to the parent/family socio-demographic details will be recorded on the participant details sheet (and included in the database and on NVivo) in order to construct parent/family trajectories over the course of the study e.g. changes in drug treatment, housing, employment, child protection status of children etc. **At the end of the fieldwork with each family**, the researcher will complete the Participant Details Sheet again to ensure completeness of data before the final contact with the family.

***Remote and online methods of data collection***: Researcher contact with parents/families will be via telephone, texts and online video calls (e.g. via MS Teams), depending in the participants’ preferences and circumstances. In general however, **the researcher will encourage participants to use online video calls** for longer conversations with the researcher so visual contact can be established between the researcher and participant, and between the researcher and other household members when present. Video calls will allow for some **observation** of the home and wider surroundings of the participants (e.g. neighbourhoods) and online video calls also allow the use of **stimulus material** to facilitate discussions on different research topics (see methods below). When required and where appropriate, participants will be offered a **smartphone and/or data sim card** to enable them to engage with the researcher using digital forms of communication. Telephone and video calls may be audio-recorded with the participants’ permission, using an encrypted digital audio-recorder, to enable the researcher to write up accurate field notes after lengthy conversations. Audio-recorded data will be deleted from the device after the field notes have been completed at the end of each day. **NOTE: Video data will NOT be collected in this study.**

***Participatory observational methods***: Fieldwork undertaken by the researchers will include home visits, observations of parents as they go about their daily lives and observations of their engagement with health and social care services. This may include accompanying the parents in their everyday activities such as attending the pharmacy to pick up their methadone, taking the children to nursery or school, going shopping or to the food bank, attending the housing department, drug treatment service or social work appointments. It may also include visiting family and friends, or meeting other social contacts in the home or in the street. **All parent/family contacts will be recorded by the researcher on a ‘Family-Researcher Contact Record’ form** (see enclosed)**.** This form will include: researcher ID number; contact details (date, time, location), who was present (IDs only), and the field note record number (to link to pseudo-anonymised qualitative data on NVivo). **Ethnographic field notes on each parent/family contact will be written by the researcher on the ‘Fieldnote Template’** (see enclosed)**.** Field notes will include a descriptive summary of the contact and analytic notes on the researchers’ own thoughts, observations, reactions and responses to the contact. Field note records will not contain personal identifiable information. They will be anonymised and uploaded onto NVivo when completed. All field note records will be **allocated a number** and will include the researcher and participant ID codes in order to enable linkage with the contact record, qualitative interview transcripts, and other data collection tools (see below).

***In-depth qualitative interviews with family members including those not related to study participants***: We anticipate that approximately three semi-structured in-depth interviews will be conducted with **each family** in the study (total n=45 interviews per site), although who in the family will be interviewed will depend on the circumstances of each family and what events happen in their lives – for example, it might include a parent, non-resident parent, kinship carer, or young person in the family. Contributing to this sample will be individually recruited AFMs, via agencies providing support to AFMs. The focus of the interview could be any **significant life event or family issue** – for example, a parent could be imprisoned, or ‘relapse’, or separate from their partner, or the children could be taken into care and placed with a grandparent. The focus of interviews with AFM not related to a study participant will remain on significant life events or family issues, using the same interview schedule. The **purpose** of conducting interviews with different family members will be to generate different perspectives on significant family topics (see enclosed **‘Interview schedules’** for parents/significant others and young people). With participants’ permission, these interviews will be audio-recorded and transcribed verbatim, scheduled with participants in advance, and conducted in private in a convenient location. Interviews would last about 1 to 1.5 hours and the anonymised transcript will be uploaded onto NVivo.

Other **data collection tools and methods** include the following.

***Ecomaps (see enclosed)***: will be used with parents in the first month after enrolment in order to map and discuss social networks, social support (informal) and contact with services (formal support). Ecomaps provide a visual representation of a person’s social environment (quality), social contacts (including frequency), social connectedness (strength) and social/’recovery’ capital (resources). Ecomaps also provide a good starting point for discussing possible participatory observation field work with each parent/family, based on their normal routines/everyday social contacts, and sporadic social contacts (e.g. appointments with the Addiction Psychiatrist). The researcher can share the ecomap online (e.g. via MS Teams) and can complete the map and give a copy to the participant. The maps will not contain any personal identifiable information (e.g. names of people or specific services), instead, codes or generic terms will be used instead (e.g. maternal grandmother, drug treatment worker, best friend etc).

***Chronologies (see enclosed)*: for each parent will be completed by the researchers during the first three** months of contact in order to build up a comprehensive and concise picture of the timeline of significant life events and major changes in the parent’s health and social circumstances and trajectory from childhood through to adulthood. The chronology will provide a brief summary of each event in date/time order and can help the research team to understand parental and family histories and the impact of life events on the parent and family. The chronology will be documented by the researcher in collaboration with each parent, and can be completed over time as the parent/family discloses information about their history. It will also be used to record contemporaneous information when significant events occur during the fieldwork/data collection time period. The aim of compiling this information is to help build a narrative of each parent and family’s life story (in conjunction with field notes, interviews and other information) and provide an explanatory account for family case studies and the observed trajectories and outcomes for families. See chronology guidance document for further details.

***‘Go along’ interviews (see enclosed)***: also known as “talk as you walk” interviewing, will be suggested to participants as a way of blending participant observation and interviewing, to explore the physical environment of the participant’s social world in real time (e.g. around the home, neighbourhood, local shopping centre or park). During the walking interview the participant guides the researcher around the real or virtual space in which he/she lives, whilst the researcher observes and listens and talks to the participant about their community. In terms of ‘place’, this can deepen the researchers' understandings of local knowledge as well as resources and the kind of environment the family inhabit. Go-along interviews can be conducted either as a face-to-face interaction, or via online video call if the participant uses a smartphone. With permission, the researcher may audio-record the interview and will write up as a field note afterwards.

***Diaries (see enclosed)***: each parent will be encouraged to keep a diary to record events and experiences in their daily lives as an extension of the ethnographic fieldwork, to supplement other data collection techniques, and offer the researchers an alternative way to engage with participants over the course of the ethnography. Participants will be offered a choice of diary formats: either digital/smartphone (facilitating voice memos, text, or photo content) or a traditional pen and paper-based journal. For example, they can use the camera or voice recorder on their smartphone to take photos or make voice memos about their everyday experiences that they could then share with the researcher during interviews, conversations and home visits (Lupton 2020).

**DATA RECORDING**: over time, the researcher will generate **family case studies and narratives** by combining the parent’s socio-demographic data, chronology, ecomap, interview data and field notes from participatory observations, including family relations and parent/family-practitioner/service relations. This may include qualitative data on the parent’s care from a variety of services - housing, welfare or employment services, drug treatment, social work and multi-agency meetings (e.g. child protection case conferences). The researcher will identify **key actors in the field**, focusing on points of contact, co-operation and tension. Observations will centre on **configurations of relations and processes between actors**, as well as cultural, ideological and organisational similarities and differences (e.g. extent of moralising, gendered practice, assessment and treatment methods, regulation and control), shared meaning-making, misunderstandings, agreements, compromises, and disputes. The production of knowledge and action through relational mechanisms will be explored - for example, by **tracing trajectories and connections between actors** to increase understanding of the social production of certain ways of thinking, talking and behaving (e.g. around notions of ‘risk’, ‘harm’, ‘stability’ and ‘recovery’). In keeping with Desmond’s approach to ethnography, much of the data collection and recording will be opportunistic and contingent upon what emerges in the field as being of significance. This body of evidence from the parent/family’s perspective will be compared and contrasted to the body of evidence from professionals and services (see below).

**AGENCY/STAFF DATA COLLECTION**: Initially, the researcher will aim to spend a considerable amount of time in each team/service (approx. 2-4 days per week) to familiarise themselves with the agency staff, role/remit, routines and culture, activities, working conditions and links with other services. Once acquainted, time spent in the agency would then become more targeted and may involve, for example, observing staff meetings and consultations with parents/families, shadowing staff to visit parents/families/kinship carers at home or in the community, observing assessment and care planning meetings e.g. parenting capacity assessments, ‘core group’ meeting, methadone titration appointments etc. Telephone, online and face-to-face contact will be negotiated with staff in the service (and any fieldwork will be conducted in line with COVID-19 guidance – see ‘mitigating risks’ section below).

Data collection in services will also include:

***Focus Groups***: with practitioners in each service site will be convened - one within the first month of the researcher ‘placement’ and one towards the end of the placement in the service. The aim of the focus groups will be to discuss and debate key policies and practices related to the care of parents who use drugs and their families that are considered important for frontline practitioners. This might include discussion about challenging or contentious practices, either within their service, or between different services, or among families who attend the service. A **focus group topic guide** (see enclosed) will guide the discussion and two researchers will facilitate each group. With the permission of participants, the focus groups will be audio-recorded and conducted online (e.g. via MS Teams) if required because of COVID-19 (see **Data Management Plan**).

***Workday debrief interviews*** (see enclosed): with selected practitioners will be conducted where possible at the start or end of their workday. These will be short, semi-structured reflection interviews focusing on the practitioner’s views and experiences of day-to-day practice and their engagement with parents/families and/or other professionals and services. Another aim of this interview method is to discuss the way professionals intervene in the lives of parents/families, including what needs and issues they address with families and what treatment and care they offer and/or provide. Hence, attention will be given to the way practitioners relate to parents/families, other colleagues, superiors (e.g. line manager), other agency staff, and how guidelines, policy, regulations and practice guidance shape the participant’s understanding of the governance of parental opioid use. See workday debrief guide.

Workday debriefs can be conducted either face-to-face, or via online video call (e.g. MS Teams) or telephone. With permission, the interviews can be audio-recorded by the researcher to assist write up of field notes post-interview. No personal identifiable data will be included in field notes and audio-recordings will be erased from the device after write up.

***Collation of agency documents and practice guidance***: the researcher will observe routine practice and request copies of agency documentation and practice guidance/operational policies relevant to the treatment and care of parents who use drugs and their families. These may include, for example, risk assessment forms, family assessment guidance, care planning forms, guidance on toxicology (drug) testing, child protection procedures, discharge policies and thresholds for interventions, such as ‘unannounced visits’ or access to certain kinds of services or resources. In summary, any documentation utilised in agencies that might influence practice and the way practitioners work with families and/or create records of their lives. The researcher will identify and catalogue these documents and then observe how they are implemented in practice. They will also include them in the policy analysis (see below).

**DATA ANALYSIS: ETHNOGRAPHY**

An **iterative approach** to data analysis will be used, intertwined with data collection, in order to gradually build a detailed account of the social ecology of the field, by focusing for example, on logics of care and the way social worlds, subjectivities and realities are produced and configured. The researchers in each site will have extensive ethnographic field notes which they will carefully log and upload each day onto a secure SharePoint folder for the project (see **Data Management Plan**). These field notes, along with interview transcripts, will be pseudonymised and anonymised by the researchers, then uploaded onto **NVivo v12** (see Data Management Plan). Each ethnographer will independently code their data, using a content, thematic and critical discursive analytic approach. Analytic and reflexive summaries will be prepared for discussion in research team meetings. Family case studies will be prepared and presented and their trajectories mapped in order to illustrate forms of governance and their impact on parents, families, practitioners, and institutions.

Likewise, **observational field notes on professional practice** within and across different teams will be discussed, paying particular attention to relations with families and other professionals/agencies, operational issues and organisational/professional culture. Points of convergence and divergence will be explored, along with gaps in evidence and understanding, to inform decisions about subsequent field work and the focus of further observation and inquiry.

**Preliminary analysis of the datasets** will compare observations and emergent themes, using a **constant comparative method** and tools such as **framework matrices in NVivo**, focusing on developing a theoretical framework to describe and explain observed phenomena (e.g. the structure, dynamics, complexity and effects of particular sets of relations and subjectivities), and testing through further fieldwork. Research team meetings will provide an opportunity to critically appraise the evidence as it emerges, deliberate on key findings with the Learning Alliances, and shape the direction of the study. In line with Desmond’s approach to **relational ethnography**, this might entail focusing more closely on processes, boundaries and ideological or cultural conflicts within the field, rather than ‘processed people’, ‘bounded groups’ and ‘group culture’. Arguably, this broader focus on relational phenomena will generate more insightful understandings of the **ecology of the field**. For example, if an ethnographer is working with a new mother and father who have a baby diagnosed with Neonatal Abstinence Syndrome, they might observe and explore how the different actors (e.g. the addiction worker, social worker, health visitor and the parents themselves), construct and enact ideas about ‘harm’, ‘risk’, ‘stability’ and ‘recovery’ within this context, and within different environments (e.g. the neonatal ward, or home environment).

**WORKSTREAM #4: CRITICAL POLICY ANALYSIS**

In tandem with the ethnographic fieldwork, researchers will also identify, collate and analyse relevant policies employed in practice, or referred to, by parents/families and practitioners. We define ‘policy’ as “the organised attempt to select goals and methods for governmental action”. Thus, we would include national and local strategies/guidance, clinical guidelines published by professional bodies, departmental or organisational strategies, and practice ‘tools’ (e.g. ‘assessment’ and ’care planning’ forms) relating to parental drug use. We anticipate that these policy documents will originate from several different sources e.g. government departments, different areas of health and social services (e.g. adult, child, maternity services, criminal justice, child protection and family law, housing support), children’s charities and addiction charities. We will begin our policy analysis in Phase One by first scrutinising national (Scottish and English) policies to help sensitise the researchers to dominant policy representations and responses in order to recognise when local policies and practices appear at odds with national ‘guidance’. In this way, further exploration of local policies can follow during the ethnographic fieldwork.

**Critical Policy Analysis**: We will use Bacchi’s analytic framework for interrogating policy called ‘What’s the Problem Represented to be?’ (WPR). The WPR approach, informed by Foucault’s theory of governmentality, argues that policy is not a reaction to ‘problems’ that sit outside the policy process waiting to be ‘addressed’. Rather, policies produce particular types of ‘problems’, with particular meanings and consequences, which are enacted and embodied in social practices, relationships and subjectivities. In essence, the WPR approach draws attention to an underlying question - How are we governed? - and the analytic task is to reflect on the complex and diverse ‘strategic relations’ that shape peoples’ lives. Bacchi’s theoretical and analytic approach therefore fits well with Desmond’s relational ethnography which focuses attention on configurations of relations between different actors within a field and the ways in which power relations produce certain governing practices and effects.

**Methods of analysis**: Guided by the process set out by Bacchi, we will address specific questions:

1. How do policies, which focus on parental drug use within the family, represent ‘the problem’?
2. What assumptions underpin these problem representations and how have they come about?
3. What are the gaps or limitations in these problem representations, and are there alternatives?
4. How are these problem representations produced, disseminated and defended, and have these been (or could these be) questioned, disrupted and replaced?

**Identification of policy documents** for inclusion in our analysis will be an iterative process, and partially contingent upon the families and services who we engage with. We are aware of ‘high level’ documents (e.g. UK and Scottish legislation and policies) that frame parental drug use, but our ethnographic work may reveal that there are other policies such as local practice guidance, or organisational specific guidelines that are much more influential on everyday practice and have a far greater impact on the way parents and families are governed. **Inclusion/exclusion criteria for the document selection** will be discussed and agreed by the research team, and cross-checked with our LAs, with the aim of including a breadth and depth of relevant policy documents, employed in practice, in order to maximise the comparative potential of the data within and between sites, yet remain feasible and deliverable within the project timescale. Selected policy documents will be catalogued, coded and analysed in line with the policy research questions. Analytic themes and illustrative excerpts will be used to provide a nuanced account of how policies directly influence the operationalisation of systems of care (e.g. child protection procedures, ‘recovery’ care plans, parenting interventions) within specific geographical areas and across jurisdictions. For instance, comparing policies between the Scotland and England will provide important information on the extent to which devolved welfare systems (e.g. in relation to health, child care and criminal justice) and substantially different populations of drug users, affect outcomes for families. Lastly, our International Co-Investigators will contribute to the policy analysis by identifying comparable policy documents in the USA, Canada and Australia to help further contextualise the findings.

**PHASE THREE**

**SYNTHESIS, CONSULTATION AND DISSEMINATION**

This final phase (approx. six months) will address **Objectives 4 & 5 and Research question 5.** It will involve the following overall work plan: First, we will critically analyse, synthesise and contextualise data from across the ethnographic fieldwork, interviews/focus groups, and policy analysis across the two sites. Second, we will convene a four-day face-to-face meeting with our International team to review and develop our analysis and theoretical insights, and embed the findings within the wider international landscape. Third, in conjunction with our Learning Alliance, we will organise **expert events** (in Scotland and London) with a broader group of stakeholders, to present preliminary findings of the study and engage them in round-table discussions to help develop inductively-produced solutions and novel ways of representing and responding to parental opioid use. Lastly, in the final three months of the study, we will develop our study outputs, implement our impact strategy and plan future collaborative work on international comparative ethnographic studies.

**Desmond's (2014) method of relational ethnography** will underpin our final synthesis of the data, which will focus on relations between different actors in the field as the **main unit of analysis** e.g. relations between parents-other family members-informal social networks-professionals and agencies-policymakers. Observational fieldwork notes, interview and focus group data, socio-demographic data on participants, ecomaps, diary data and chronologies/family trajectories, will be examined, triangulated and compared using framework matrices on NVivo. **Comparative analysis** of the data sets within and across the two research sites in Scotland and England will be summarised, discussed and refined in research team meetings to enable the building and testing of explanatory theories on the **ecology of the field as a whole**. The policy analysis, informed by post-structuralist theory, will contribute to this final analysis by considering how parents who use drugs and their families are represented in governmental and local policies and how these are interpreted and enacted in real world clinical practice through particular forms of governing practices - observed and documented in the ethnographic data and family trajectories (family impact case studies). Synthesising our policy and ethnographic analysis will help to explain, from an **ecological perspective**, how governing policies and practices shape the lives of parents who use drugs and their families.

Our final analysis and recommendations for policy, practice and service delivery will be based on the combined learning from the synthesis of the ethnographic fieldwork, policy analysis, and co-produced learning from stakeholders in the Learning Alliance (LA).

**DISSEMINATION PLAN**

**EXPERT EVENTS/CONSULTATION:** Our expert events (Scotland/London) convened in month 30, will allow the research team and LA to engage with a broader group of invited key stakeholders to present and discuss preliminary findings with the aim of generating inductively-produced ‘next step’ solutions. These events will focus on key points of evidence on the social ecology of the field and ways in which parental opioid use is represented and responding to in policy and practice. Research group members, including our International Co-Investigators, will present key findings and facilitate round table discussions on how to address some of the most challenging study findings. Crucially, these expert events will be an opportunity to work all the research beneficiaries and will help the research team to identify areas for further analysis and dissemination of findings e.g, publications and opportunities to hold workshops or talks. Data from our expert events and LA will inform our impact strategy, outputs, final report and recommendations.

**OUTPUTS AND IMPACT:** A wide range of academic and non-academic outputs are planned, with activity designed to maximise impact. Translation and dissemination methods include the following:

1. Eight tailored policy briefings and four infographics (which visually summarise the key findings) will be developed with input from LA members, and drawing on insights from the expert events. These will be targeted at practitioners and policymakers working in specific areas e.g. housing, social work, communities and local government, public health, drug policy, drug services, early years.

2. Creative outputs designed by participants in a series of arts-based workshops will be convened in Phase Three, with participants invited to attend between one and three workshops. These workshops will involve professional artists working with invited members in order to work with the stories generated through the ethnographic study. These artistic approaches will support meaning-making and produce outputs which can support further public engagement activities [34].

3. A programme of formal launch events will be held in Phase Three (in England and Scotland), showcasing findings, briefings, creative outputs and infographics to diverse audiences of practitioners and policy makers.

4. Website and social media. An evolving digital record of research outputs will be hosted on a dedicated website, including a research blog (populated by research team members and Learning Alliance members). The website will also provide a digital home for creative outputs generated by the arts-informed public engagement activities (see below). This will be complemented by maintaining a proactive social media presence, facilitated by twitter, to engage with a range of stakeholders, and contribute to current debates.

5. Throughout the project the research team will present findings from the research to a range of audiences, generating interest in the project, and allowing the team to benefit from critical input from peers. ECR team members will be especially supported to attend and present at conferences.

6. Three international KE events will be held at the end of the study in the USA, Canada and Australia, hosted by our international research team members. These will showcase the research, whilst giving space to consider the relevance and implications of the findings and methodological approaches in different international contexts. This will contribute to a longer-term legacy whereby this research will stimulate similar studies, led by our collaborators, in other countries.

7. At least eight academic journal articles will be written, reporting findings from the study. These will be led by different members of the research team, according to their speciality (social work, social policy, sociology, drug policy, addiction treatment). Papers will address substantive findings, and methodological and theoretical insights. The four RFs will each act as lead author for at least one journal article each.

**ETHICAL CONSIDERATIONS AND RESEARCH GOVERNANCE**

The University of Stirling (UoS) will act as sponsor for this study and our research team will strictly comply with the UK research governance framework for health and social care research (2017), HRA regulatory requirements, and UK laws on Data Protection and GDPR. Our project will also comply with NHS Research Ethics Committee requirements and recommendations as well as NHS R&D Office requirements at both sites in Scotland and England. **Our primary focus will be on ensuring that the rights, safety, dignity and wellbeing of study participants as well as the health, safety and wellbeing of the researchers**. We will carefully consider ethical considerations which are relevant to the study - for example, informed consent, handling sensitive topics and observational fieldwork, confidentiality, child and adult protection, anonymity of participants in study publications, management of adverse events, researcher safety protocols, and data protection (see **‘mitigating risks’** section below and **Data Management Plan** for further information).

**MITIGATING RISKS:** The potential risks involved in this project are relatively low and primarily related to child and adult protection; retention of parent/family participants, burden on participants and level of intrusion, online data collection methods, handling sensitive topics and participant distress, researcher safety and wellbeing, COVID-19 and the management of adverse events. We will mitigate these potential risks by adopting robust strategies to manage these risks - outlined below:

|  |  |
| --- | --- |
| **Potential risk** | **Solutions and strategies to manage and mitigate risk** |
| **Child and adult protection** | Parents who use drugs and their families can be quite guarded and distrustful of people in authority unless they believe that the information they provide will be treated as private and confidential. This is true in respect of researchers as well. In this study confidentiality will be strictly adhered to with the understanding that confidentiality cannot be 100% guaranteed because of **public protection responsibilities and procedures which must be followed if there is an actual or potential risk of significant harm to a child or vulnerable adult**. In these circumstances, the researcher may have to breach confidentiality in order to implement safeguarding procedures (e.g. report to child protection team (health) or social services, or call the police or an ambulance). However, in most cases, this would be done with the knowledge of the participant/s concerned. This will be clearly explained to potential participants when they consent to take part in the study and examples will be given to aid understanding of the limits to confidentiality so they can make an informed decision about study participation.  In addition, after enrolment in the study and during the ethnographic phase, the researchers will follow a **public protection protocol** whereby they will notify their line manager of any child or adult protection concerns that come to light during the fieldwork and record these on the study ‘**Welfare Concern’ form** (see enclosed). These records will be discussed in regular supervision sessions with the lime manager and any actions to be taken will be agreed and recorded. In circumstances where there is an **immediate risk of significant harm to a child or vulnerable adult,** the researcher will contact their line manager (using the study mobile phone) for advice on how to respond to the concern at the time of the event/disclosure. The line manager will discuss and agree an immediate action plan and will intervene if necessary to ensure study participants (child or adult) are safeguarded. If the research fellow is faced with an **emergency child or adult protection situation** (e.g. child abandoned, participant unresponsive or seriously injured, attempted suicide), they will call an ambulance or the police, and will notify and discuss the situation with their line manager after help has arrived or when it is safe to do so.    **All recorded incidents of child and adult safeguarding that involve immediate or emergency procedures to be implemented, will be discussed with the PI, Professor Whittaker**, who will decide whether the **adverse events** protocol needs to be followed (see below). |
| **Retention in the study** | Retaining parents who use drugs in our study may be challenging so we will utilise a range of strategies to minimise drop out following enrolment and to maximise engagement with the researcher-ethnographer. Firstly, experienced researchers with a proven track record of successfully engaging with marginalised and stigmatised population have been employed on the project. Families will receive **gift vouchers** (of their choice) and expenses for taking part in the study to ensure that they are not disadvantaged financially or otherwise and are compensated for any out-of-pocket expenses, including any travel, subsistence and child care costs. £30 vouchers will be paid once a month for every month the parent remains in the study. In addition, we will seek consent to use an **‘alternative contacts’ form**, in the event that families are unobtainable. This will help the researcher to re-establish contact with the family should they move house, change mobile phone numbers or have a period of time in prison or rehab, for example. We will also establish an open and flexible system of contact to enable families to remain in the study for as long as possible, for example, by allowing periods of absence and re-engagement, unless families specifically indicate that they wish to withdraw from the study. We will also use strategies such as sending the family birthday and Christmas cards and by arranging online video calls, home visits and regular meet ups for coffee or lunch in local cafes/community centres. We will also **purchase smartphone devices** and **mobile phone data sims** for parent participants (who do not have a phone which is capable of connecting to the internet and/or who cannot afford data). The phone will become the property of the participant and will not be replaced if lost/stolen. In addition, the researchers will have access to a small amount of **petty cash** to pay for any incidental costs associated with meeting participants - for example, if they meet parents in a cafe, the researcher will pay for their coffee and a sandwich. |
| **Burden on participants and level of intrusion** | The time burden for participants in this study is potentially onerous so this will be discussed in detail with participants before they consent to take part in the study. The researcher will negotiate with each parent suitable days/times to make contact, either remotely (by phone or online video call) or in person (home visits or accompanying the parent to appointments or outings). This will likely vary from week to week and month to month, depending on the circumstances of the parents enrolled in the study. At all times, the researcher will remain as flexible as possible and will accommodate the parents' wishes as well as their normal daily routines and family responsibilities. The aim would be to ensure minimal inconvenience, intrusion and changes to people's lives as a result of the research. The time commitment for each parent/family will likely reduce over time after the researcher gets to know the family and can then arrange contact sessions at times when important events in the family occur (for example, around the time of child protection meetings, rehousing, starting a new drug treatment intervention, or if one of the parents receives a custodial sentence). Participants will be reminded that they are free to withdraw from the study at any time and may also limit contact with the researcher, if they find the time burden too onerous at certain time periods. Thus, level of engagement, will be flexible and negotiable. |
| **Remote and online data collection methods** | Remote and digital methods of data collection can be more challenging than face-to-face methods with this population of families for building a rapport, ensuring a reliable means of contact, and for establishing privacy and confidentiality. In order to maximise our chances of talking to participants when face-to-face meetings are not possible, we will purchase smartphone handsets and internet data to alleviate the potential lack of both the hardware and the cost of phone calls, texts and access to data for online video calls. On enrolment in the study, the researcher will assess the parent’s needs for these items and will provide the necessary equipment and data to enable them to fully take part in the study. In addition, we will provide technical support to help parents manage online video calls via secure platforms such as NearMe, WhatsApp and MS Teams.    To ensure privacy and confidentiality (as far as possible), **earphone sets** will be provided to participants so the conversation from the researcher cannot be overheard and the participants can indicate (‘yes’ or ‘no’) that they have a private and safe space to talk freely to the researcher. This may be especially important where sensitive topics such as domestic abuse and drug use are being discussed and there may be other people in the home (e.g. partner, children). We have also included the use of data collection tools (e.g. ecomaps) and methods (e.g. ‘go-along interviews’) as there is evidence that these can prompt discussion and challenge power relationships of traditional researcher-participant interview methods. |
| **Handling sensitive topics and participant distress** | This research involves discussion of highly sensitive topics with parents/families. Conversations and interviews need to be handled carefully and sensitively by the researchers as some discussions may elicit strong emotional reactions and participants may become upset or distressed - for example, if they talk about child removal or the involvement of child protection services, trauma or loss etc. Some parents may be anxious or embarrassed about being observed in certain situations (e.g. taking their methadone, going to a food bank, playing with their children during a contact visit). They may be fearful of the consequences of certain types of disclosure e.g. taking illicit drugs, not coping with parenting or child care. Regardless, the researcher needs to be prepared for a range of emotional reactions and must foster a trusting, respectful and empathic researcher-participant relationship so that parents feel able to be candid and the researcher can respond appropriately to their wishes. Participants will be reminded on a regular basis that they are free to decide on the nature and extent of the researcher contact with the family and what they chose to talk about, or not talk about, with the researcher. When participants do discuss sensitive topics and become emotional, the researcher will follow a **'debrief and distress protocol'** (see below and IRAS form) to ensure the participants are calm at the end of any contact and if they need additional follow-up support, that this is agreed and put in place before the contact is ended. All families recruited into the study will also be given a ‘**Support Services’ list** (see enclosed) to keep which provides the name and contact details of support agencies, including 24/7 crisis services and helplines.  **DEBRIEF and DISTRESS PROTOCOL**: If at any time, participants present in a very distressed state and require immediate additional support, the researcher will provide practical help to arrange this e.g. by booking an emergency appointment with the participants' GP or mental health crisis centre. The line managers for each site will be informed of any participant that requires immediate help and will assist with any arrangements if required. This may include arranging an emergency appointment at a mental health crisis service or phoning an ambulance, or arranging an escort to a GP appointment. This may also involve arrangements to ensure any children are appropriately looked after. |
| **Researcher safety and wellbeing** | The wellbeing and safety of the researchers in this project is crucial, especially given the extensive fieldwork, participatory observation and longitudinal nature of the research where they will be exposed to potentially distressing stories and events and potentially unsafe environments. COVID-19 infection and transmission is also a major public health concern currently (see COVID-19 section below). We will adopt the Social Research Association’s (2001) *Code of Practice for the Safety of Researchers* which encourages planning to mitigate against the range of risks researchers may be exposed to and use this to complete fieldwork risk assessments. We will also follow University guidance on risk assessments for researchers.  Regular **support and supervision** for the RFs will be provided by the PIs (WHITTAKER & RADCLIFFE) and other members of the research team as required. The PIs in both sites will be **available by mobile phone** should the researchers need to debrief after a distressing or challenging encounter. The researchers will also use the ‘**Welfare Concern’** form to record any incidents or disclosures that they found particularly distressing or difficult to deal with, and these reports will be discussed in supervision with the line manager and an action plan will be agreed if further support for the RF is required. **Peer supervision** among the four researchers will also be scheduled where they can share fieldwork experiences and how they handled any challenging situations. The RFs will have access to **staff counselling services** at their respective institutions if required.  The researchers will follow NHS and University **lone working and home visiting policies**. This includes **two members of staff** visiting the home on the first visit to meet the family and assess any risks for future visits (e.g. unsafe premises or locations, and/or threat of aggression/violence). Referrers will also be asked to advise on any known or potential risks with undertaking lone working/home visiting as an additional precaution. If there are any concerns about lone working or home visiting with the family, two researchers will visit the family at home, of if it is not safe to visit a family at home, appointments will be arranged elsewhere - for example, at a recovery hub or other suitable community venue where security arrangements are in place, or in local cafes and community centres with crèche facilities.  A **fieldwork safety protocol** will be in place for all fieldwork visits to both families and agencies so the whereabouts of the researchers are known by the RF line managers. The researcher will inform the PI of the details of the family/site being visited including the location (address), the time and expected length of the visit, estimated time of arrival and departure, and the route there and back (e.g. car, bus etc). The researchers will ‘check-in’ at agreed times using their **study mobile phone**. When visits are completed, the researcher will inform the PI that they have left the parent/family/site via mobile phone call/text, and again when they have arrived safely back in the office. Should the researcher not make contact at the agreed time, efforts will be made to contact them by mobile phone and if no response is received within one hour, the police will be informed. The researchers will also carry **personal satellite alarm systems with GPS** (e.g. 'Skyguard' <https://skyguard.co.uk>) in case of emergencies, and to send an alert if they collapse so they can be located. Guidance on safer travel arrangements for the RFs includes a budget for taxis fares to avoid compromising safety for example, if travelling after dark or in remote, risky or unknown locations. |
| **COVID-19 public health measures and risk assessments** | We will follow the latest Health Protection Scotland (HPS) guidance and Scottish Government advice on COVID-19. In addition, we will adhere to both University and NHS R&D guidance on conducting fieldwork/research in the context of COVID-19. Likewise, the London (England) research site will follow Public Health England (PHE), NHS R&D and University guidance on COVID-19 and any fieldwork restrictions will be strictly adhered to. If travel is permitted for fieldwork and face-to-face indoor and/or outdoor meetings are possible, as well as entry to services for observational fieldwork, then the appropriate checks will be done before each visit is undertaken (see below), and PPE will be used as per HPS recommendations, relevant to the type of contact and level of risk.  **COVID-19 CHECKS BEFORE VISITS**: If either the participant or researcher are self-isolating or have symptoms, or anyone in the household has symptoms or has had a positive COVID-19 test, then the fieldwork visit will be cancelled and re-arranged when safe to do so. In addition, if anyone in the household is shielding or in high risk health category, the researcher will not conduct a home visit. Checks before each visit will be done via telephone and remote/online forms of communication will be used if it is not deemed safe for participants and researchers to meet in person indoors or outdoors. Public health measures in place within services will also be adhered to (e.g. hand washing, social distancing, mask wearing, one-way systems etc). This protocol will be adhered to, irrespective of whether participants or researchers have been fully vaccinated for COVID-19. |
| **Adverse events** | No adverse events are anticipated as a result of the study itself, however, the population of parents and families involved in this project **are at increased risk of adverse events** on account of their health and social circumstances and lifestyle. For example, they are at increased risk of drug-related deaths (accidental overdose or intentional overdose), mental health crisis admissions, A&E admissions, street violence and domestic abuse, child maltreatment/emergency child protection orders, victimisation and exploitation, police custody and imprisonment. Although these kind of events are to be expected in this study population, and the researchers will record these events in the participant’s field notes and chronology (when reported), the following procedures will be followed:  **Adverse events** (examples listed above) where the welfare of parents/family members is of serious concern – for example, because of **child and adult safeguarding** - will be recorded on the ‘Welfare Concern’ form (see enclosed) and discussed with the University site line manager (RADCLIFFE for KCL and WHITTAKER for UoS). The welfare concern form will include any actions to be taken by the researcher/research team in response to the reported adverse event.  **Serious Adverse Events (SAE)** – specifically the death of a study participant (parent or dependent child) – will be reported immediately to the PI, Professor WHITTAKER, who will obtain details on the circumstances of the SAE (where possible) and ensure that the family have appropriate supports in place. The PI will **notify the Sponsor** of the study and **discuss with the research team and Study Advisory Group**. **The PI will also notify the relevant R&D Office of the death and any necessary procedures for SAEs will be followed.** Any learning or action points from the SAE review will be recorded and communicated in writing to the Sponsor, RFs and Research project co-applicants. The continuing inclusion of the family in the study will be discussed and determined. If withdrawal of the family from the study is agreed, this will be handled sensitively and carefully by the PI and the researcher. The researcher will be provided with supervision and support to help them deal with any emotional impact of the death on their own wellbeing. |

**PROJECT MANAGEMENT**

Our project includes an interdisciplinary team of UK and International social scientists and clinical academics who have a track record in applied health and social science research on parental drug use and children and families. PROFESSOR WHITTAKER (AW), University of Stirling (UoS), is an experienced project manager and clinical academic in addictions and mental health. She will lead the study and take overall responsibility for its conduct, management and co-ordination. AW will act as PI for the site in Scotland, provide line management for the two Research Fellows (RFs) in Scotland, chair the Learning Alliance, and lead on the data analysis, write up, dissemination and the final report. Co-Investigator: RADCLIFFE, an experienced social scientist in the National Addictions Centre, Kings College London (KCL), will lead workstreams #2 & #3 in London, provide day-to-day line management for the two London-based RFs, and co-chair the Learning Alliance. FINCH, Clinical Lead and Consultant Psychiatrist in Addictions, at the South London and Maudsley NHS Foundation Trust, will assist with recruitment in London and provide expert advice on addiction treatment and care. WINCUP, Independent academic and qualitative research lead, at Joseph Rowntree Foundation, will lead on the policy analysis (workstream #4) for the English site. MUNRO, Senior Lecturer and sociologist, at the University of Dundee, will lead on the policy analysis (workstream #4) for the Scottish site and provide expert advice on the drug policy environment. TAYLOR, Emeritus Professor in Public Health, at the University of the West of Scotland, will provide expert advice on ethnographic work in drug-using environments. CALLAGHAN, Professor and Director, Child Care and Protection Centre, UoS, will provide expert advice on child welfare and social work environments. CHANDLER, Senior Lecturer and Chancellor’s Fellow at the University of Edinburgh will lead on our impact strategy and will contribute to the support and supervision of the RFs in Scotland. CARVER, Lecturer in Substance Use, UoS, will lead on workstream #1, organising and facilitating the Learning Alliances and will ensure dedicated support in available for service user involvement. All co-applicants and research fellows will contribute to the study workstreams, expert events, impact strategy, and write up.

**EARLY CAREER RESEARCHERS**: Our project includes five early career researchers (ECRs). One co-applicant ECR (CARVER), and our four Research Fellows (COLES, TODD, FLAHERTY & KUESTER). They will be mentored by senior team members and offered personal and professional development opportunities. They will conduct the fieldwork and assist with all aspects of the study. The line managers for the RFs will ensure appointed staff are supported to attend to career enhancement opportunities. Two RFs will be based with WHITTAKER in the Nursing, Midwifery and Allied Health Professions Research Unit – NMAHP-RU <https://www.nmahp-ru.ac.uk/> funded by the Scottish Government Health Directorate Chief Scientist Office. Likewise, two RFs will be based with RADCLIFFE in the Institute of Psychiatry, Psychology and Neuroscience - IoPPN <https://www.kcl.ac.uk/ioppn/index.aspx> - which has a very active post-doctoral network and research culture.

**INTERNATIONAL CO-INVESTIGATORS**: Our international team of social scientists and clinical academics will provide an international perspective and expert advice on specific aspects of the study, with each making a unique contribution to the project: BOERI (USA) approaches to ethnography and recovery; MCMAHON (USA) effective interventions for families; MARTIN (Canada) international comparative policy analysis; SALMON (Canada) knowledge translation; and OLSEN (Australia) sociological theories on addiction and ethics.

**PROJECT OVERSIGHT**

**RESEARCH TEAM MEEINGS AND COMMUNICATION**: Research team meetings will be held weekly where the Co-Investigators and Research Fellows can discuss progress reports on the workstreams and any ethical and governance issues. Separate supervision sessions will be convened for the RFs to support their ethnographic fieldwork and policy analysis work. Peer supervision among the RFs will also be established to support shared learning during the data collection phase. Face-to-face or online meetings of UK-based investigators will be organised once every 6 months for the duration of the project to fully utilise the interdisciplinary knowledge and skills of the team. We will discuss and review progress with reports from workstream leads and presentation of analytic summaries from the four RFs. Our International Co-Investigators will join by video-conference meetings where possible to contribute to the work of the project. They will also travel to the UK twice to collaborate with the UK investigators. Currently, this is planned for early 2022 and early 2013.

**STUDY ADVISORY GROUP**: A Study Advisory Group (SAG) will oversee the conduct, governance and delivery of the project, meeting once every six months with the research team to discuss and review progress. The SAG will consist of senior academics from relevant fields (e.g. addictions, child health and wellbeing, social work, and policy) with experience of working collaboratively with the NHS, Social Services, Third Sector and service users. The Chair of our SAG is Associate Professor, Dr Magdalena Harris, based at the LSHTM. Other members include: Professor Nina Biehal, Professor Jane Appleton; Senior Lecturer, Dr Simon Flacks and Senior Lecturer, Dr Aileen O’Gorman.

**SUPPORT FORM SPONSOR, FUNDER AND RESEARCH OFFICES**

The PI, Professor WHITTAKER, will also liaise closely with the Sponsor and funder, ESRC, to provide updates on the progress of the project as required and to discuss any study design, conduct, governance and delivery issues as they arise (for example, in relation to substantial amendments and COVID-19). The PI will also liaise closely with the respective R&D Offices involved with this project, including University, NHS, Local Authority and Third Sector R&D Offices who provide research management support and advice.

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