**FULL/LONG TITLE OF THE STUDY**

Emergent everyday ethics in infrastructures for smart care: perspectives of healthcare professionals and service users

**SHORT STUDY TITLE / ACRONYM**

Everyday ethics of smart care: health professionals and service users

**PROTOCOL VERSION NUMBER AND DATE**

Version 5.0

13 September 2022

**RESEARCH REFERENCE NUMBERS**

|  |  |
| --- | --- |
| **IRAS Number:** | 301772 |
| **SPONSORS Number:** | SPON 2021 14 FASS |
| **FUNDERS Number:** | APX\R1\201173 |

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Appendix 1 Covering letter for potential service user participants

Appendix 2 Covering email for potential care team participants

# KEY STUDY CONTACTS

|  |  |
| --- | --- |
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| Funder(s) | APEX grant jointly awarded by Royal Society, British Academy and Royal Academy of Engineering with the support of the Leverhulme Trust  Administered by:  Royal Society  6-9 Carlton House Terrace  London  SW1Y 5AG  Telephone 0207 451 2500  Email grants@royalsociety.org |

**STUDY SUMMARY**

|  |  |
| --- | --- |
| Study Title | Emergent everyday ethics in infrastructures for smart care: perspectives of healthcare professionals and service users |
| Internal ref. no. (or short title) | Everyday ethics of smart care: health professionals and service users |
| Study Design | A qualitative in-depth interview study to explore perceptions of ethics among people involved in implementations of smart care. |
| Study Participants | Service users of smart care (remote monitoring in-home for people living with long term conditions such as dementia) and their carers.  Healthcare professionals involved in smart care service delivery (care team). |
| Planned Size of Sample (if applicable) | 10 healthcare professionals  15 service users and 15 carers (paired interviews) |
| Follow up duration (if applicable) | N/A |
| Planned Study Period | 1/10/2020 – 31/03/2023 (full grant period)  1/11/2021 – 31/03/2023 (data collection and analysis for the phase of research described in this protocol) |
| Research Question/Aim(s) | The overarching objective of the research is to identify when and how ethical concerns become apparent to participants within initiatives in smart care, and to identify mechanisms to address these ethical concerns more effectively. |

**INVESTIGATORS**

|  |  |  |
| --- | --- | --- |
| **NAME** | **Position** | **Signature (optional, Mandatory CTIMPs)** |
| **Christine Hine** | **Professor of Sociology, University of Surrey** |  |
|  |  |  |

# STUDY FLOW CHART

**Healthcare professionals: care team**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Procedure | Recruitment | Week 1 | Week 8 | Week 16 |
| Informed consent | x |  |  |  |
| Interview (1 hour) |  | x |  |  |
| Follow-up interview (15 minutes) |  |  | x |  |
| Follow-up interview (15 minutes) |  |  |  | x |

**Service users and carers**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Procedure | Recruitment | Week 1 | Week 4 | Week 8 |
| Informed consent | x |  |  |  |
| Interview (1 hour) |  | x |  |  |
| Follow-up interview (15 minutes) |  |  | x |  |
| Follow-up interview (15 minutes) |  |  |  | x |

**STUDY PROTOCOL** Emergent everyday ethics in infrastructures for smart care: perspectives of healthcare professionals and service users

# 1 BACKGROUND

In recent years there has been an explosion in discussion around the ethics of data-driven technologies such as the artificial intelligence underpinning “smart” forms of decision-making (Floridi and Cowls, 2019). While concerns about possible ethical challenges raised by artificial intelligence have been live since the emergence of the field itself, the debate has become significantly more active in recent years with the increasing mainstreaming of these technologies. Increases in computing power and the availability of wireless connections and the raw data to fuel machine learning have fostered a flourishing domain of research and commercial application and along with this, a flourishing domain of commentary and concern about potential undesirable consequences such as breaches of privacy, loss of autonomy and lack of human oversight. In order to alleviate such prospects, a need to articulate standards for the field and set boundaries for acceptable practice has been proposed repeatedly, and indeed Floridi and Cowls (2019) describe a “principle proliferation” occurring, as multiple authors and institutions seek to identify the ethical principles that should prevail. Floridi and Cowls (2019) identify five over-arching ethical principles that arise repeatedly or subsume more granular principles: beneficence, non-maleficence, autonomy, justice and explicability. In short, it appears that there is considerable consensus that we want data-driven technologies to work for good and not to do harm, that they should enshrine human autonomy and not machine autonomy, that they operate in the interests of justice rather than discrimination and that all of the principles are achieved through technologies that are open to interrogation because they are intelligible and can be held to account.

While there might be some convergence in terms of over-arching principles, there is as yet little progress towards consensus on how the principles are to be enshrined in practice (Morley et al, 2019). In relation to artificial intelligence in healthcare Nebeker et al (2019) argue that we are still some distance from an “actionable ethics” in this field and that we need interdisciplinary research to “improve meaningful connections between [the] groups that are integral to digital health research and the use of AI in the health care sector” (p4). There is considerable potential for clinicians, engineers, scientists, patients and carers to take different perspectives and to disagree among themselves. Ethical traditions differ between disciplines, as do mechanisms for establishing the nature and governance of ethical issues. We have established modes of ethical review in both medical and university settings but it is not clear that anticipatory governance aiming to identify and mitigate ethical challenges in advance is feasible for the complexities of artificial intelligence (Hine, 2021). For this reason the proposed research will explore ethical challenges as they arise for the diverse participants in smart care initiatives in the course of everyday practice, as a starting point for consideration of how best this form of ethical issue might be addressed.

The approach to ethics taken here is in dialogue with over-arching ethical principles but begins from a more everyday understanding of ethical issues as emergent through practice in context – the focus is therefore on understanding how diverse participants recognize and manage issues that count to them as “ethically important moments” (Guillemin and Gillam, 2004) and how participants separate out and manage issues identified in this way differently as compared to those labelled as technical problems, misunderstandings or disagreements. According to the perspectives on infrastructure developed in Science and Technology Studies (Bowker at al, 2009), in the building of an infrastructure participants are building in social, political and ethical choices and facing continual challenges in aligning different sets of values. The proposed research brings this sociological perspective on everyday ethics and infrastructural work to the challenges of engineering appropriate solutions in the domain of smart technologies.

This research takes place within a healthcare setting that brings multiple practical and ethical challenges. Care for the elderly and vulnerable exists in a liminal space between medical care and the care of kin for one another, and healthcare professionals are often involved alongside informal carers such as partners and family members. Pols (2015) suggests taking an empirical approach to the ethics of care that expects ideas about what counts as good care to emerge in relations between people as they participate in caring relationships, rather than expecting to define a singular pre-existing notion of good care. Networks of care develop around the cared-for person including monitoring staff, GPs, informal carers and the technologies themselves (Pols, 2015). Monitoring technologies participate in these relations, as they afford certain activities and preclude others, as they make new forms of knowledge available and as they shift responsibilities for action on the basis of that knowledge. The development of new technologies for dementia care in the home is a particularly potent site for the research, involving multiple disciplines and perspectives and developing pioneering approaches at the forefront of capabilities in smart technologies for care settings. As the NHS (2019) long-term plan outlines, digitally-enabled care is likely to become increasingly significant in the coming years. We will therefore need to make careful consideration of the new ethical challenges such innovations may bring from the perspective of all stakeholders and to work out how best these may be anticipated and managed.

The research arises from a collaborative project funded by the Royal Society, British Academy and Royal Academy of Engineering with the support of the Leverhulme Trust through the APEX scheme designed to support interdisciplinary research. The grant was awarded to Christine Hine as a sociologist to work with Prof Payam Barnaghi of the Care Research and Technology Centre of the UK Dementia Research Institute at Imperial College, London. Prof Barnaghi’s team have worked with Surrey and Borders Partnership NHS Foundation Trust (SABP) on development of a smart care system for remote in-home monitoring now rolled out to over 600 participants (Enshaeifar et al. 2018). The system incorporates in-home sensors and daily physiological measurements into a machine learning model that aims to identify signs of concerning behaviours or conditions such as urine infections at an early stage. Prof Ramin Nilforooshan of SABP has advised on development of the current phase of the research described in this protocol to explore ethical perspectives of the care team and service users of this system (MINDER, previously known as TIHM). Hine, Nilforooshan and Barnaghi have co-authored a paper exploring the potential ethical challenges raised by this kind of smart care and considering the steps that designers can take to meet such challenges (Hine et al, submitted). The research described in this protocol would allow us to extend this work by conducting primary research to explore how ethical issues arise in practice across the various stakeholder groups.

The primary research will involve Christine Hine conducting a series of interviews with participants in initiatives focused on developing smart care infrastructures, including researchers, technicians, clinicians, carers and service users. Interviews with researchers and developers working in a university setting are already underway, having been approved under a separate application for ethical review by University of Surrey. Each interviewee across the various participant groups will be invited to take part in three interviews, one lengthy introductory interview and two shorter follow-ups, allowing for an appreciation of the emergence of ethical issues across the life span of initiatives. Interviews will be semi- structured and focus on exploring with participants their developing perceptions of the ethical dimensions of the initiatives they are involved in from their own and others’ perspectives and exploring with them the role of their prior knowledge and professional or personal background. Service users and their carers will be interviewed together, in order to provide a supportive environment for the interview. Interviews will be recorded, transcribed verbatim and analysed using the qualitative data analysis software NVivo to code emergent themes in answer to the research questions and to explore the different perceptions of participants. It is anticipated that interviewees will be invited to take part in focus groups in the final six months of the project during which they will discuss the predictability or otherwise of ethical concerns in this domain and explore suitable support mechanisms to facilitate better management of these issues. These focus groups will be the subject of an amendment nearer the time when the content and scope of the focus groups has been determined: the current application for ethical review includes consent processes for interviewees to be re-contacted to invited them to focus groups. The research grant is accompanied by a dedicated sum for public engagement: this will be used in development of resources to support decision-making around smart care for potential users.

# 2 RATIONALE

This research employs qualitative methods to achieve a rich understanding of the perspectives of participants in smart care. Smart healthcare systems are subject to pre-emptive ethical review that aims to identify and avoid or mitigate the worst ethical harms. There are many steps that the designers of such systems can take to embed ethical principles into the design of the infrastructure for smart care. However, as Mittelstadt (2017) argues, there are limits to the extent to which ethics can be designed into a smart healthcare system and much is dependent on the specifics of deployment. Whatever pre-emptive steps are taken, however, we may expect that there will be everyday ethical challenges in the implementation of such systems. These may include changes experienced in the caring relationship at both practical and emotional level, as those involved in offering and receiving care find themselves incorporating the system into their judgments and their daily routines. Privacy and data security are important factors in system design, but do not in themselves ensure an ethical system, from all perspectives. The ability of smart care systems to offer risk assessments and to identify trajectories may bring ethical challenges as it transforms the ability of carers and people living with dementia to recognize changes and act accordingly. A prediction of the future, albeit one based on risks and probabilities, can impact on our understanding of ethical duties in the present. Healthcare professionals involved in delivery of smart care may find themselves facing challenges to their understanding of ethical practice at the same time as they are called upon to act as ambassadors for the technology, taking on a role of education and reassurance for users who may have limited technical understanding of the system. There is a need for research into the lived experience of smart care systems to be conducted alongside the technical and clinical research that enables their implementation. Such research should feed into the development of stronger pre-emptive ethical review for such systems, into training and support for the healthcare professionals involved in their implementation and in a clearer understanding of user needs for support in decision-making about smart care.

# 3 RESEARCH QUESTION/AIM(S)

**3.1 Objective**

The overarching objective of the research is to identify when and how ethical concerns become apparent to participants within innovative initiatives in smart care, and to work collaboratively with participants to identify mechanisms to address these ethical concerns more effectively.

**3.2 Research questions**

This objective is met through exploring a set of research questions:

* At what points in the design and implementation process of a smart care infrastructure are ethical issues or dilemmas identified and by whom?
* How are ethical issues and dilemmas practically and morally distinguished from “business as usual” and from other hitches, such as technical failures, misunderstandings or disagreements?
* What formal and informal mechanisms are deployed to deal with the issues identified as having ethical connotations?
* How do participants experience the process of dealing with ethical issues and dilemmas? What forms of authority do they recognize? What ethical principles and forms of governance do they refer to? Are they satisfied with the outcomes? Does past experiences inform their future practice?
* To what extent is it possible to anticipate and design out ethical issues and dilemmas? What mechanisms would help these issues to be addressed throughout the design and implementation process, to the satisfaction of participants?

**3.3 Outcome**

The outcome of the research will be a rich understanding of the ethical issues identified by the various participants within an innovative initiative in smart care. This will be used to identify possible mechanisms to address these ethical concerns more effectively and also used to develop resources to support decision-making around smart care for potential users.

# 4 STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYSIS

The study design incorporates qualitative in-depth semi-structured interviews aimed at capturing the participants’ perspective on involvement in smart care, with particular reference to the ways in which ethical issues arise and are managed. Participants, in this context, includes researchers and developers (this group are the subject of a separate application for ethical review to University of Surrey), service users, their carers and healthcare professionals involved in service delivery. It is anticipated that each group will have distinctive perspectives and experiences and that a comprehensive and nuanced approach to ethics in this field will require appreciation of the perspectives of all interested parties. An interview guide has been developed to encourage recounting of experiences from the participant’s perspective and including a section based on a review of the literature on ethical principles of artificial intelligence to encourage detailed discussion of these issues. The recounting of experience precedes the discussion of specific ethical principles in order to avoid those principles overly influencing the initial narrative of experiences. The same topics will be covered with each group of participants with the presentation adapted for accessibility in each group. A similar format of interview will be adopted for each group, with an initial long interview supplemented by two short follow-up interviews. These follow-up interviews offer the prospect of building a rapport with the participant enabling them to raise issues that appear relevant to them subsequent on the initial interview once they are aware of the agenda. It is to be anticipated that after reflection on the content of the initial interview participants may find that they wish to add to or qualify their previous responses. This approach adds a longitudinal element to the research without the participant burden of full repeat interviews.

**Healthcare professionals**

Following return of a completed consent form, arrangements will be made for a mutually convenient time to conduct an interview via Microsoft Teams for healthcare professional. It is anticipated that this will be a comfortable and familiar environment for the majority of participants. The interview will last for approximately one hour, following the interview guide in Appendix 1. Interviews are semi-structured – the questions listed here express the scope and sequence of the interview conversation and are not necessarily to be delivered verbatim as the goal is to maintain a conversation that responds to the interviewee’s contributions and flows as naturally as possible. Material in italics covers potential prompts to encourage detail in the interviewee’s responses. Following an initial long interview, participants will be invited to take part in two further follow-up interviews each lasting approximately 15 minutes. The scope of these interviews is outlined in Appendix 1. The initial consent process covers consent for the repeat contact, but at each stage continued consent will be checked and participants will be free to withdraw at any time.

**Service users and carers**

Interviews with service users and carers will be conducted within their own home settings or via the video calling service Zoom if they prefer or if restrictions in place at the time of the interview require. Following return of a completed consent form arrangements will be made for a mutually convenient time and medium to conduct an interview. Interviews will be conducted with both service user and carer present and both will be consented. The interview will last for approximately one hour, following the interview guide in Appendix 2. Interviews are semi-structured – the questions listed here express the scope and sequence of the interview conversation and are not necessarily to be delivered verbatim as the goal is to maintain a conversation that responds to the interviewee’s contributions and flows as naturally as possible. Material in italics covers potential prompts to encourage detail in the interviewee’s responses. Following an initial long interview, participants will be invited to take part in two further follow-up interviews by telephone or Zoom each lasting approximately 15 minutes. The scope of these interviews is outlined in Appendix 2. The initial consent process covers consent for the repeat contact, but at each stage continued consent will be checked and participants will be free to withdraw at any time.

**Analysis**

All interviews will be audio-recorded and transcribed to reflect participants’ verbatim contributions. The transcription will be conducted by a professional transcribing service based in the UK who offer secure file upload and confidentiality agreement (TypeOut – see further details in TypeOut security statement). Transcripts will be anonymised to remove all identifying details. The method of analysis is a qualitative thematic analysis, coding for emergent themes across all groups of participants. All interview transcripts will be uploaded to NVivo qualitative data analysis software to support an iterative coding process that begins by identifying a bottom-level of codes based closely on the content and then proceeds to group codes at increasing levels of abstraction. The coding process will allow for identification of ethically relevant issues both across and within groups of interviewees. The results of the coding will then be compared with the existing literature on ethics and artificial intelligence to identify gaps and commonalities both in the ethical principles and the recommended governance processes. The results of the analysis of interviews will be used to develop an agenda for focus groups to explore possible responses in the form of additional support and training aimed at service users, healthcare professionals or researchers and developers or new governance mechanisms.

# 5 STUDY SETTING

Since the research focuses on the experience of participants in smart care initiatives it is essential that the study site(s) be involved in delivery of a relevant initiative. The research has been conceived in collaboration with Prof Payam Barnaghi of the Care Research and Technology Centre at the UK Dementia Research Institute, Imperial College London. Prof Barnaghi has been involved with the development of the TIHM (Technology Integrated Healthcare Management) system with Surrey and Borders Partnership NHS Foundation Trust. This smart care initiative offers a remote monitoring service to people living with long term conditions such as dementia in their own homes. The system is enabled by artificial intelligence to interpret data derived from a variety of in-home sensors and daily physiological measurements, with the goal of identifying events such as urine infections and reducing hospital admissions. This system therefore offers a suitable site to explore the experience of participants in smart care initiatives. Researchers and developers working on the system in a university context have already taken part in interviews. Prof Ramin Nilforooshan at SABP has advised on the development of the research and has agreed in principle for the care team to be approached to participate in research interviews and to assist in identification of potential participants among the service users of the MINDER system (see letter of support). This system currently has more than 600 users and hence offers a large pool of potential interviewees for the research. Following successful ethical review the researcher will apply for research passport with SABP to allow for the research to proceed at this site.

If sufficient participants are forthcoming from the SABP MINDER system the study will be restricted to this one site. In principle it is possible that further sites could be added but this would be dependent on that site being involved in delivery of a suitable smart care initiative, involving remote monitoring of service users at home and use of artificial intelligence to interpret the resulting data.

**6 SAMPLE AND RECRUITMENT**

**6.1 Eligibility Criteria**

To be eligible for the study a participant must have relevant experience of a remote smart monitoring system and be willing and able to consent to participate in an interview. In order to generate suitably rich qualitative data, it is important that the participant be able to interact with the researcher. Fluency in the English language is required for eligibility since live translation is not practical. Where a participant has hearing impairment adaptations may be made to suit the participant, for example by use of transparent face masks to facilitate lip reading or by use of live subtitling or written prompt texts by the researcher.

**6.1.1 Inclusion criteria**

**Service users/carers**

Service users of a smart remote monitoring system such as the MINDER system (previously TIHM) who have an accompanying carer who is also willing to participate

Capacity to consent

Able to understand participant information in written English and participate in an interview conducted in spoken English.

**Healthcare professionals**

Healthcare professionals involved in the delivery of a smart remote monitoring system such as the MINDER system (previously TIHM) delivered by Surrey and Borders Partnership NHS Trust.

**6.1.2 Exclusion criteria**

Participants will be excluded if they are not involved in a relevant remote monitoring system, and if they do not consent, withdraw consent or are deemed not to have the capacity to consent. Participants will be excluded if they are not able to understand participant information in written English or participate in an interview conducted in spoken English.

**6.2 Recruitment**

**6.2.1 Participant identification**

Service users will initially be contacted by the care team (e.g. the care team delivering the MINDER service at SABP) to invite them to participate. The care team will be briefed in advance by the researcher on the inclusion criteria and the nature of the commitment being asked of participants. Within the overall inclusion criteria the care team will be briefed to prioritise socio-demographic diversity with a variety of difference domestic circumstances (including living with spouse/carer, supported by family living separately) and to approach only those potential participants whom they deem to have capacity to consent. Contact details for all potential participants who express an interest in learning more about the research will be passed by the care team to the researcher who will send the information sheet and consent form with a covering letter (see Appendix 3) and then follow up within one week with a telephone call to answer any questions and ascertain willingness to proceed. It is to be expected that there will be substantial drop-out at this stage: recruitment will therefore proceed in waves of 10 potential participants’ details being passed to the researcher at a time until the target number of interviews is achieved. The care team will make a note on the service user’s electronic record of their verbal consent for contact details to be passed to the researcher.

The care team will be sent the participant information sheet and consent form by email and invited to contactthe researcher directly to indicate willingness to participate and arrange an interview (see Appendix 4).

**6.2.2 Consent**

All potential participants will be provided with a written participant information sheet tailored appropriately for either service users and carers or care team. They will be given at least five days following receipt of written information before a follow-up from the researcher to enquire as to willingness to participate and answer any questions. Written consent forms will be returned before any interview takes place.

The care team will be briefed to assess that potential participants are deemed to have capacity to consent before their details are passed to the researcher. This means that in their judgment the potential participant is able to

* + understand the purpose and nature of the research
  + understand what the research involves, its benefits (or lack of benefits), risks and burdens
  + understand the alternatives to taking part
  + be able to retain the information long enough to make an effective decision.
  + be able to make a free choice
  + be capable of making this particular decision at the time it needs to be made (though their capacity may fluctuate, and they may be capable of making some decisions but not others depending on their complexity)
  + where participants are capable of consenting for themselves but are particularly susceptible to coercion, it is important to explain how their interests will be protected

In particular, during consent taking it will be stressed that the decision for a service user has no repercussions for the care that they receive and for a member of the care team that their decision has no repercussions for their employment.

Where the researcher at any point in the research deems that a participant appears to have lost the capacity to consent under these criteria, that participant will be withdrawn from the study and no further data collected. Data collected up to the point that the participant was deemed to have lost capacity will be retained within the study.

**6.2.2 Withdrawal of Consent**

Participants are assured that they are free to withdraw from the study at any time, without giving a reason. If they indicate that they wish to withdraw during the interview they can ask to stop and will be offered the opportunity for any data collected up to that point to be deleted. If they wish to withdraw data after the interview has been completed interviewees are informed that they can contact the researcher up to one month after the date of their final interview or follow-up call and any interview data collected up to that point will be deleted. Beyond this point it will not be possible to withdraw interview data because it will have been anonymised and included in analysis. If participants wish not to take part in a follow-up call they can inform the researcher at any point or simply say that they are no longer willing to take part when re-contacted. At that point any interview data previously collected will be deleted if the participant wishes. A record will be maintained of the date of withdrawal and the nature of the data withdrawn.

# 7 ETHICAL AND REGULATORY CONSIDERATIONS

# This research aims at a long-term benefit by informing the management of ethical issues in services involving remote monitoring and artificial intelligence, but it has no direct short-term benefit to participants beyond the opportunity to reflect and share their views. It is important therefore to minimize the burden on participants, to make the nature of the commitment clear and to ensure meaningful consent. Safeguarding and accessibility concerns are important in the context of face-to-face interviews, particularly since while participants will have capacity to consent they may have some cognitive impairment. Data security is important to secure personal data and audio-recordings and thus protect the privacy of participants. These areas are covered in more detail below.

# *Burden of research* Interviews will require a time commitment from service users and carers beyond the existing burdens of smart care. In determining the nature and length of interviews the concern is to meet the requirements of in-depth qualitative research in a way that would not be excessively burdensome for participants. While remote interviews, e.g. via Zoom are possible in some circumstances, for this target group they may also raise concerns about accessibility and acceptability. Conducting an initial one-hour interview face-to-face offers the opportunity to develop trust and rapport with service users and carers and for the interviewer to be responsive to signs of tiredness or need for clarification. While repeat interviews would be preferable in terms of data richness and ability to track ethical issues as they emerge, in practice this would place a significant burden on participants. The decision has therefore been taken to implement a research design that ~~involves~~ allows for an initial face-to-face interview if that is the participant’s preference and if restrictions in place at the time allow, followed by two follow-up telephone interviews. If participants prefer or restrictions dictate, interviews and follow ups will be conducted via Zoom. Further information on Zoom will be provided to potential participants who ask for it, using resources on Zoom provided by the Dementia Voices network <https://www.dementiavoices.org.uk/group/zoomettes/> )

# The follow-up interviews allow for participants to raise any issues that have occurred to them subsequent on the initial interview and thus reduce the pressure to recall and raise all relevant issues in the initial visit. Re-contact will happen four weeks after the initial interview for service users and carers (rather than the eight week delay for participants who are healthcare professionals or researchers/developers) to increase the prospects for recall of the initial interview. Participants will be reassured that the researcher carries the responsibility for remembering appointments and sending reminders. Recruitment and interview processes have been designed with reference to advice published by the Alzheimer’s Society on conducting research with people who are living with dementia. Participants will not be drawn from the MINDER champions who have already taken part in extensive research and design activities, in order to broaden participation and avoid a concentration of burden on these individuals.

# *Capacity to consent* Participants will be recruited through initial contact with staff directly involved in their care. Staff will be briefed on the inclusion criteria including the requirement only to approach potential participants who they deem to have the capacity to consent according to MCA. Should any participant appear to have lost the capacity to consent during the study no further involvement will be requested from them and no further data will be collected. Specific signs of lack of capacity to consent to participate in this research may include:

misunderstanding of the researcher’s identity – confusing the researcher with a healthcare professional or carer

expression of feeling under obligation to participate

repeated confusion about the nature of the interview, despite explanations offered by the researcher

According to the second principle of the Mental Capacity Act, a person should not be treated as incapable of making a decision unless all practical steps have been taken to enable them to do so. In the first instance of concern about potential lack of capacity the researcher will therefore make efforts to explain any areas of confusion about the research that have emerged in communications with a potential participant. Only if these clarifications do not lead to improved understanding of the research (evidenced by continuing misunderstanding of key aspects of the research) will the decision be taken that the potential participant lacks the capacity to consent to this research at this time. If, after making attempts to support the person to understand the relevant facts about the research and their participation in it, there is a reasonable belief that the potential participant does not have the capacity for informed consent then they will not be enrolled into the research – they will be thanked for their time and informed that they are not required at this time. Should any participant be deemed to have lost the capacity to consent during the study, as a result of evidencing the forms of relevant confusion about the research outlined above they will be withdrawn from the study and no further data will be collected from them. The monitoring team will not be notified unless there are concerns about a risk of serious harm to a participant.

# Given the involvement of the care team in the initial recruitment, there is potential for confusion between the service and this research. All study documentation will be clear on the relationship, bearing only the University of Surrey logo, and participants will be reassured that their decisions and involvement will have no impact on their care. There is a risk that potential participants feel some perceived obligation to participate. This will be offset through a consent process that involves initial verbal consent taken by NHS staff but full consent being taken by the researcher. No audio recordings or list of the eventual participants will be shared beyond the researcher.

# *Safeguarding and wellbeing* The researcher will be in possession of enhanced DBS before the recruitment process commences. Any face-to-face interviews will be conducted according to national and local guidelines for Covid-secure contact. The researcher will follow University of Surrey guidance on safety in lone working. The interviews are unlikely to cover any sensitive or distressing issues. Participants are already under direct care and monitoring and it is therefore unlikely that the researcher will become aware, in interview, of any concerns for wellbeing that are not already known to the care team. In the event that a participant raises an issue of concern about their own wellbeing or concerns about the service delivered they will be directed to contact the appropriate NHS contact point e.g. MINDER care team or PALS. If a concern about a risk of serious harm to a participant should arise during the study the researcher will exceptionally breach the confidentiality of the interview to inform the monitoring team who will make a record of the concern. The Participant Information Sheet informs participants of this possibility.

*Data security* Interviews will be audio-recorded on an encrypted device, transferred as soon as possible to secure storage on University servers and transcribed through a professional service that offers secure file upload and confidentiality agreement. Transcripts will be anonymized and original audio-recordings then deleted. Personal data for participant tracking will be stored securely on University servers in password protected spreadsheets. Participants taking part in Zoom interviews will be made aware via PIS and consent form that the interview is subject to Zoom privacy policies. Recordings will not be made using the in-built facilities of the platform due to lack of control over the location of data storage.

## **7.1 Assessment and management of risk**

| 1. **Identified Risks** | 1. **Likelihood** | 1. **Potential Impact/**   **Outcome** | 1. **Potential Severity of Outcome** | 1. **Risk Management/Mitigating Factors** |
| --- | --- | --- | --- | --- |
| Disclosure of  information that  might need reporting to authorities such as complaint about service delivery | Unlikely | Researcher compromised by connections with service delivery team/ unqualified to follow up concern | High | Interviewees will be directed to raise issues with existing NHS complaints process via PALS |
| Disclosure of information that raises safeguarding concerns about the interviewee | Unlikely | Concerns for interviewee safeguarding go unreported | High | In mitigation, the care team will be asked not to propose potential participants if there are existing concerns of this kind. Given the close monitoring of service users already being undertaken, this kind of concern is highly unlikely to arise in interview. If any relevant concerns are explicitly raised in the interview, interviewees will be advised to consult the care team.  If the researcher should become aware of a serious risk of harm during the interview the monitoring team will be informed. The PIS informs interviewees of this possibility. |
| Risks to researcher attendant on lone working in service users’ homes | Unlikely | Risks to personal safety and exposure to unfounded accusations of inappropriate actions. | High | In mitigation the researcher will follow University of Surrey guidance on safety in lone working, leaving a sealed record of their location with a trusted colleague to be destroyed unopened after successful completion of the interview.  The researcher will undergo enhanced DBS check.  The researcher will conduct interviews with both service user and carer together, reducing the likelihood of concerns being raised about inappropriate actions. |
| Risk of data loss | Unlikely | Participant time wasted.  Scope of research reduced by loss of participant data | Medium | Interviews will be recorded on encrypted audio device and backed up to secure servers as soon as possible  Anonymised transcripts will be stored in a secure location on University servers where automatic backups take place. |
| Risk of breaching participant confidentiality | Possible | Embarrassment and reputational risk to interviewee |  | Interviews will be recorded on encrypted audio device and not on Zoom/Teams  Recordings will be securely stored until transcription and then destroyed  Transcription will be carried out by professional transcribers using secure upload/download  Pseudonyms will be agreed with participants to provide confidentiality  Care team participants will be made aware that unique details may render them identifiable. |
| Participants may feel under obligation to participate | Possible | Feelings of coercion to participate, leading to participant distress and compromising data quality | Medium | Assure all participants of no obligation to participate and no consequences for declining.  No data in which participants are identified to be shared with care team |

**7.2 Research Ethics Committee (REC) and other Regulatory review and reports**

7.2.1 Approvals. Before the study commences a favourable opinion on the protocol and associated documents will be sought from the UK Health Departments Research Ethics Service, the HRA, and confirmation of capability and capacity from NHS sites where necessary. All correspondence with the REC will be retained.

7.2.2 Amendments. Should any amendments to the protocol be required the researcher will contact the University RIGO office (Sponsor) to determine if its substantial or non-substantial, upon clarification of the amendment categorisation, the researcher will submit the amendment as per current HRA practice, the amendment will not be implemented until all approvals have been completed.

7.2.3 Annual Progress reports. An annual progress report (APR) will be submitted to the REC within 30 days of the anniversary date on which the favourable opinion was given, and annually until the study is declared ended following HRA current practice

7.2.4 The researcher will notify the REC of the end of the study with 90 days of the last data collection point using HRA current practice.

7.2.5 End of study report. Within one year after the end of the study, the researcher will submit a final report with the results, including any publications/abstracts, to the REC.

**7.3 Supervisor/ Peer review**

This research has undergone independent expert peer review conducted by the funding body as part of a competitive funding allocation process.

**7.4 Patient & Public Involvement**

Participant-facing materials (information sheet, consent form and interview guide) have been shared with the MINDER champions for feedback. This group of service users has volunteered to provide additional feedback on their experiences with the system to inform ongoing development. The MINDER champions will not be invited to participate in the interviews in order to avoid excessive burden on them.

Interviews will be conducted with MINDER service users to gain their perspectives on ethical aspects of the system.

Any participants will be able to contact the researcher to receive findings of the research. Following completion of the data collection and analysis a series of public engagement activities will be undertaken to develop resources to aid in decision-making around smart care.

* 1. **Protocol compliance, adverse events reporting and breaches**

Protocol deviations, non-compliances, or breaches are departures from the approved protocol.

7.5.1 Minor protocol deviations will be documented on the relevant forms and reported to the Chief Investigator or supervisor and Sponsor.

7.5.2 Adverse events will be discussed with the researcher’s supervisor and the sponsor, adverse events will be documented in the trial files. Serious adverse events will be reported to the Sponsor as per the sponsor SOP.

7.5.3 Serious Breaches of the protocol, where a participant has been put at risk by a deviation from the approved protocol will be reported to the sponsor as per SOP

**7.6 Data protection and patient confidentiality**

All investigators and study site staff must comply with the requirements of the Data Protection Act 2018 (GDPR) with regards to the collection, storage, processing and disclosure of personal information and will uphold the Act’s core principles. The researcher will act as data custodian. Personal data collected and stored will be kept to the minimum required to conduct the study and all data collected will be anonymised as soon as possible by removal of any identifying details and replacement of identifying information with an unrelated identifier.

Personal data in the form of contact information for potential participants will be passed to the researcher by the care team with the verbal consent of the potential participant. A password protected file will be used for the transfer. Only the researcher will have access to the personal data from this point, and only the researcher will have access to the final list of actual participants drawn from this list of potential participants. Similarly, only the researcher will have access to the list of actual participants drawn from the care team.

Completed consent forms will be kept in the researcher’s office at the University of Surrey in a locked filing cabinet. Personal data, in the form of participant details used to contact and keep track of recruitment and interview arrangements, will be stored in a password protected spreadsheet stored on the University of Surrey’s servers. Only the researcher will have access.

Audio recordings will be made on an encrypted device and uploaded as soon as possible to an area on the University of Surrey’s servers to which only the researcher has access and deleted from the recording device. Transcription will be carried out by a professional transcription service in the UK that offers secure file upload and confidentiality agreement (see TypeOut security statement). After checking of the transcript the audio recording will be deleted and any identifying details redacted.

The password protected spreadsheet used to keep track of participant recruitment and interview arrangements will contain an identifier assigned to each participant. Audio recordings and transcripts will be stored with filenames that contain this identifier. Within three months of completion of the project the spreadsheet linking personal data with identifiers will be deleted.

* 1. Indemnity and Insurance

The sponsor has in place relevant insurance for the design and the management of the study. The NHS indemnity scheme is in place to provide insurance for the conduct of the research on NHS premises. The sponsor has arrangements in place for payment of compensation in the event of harm to the research participants where no legal liability arises.

**7.8 Access to the final study dataset**

Only the researcher, Prof Hine, will have access to the full raw dataset and the identity of those who participated in interviews.

Anonymised transcripts will be offered, with participant consent, to the UK Data Archive to be made available to the research community under licence. Any identifying information will be removed before archiving takes place.

### 8 DISSEMINATION POLICY

### 8.1 Dissemination policy

The anonymised data arising from the study will be offered to the UK Data Archive for use under licence by the research community within three months of the end of the award. Meta data concerning the study will be archived alongside the transcripts: this will include study protocols, participant-facing information and interview guides.

A final study report will be prepared, including findings from all phases of data collection, according to the requirements of the funder within three months of the end of the award. This report will be submitted to the REC and also made available to participants on application.

The findings from the series of interviews described in this protocol will be combined with results of the other phases of the research to contribute to conference presentations and journal articles. A social media presence will be developed to share emerging findings and form a focal point for collecting and disseminating insights into the everyday ethics of smart technologies and formulating best practice. Following completion of the project a book-length publication accessible to a non-specialist audience will be developed to broaden access to the project’s findings and inform best practice on managing the ethics of smart care. These publications may make use of anonymised quotations from interviews, chosen so as to avoid use of any specific identifying details. Funding for an additional set of activities for public engagement has been awarded: the researcher will develop educational materials, including an informative video exploring the issues that arise when choices are made about technology and care, and the impact of these decisions. They will present these resources at a range of events to foster further discussion between care recipients and their families as well as professional care providers and organisations advocating these audience groups.

The support of the funder will be acknowledged in all publications.

**8.2 Authorship eligibility guidelines and any intended use of professional writers**

Authorship of reports and other publications ensuing from the research will reflect substantive contributions to the research and/or writing process and willingness to take responsibility for the submitted version. Authorship will be discussed at the beginning of drafting in each case and reviewed before submission to ensure that this policy has been followed.

### 9 REFERENCES

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### 10 Protocol History

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| --- | --- | --- | --- | --- |
| *Amendment No.* | *Protocol version no.* | *Date issued* | *Author(s) of changes* | *Details of changes made* |
| Approved version following REC review and feedback | 3.0 | 29/10/2021 | CH | Interview guides separated out into separate files and appendices renumbered accordingly.  Clarification of process for withdrawal of interview data.  Clarification of process for assessing capacity.  Addition of exception to confidentiality for concerns about serious risk of harm. |
| 1 | 4.0 | 6/12/2021 | CH | Addition of information about Zoom as an alternative interview medium |
| 2 | 5.0 | 13/9/22 | CH | Amendment of study end date to reflect extension to grant award period. |

Appendix 1 Covering letter for potential service user participants

[on University of Surrey headed paper]

My name is Christine Hine and I am a Professor of Sociology at the University of Surrey. I am writing to you to give you more information about a research project that was mentioned to you by the [insert name of service] care team. With your permission they have passed me your contact details to send you this information.

As you may know, the [insert name of service] is a pioneering remote monitoring and smart care service. There may be many more such services in future, so it is important to learn from the experiences of those involved and consider how best to design and implement this kind of service going forwards. I am particularly interested in how we decide what is ethical in a smart care setting to best serve the needs of those involved. In order to find out, I need to talk to people like you who have direct experience of receiving this kind of care.

If you are willing, I would visit to talk with you about your experiences with smart care Recruitment and data collection as outlined in the original application has been completed - the additional six months will be spent conducting data analysis and reporting activities that do not pose any additional burden on NHS resources..

The interview will take about an hour, and I would want to talk with the person receiving care and a carer together – this might be a friend or family member who helps with managing the smart care monitoring. I would aim to make an appointment at a time convenient to you both.

I have enclosed further information about taking part in order to help you to decide, and consent forms that would need to be signed by both of you if you decide to go ahead. I will contact you in a week’s time to answer any questions you may have and find out if you are willing to take part. I can also send you more information about using Zoom if you like. There is no obligation to say yes, and your decision will not have any impact on the care you receive.

Yours sincerely

Christine Hine

Appendix 2 Covering email for potential care team participants

I am emailing to introduce myself and ask if you would be willing to share a small amount of time to help with a research project. I am a sociologist working at University of Surrey and have been funded to carry out interviews that will help us to learn more about the challenges and opportunities of smart care, focusing in particular on the ethics of care. I am contacting you because you are involved in delivery of smart care through the [insert name of service]. As you know, this is a pioneering project that may be the forerunner of many more services offering digitally-enabled care in the future. It is important to learn from the experience of people who have direct involvement in smart care delivery to inform future initiatives. I would be really grateful if you would be willing to take part in an interview to share your valuable experiences with me. I attach further information and a consent form. Please let me know if you have any questions. If I don’t hear back from you in one week I will send a reminder, but if I don’t hear back from you after that I will assume that you won’t be taking part and apologise for bothering you.