**Study Title:** Development and validation of a risk assessment tool for self-harm in prisoners

**Internal Reference Number / Short title:** RAPSS (Risk Assessment for Prisoners at risk of Self-harm and Suicide)

**Ethics Ref:** N/A

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| | |
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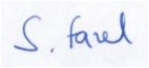
**Chief Investigator Signature:** 

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**Confidentiality Statement**

This document contains confidential information that must not be disclosed to anyone other than the Sponsor, the Investigator Team, HRA, host organisation, and members of the Research Ethics Committee, unless authorised to do so.

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## 1. KEY CONTACTS

| | |
|---|---|
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| **Committees** | N/A |

## 2. LAY SUMMARY

Rates of self-harm in prisoners are high and have been increasing over the last few years. In 2015-16, there were 34,586 reported incidents of self-harm in 10,012 prisoners, a 27% increase on the previous year. One approach of the Prison Service to deal with these high rates has been to reduce the recurrence of self-harm, which is estimated at around 25% within 6 months. Current practice in prisons for those that have suicidal ideation or have self-harmed is to place them on a suicide risk management plan, called an 'Assessment, Care in Custody and Teamwork' or 'ACCT'). The current assessment of risk of recurrent self-harm on closure of ACCT lacks a structured approach. Any reduction in self-harm will have large benefits for the Prison Service and NHS in reducing individual prisoner's physical and psychiatric morbidity, attendant healthcare costs, possible disruption to release planning, and also improve the prison environment more widely. This project has three parts:

1. Development of a risk assessment tool. We will develop the tool using routinely collected information. It will aim to identify risk of repeat self-harm within 3 months following the closure of an ACCT.
2. Qualitative study. We will then assess the acceptability of the new tool to relevant stakeholders (prisoners, clinicians and prison staff) and examine barriers to implementation.
3. Prospective study. After information from the qualitative study on feasibility and acceptability has been gathered, we will then conduct a validation study and test whether the tool predicts self-harm in prisoners after closure of their ACCTs.

## 3. SYNOPSIS

| | |
|---|---|
| Study Title | Development and validation of a risk assessment tool for self-harm in prisoners |
| Internal ref. no. / short title | RAPSS (Risk Assessment for Prisoners at risk of Self-harm and Suicide) |
| Study registration | ISRCTN 41021444 |
| Sponsor | University of Oxford |
| Funder | HTA Programme, NIHR |
| Study Design | Three Stages:<br>1. Development of self-harm prediction tool for prisoners, using retrospective cohort design.<br>2. Qualitative study assessing acceptability of tool and barriers to implementation and using action learning processes to develop an implementation/operational pathway to for the tool.<br>3. Prospective cohort validation study assessing predictive ability of the risk assessment tool. |
| Study Participants | For stage 1: Records of prisoners who have been on an ACCT that closed within the last 18 months and remain in the establishment combined with further information from prison and medical records, including the ACCT documents themselves.<br>For stage 2: clinicians, prison staff and prisoners<br>For stage 3: Male and female prisoners, aged >18, who have been on an ACCT (risk assessment management plan) that has closed. |
| Sample Size | Stage 1: approx. 750 prisoners' records<br>Stage 2: action learning groups of up to 10 people.<br>Stage 3: to be guided by the results from Stage 1. Estimated sample size of >500 prisoners |
| Planned Study Period | Total study period: 01/02/2020 – 31/08/2023.<br>Individual participants for Stage 1 and 3 will not be required to attend interviews or follow-up. Data will be collected from previously/routinely collected information, for those in stage 3, with follow-up over 3 months. Participants in Stage 2 will be asked to attend action learning group meetings for 3 months. |

| Planned Recruitment period | December 2021 to July 2023 | | |
|---|---|---|---|
| | Objectives | Outcome Measures | Timepoint(s) |
| Primary | Create a risk assessment tool that will identify the risk of repeat self-harm within 3 months following an ACCT closure. | Details from self-harm (first episode) within 3 months of ACCT closure, collected from routinely recorded medical and case records. These will include age, index offence, duration of imprisonment, nature of current self-harm, medical diagnoses, medications, and the number and recency of prison transfers during the current prison stay, and whether self-harm and suicide risk information is routinely communicated between residential and healthcare departments. We will define self-harm to include any intentional self-poisoning or self-injury, irrespective of the degree of suicidal intent or underlying motive, which is used by the Her Majesty's Prison and Probation Service (HMPPS). | Closure of ACCT<br><br>3 months after closure of ACCT |
| Secondary | Assess the acceptability of the new risk prediction tool to relevant stakeholders (prisoners, clinicians, prison staff) and develop an operational/implementation pathway to embed the tool in practice. | Feedback from multi-agency action learning groups in prison establishments. | Monthly focus group meetings over a 3 month period. |
| | Evaluate the ability of the tool to predict further self-harm in a cohort of prisoners at the end of their ACCT. | Measures of discrimination (sensitivity, specificity, positive and negative predictive value, C-index) and calibration. | Closure of ACCT<br><br>3 months after closure of ACCT |
| Intervention(s) | None. The study concerns the development of a risk assessment tool. | | |
| Comparator | None | | |

## 4. ABBREVIATIONS

| | |
|---|---|
| ACCT | 'Assessment, Care in Custody and Teamwork': a suicide risk management plan currently used for prisoners. |
| CI | Chief Investigator |
| CRF | Case Report Form |
| GCP | Good Clinical Practice |
| HRA | Health Research Authority |
| ICF | Informed Consent Form |
| NHS | National Health Service |
| RES | Research Ethics Service |
| PI | Principal Investigator |
| PIL | Participant/ Patient Information Leaflet |
| R&D | NHS Trust R&D Department |
| RAT | Risk Assessment Tool |
| REC | Research Ethics Committee |
| RGEA | Research Governance Ethics and Assurance |
| SOP | Standard Operating Procedure |

## 5. BACKGROUND AND RATIONALE

**Self-harm in prisoners: characteristics and current management**

Rates of self-harm in prisoners are high in absolute and relative terms. In 2015-16, there were 34,586 reported incidents of self-harm in 10,012 prisoners, a 27% increase on the previous year. There were 26,805 incidents of self-harm in male prisoners, up 31% on the previous year, equating to a rate of 3,280/10,000 prisoners. In women, there were 7,781 incidents of self-harm (a rate of 20,340/10,000), up 13% on the previous year (MOJ, 2016). Over the same period, there were 2,455 hospital attendances as a result of self-harm incidents, equivalent to a rate substantially higher than in community-based persons (MHF, 2016). The latest figures show that in the year to December 2016, there were a record 40,161 incidents of self-harm, up 7,848 from the previous year, which represents a 24% rise, and a 73% increase between 2012 and 2016. At the same time self-inflicted deaths have also increased. In the 12 months to March 2017, there were 113 self-inflicted deaths in English and Welsh prisons. This equates to a rate of 1.3 self-inflicted deaths per 1000 prisoners which is double the rate recorded in 2013 (MoJ Safety in Custody Statistics).

Current practice in prisons for those that have suicidal ideation or have self-harmed is to place them on a suicide risk management plan, called an ACCT. Although this approach has proven effective in managing

the immediate risk (while the ACCT lasts), evidence suggest that the risk of self-harm (and suicide) is high in the few weeks after the closure of the ACCT. Recent research showed that 28% of prisoners self-harmed in the 6 months following closure of the ACCT document (Horton, 2014). A particular problem identified was the lack of a structured approach for the assessment of risk of recurrent self-harm on ACCT closure. Hence, devising a tool that can stratify risk after an ACCT is required.

As mentioned above, nearly one third of prisoners will go on to self-harm again within six months of the closure of their ACCT document (Horton 2014). This has significant implications for the criminal justice system and public health. Alongside the physical injuries arising from self-harming behaviour, the psychological distress of staff, prisoners, and their families also needs to be considered. This leads to additional resources being required to escort prisoners to hospital, increased referral rates to prison mental health inreach teams, and days off work for staff due to stress. All this impacts on the capacity of the prison to provide a stable environment and rehabilitative possibilities. If the research succeeds in developing an effective risk assessment tool that accurately predicts who remains at risk of further self-harming behaviour following the closure of their ACCT, there is the potential for significant resource savings for the criminal justice system as well as reducing distress for those involved. Future work can investigate how to link more accurate risk stratification into effective care pathways to improve risk management, and also by potentially screening out low risk persons, it may free up resources.

**Developing and implementing a risk assessment tool for repeat self-harm**

This project has three parts.

1. Development of a risk assessment tool which will aim to identify risk of repeat self-harm within 3 months following the closure of an ACCT. We will develop the tool using routinely collected information for reasons of feasibility and ease of translation. Following consensus guidelines for prognostic research, we will create a statistical model based on a pre-specified list of predictors based on previous evidence and new risk factors that will be tested in multivariable models. These factors will include socio-demographic, criminal history, and clinical ones, including those collected in the ACCT process, some of which are dynamic.
2. Qualitative study. We will then assess the acceptability of the new tool to relevant stakeholders (prisoners, clinicians and prison staff) based in two settings (one male and one female prison) and examine barriers to implementation. Using action learning processes, we will work with staff and prisoner groups over three months (via monthly sessions) to develop an implementation/operational pathway to embed the new tool within existing ACCT, post-ACCT procedures, and any other relevant processes.
3. Prospective study. When information from the qualitative study on feasibility and acceptability has been gathered, we will then conduct a validation study and prospectively test the tool's predictive ability in a cohort of prisoners at the end of their ACCTs.

Our target population includes male and female prisoners, aged 18 and over, who are held in category A to C prisons, who are placed on an ACCT document whilst in prison custody.

**Findings from previous studies and rationale for study design**

The most successful prognostic tools in medicine are those that are underpinned by the strongest empirical base, including large representative samples for their development and validation, transparent reporting of methods and results, and parsimonious models that can be easily introduced into practice (Siontis,

2015). Guidelines recommend pre-specifying risk factors for investigation, how variables will be characterised, and pre-determined thresholds so that a range of performance metrics can be reported (Collins, 2015). It is important to highlight the challenges of developing and validating such instruments without an adequate sample size (Peduzzi, 1996; Harrell, 1996). In mental health, one example is a scalable risk assessment tool for reoffending in released prisoners that was developed by two of the applicants. This was developed in around 30,000 prisoners and validated in more than 10,000 prisoners (Fazel, 2016). The tool is based on 14 routinely collected items, and performs as well as current approaches that can take many hours.

In the tool development, we plan to include risk factors based on research primarily in English and Welsh prisons (Marzano, 2016; Shaw, 2004; Humber, 2013): pre-existing mental and physical health problems, psychotropic medications, and specific questions from ACCTs on mental state, ongoing suicidal ideation, activities, whether problems identified at the start of an ACCT have been resolved in the post-closure review (which typically occurs one week after an ACCT is closed), and whether self-harm and suicide risk information is routinely communicated between residential and healthcare departments.

The qualitative aspect of the proposed study is integral since it will highlight challenges and barriers in the implementation of the tool and consider how to overcome them. It will be based on research creating service models for the delivery of healthcare interventions in non-health settings, including a health and social care planning tool for older prisoners that some of the co-applicants developed (Walsh, 2014). Additionally, it is informed by research in other settings where tools have been created but not embedded into practice without clear pathways following different risk scores or categories.

## 6. OBJECTIVES AND OUTCOME MEASURES

| **Objectives** | **Outcome Measures** | **Timepoint(s) of evaluation of this outcome measure (if applicable)** |
|---|---|---|
| **Primary Objective**<br>To create a risk assessment tool that will identify the risk of repeat self-harm within 3 months following an ACCT closure. | Details from self-harm (first episode) within 3 months of ACCT closure, collected from routinely recorded medical and case records. These will include age, index offence, duration of imprisonment, nature of current self-harm, medical diagnoses, medications, and the number and recency of prison transfers during the current prison stay and whether self-harm and suicide risk information is routinely communicated between residential and healthcare departments. | Point of ACCT closure<br><br>3 months post-ACCT closure |

| | | |
|---|---|---|
| | We will define self-harm to include any intentional self-poisoning or self-injury, irrespective of the degree of suicidal intent or underlying motive, which is used by the Her Majesty's Prison and Probation Service (HMPPS). | |
| **Secondary Objectives**<br>Assess the acceptability of the new risk prediction tool to relevant stakeholders (prisoners, clinicians, prison staff) and develop an operational/implementation pathway to embed the tool in practice. | Feedback from multi-agency action learning groups in prison establishments. | Monthly focus group meetings over a 3 month period. |
| To prospectively evaluate the risk assessment tool's ability to predict risk of further self-harm (and suicide) in a cohort of prisoners at the end of their ACCTs. | Measures of discrimination (sensitivity, specificity, positive and negative predictive value, C-index) and calibration (calibration slope and intercept) for the tool in predicting self-harm within 3 months of ACCT closure. | Closure of ACCT<br>Post-closure ACCT review<br>3 months after closure of ACCT |

## 7. STUDY DESIGN

**Overview**

The proposed research comprises 3 stages: i. Development of a risk assessment tool, ii. Qualitative research to assess acceptability to prisoners, clinicians and the prison service, and barriers to implementation, iii. A prospective cohort study to evaluate the predictive performance of the tool.

In the first part of the study a retrospective cohort will be used to develop the risk assessment tool. We intend to develop the risk assessment tool (RAT) through the analysis of the records of a minimum of 750 prisoners who have had an ACCT closed in the previous 18 months. We will need to extract information from routine medical and prison records, as well as from the ACCT documents themselves for the development of the new RAT. We intend to develop a tool that will identify the risk of repeat self-harm within three months post-closure of any ACCT document.

The second part of the project is qualitative. This will assess the acceptability of the new tool to prisoners, clinicians, and prison staff, and examine barriers to implementation across the prison estate. This stage will use action learning processes. We will work with prison staff and prisoners to develop an operational pathway that embeds the RAT within existing ACCT procedures. Importantly it will develop a pathway for how the scores from the RAT should be used in practice. We will work with staff and prisoner groups over three months (via monthly sessions and face to face sessions) to develop an implementation/operational

pathway to embed the new tool within existing ACCT, post-ACCT procedures, and any other relevant health and social care support processes using action learning processes.

The third part of the study will involve prospectively testing the tool's predictive ability in a cohort of prisoners at the end of their ACCT processes. This will involve a separate, multi-centre, prospective cohort study. The sample size will be guided by the results from the development of the RAT, although we have estimated that we will need to administer the tool to more than 500 prisoners. The records of identified prisoners will be used; the RAT will be administered, and its performance compared at two points, when the ACCT is closed, and at the post-closure ACCT reviews (to test additional dynamic factors). Self-harm episodes (and suicide) will be identified for these prisoners in the 3-month period following closure.

**Study settings:**

The settings are prisons and university sites. In the first part of the study the RAT will be developed through the analysis of ACCT documents, medical records, and prison records. ACCT documents and healthcare and prison data extraction will primarily be undertaken in selected northern England prison establishments or via remote access. Selection will partly be down to pragmatic reasons; proximity to the researchers who will be based in Manchester and the Northeast of England, and those where the ACCT turnover is high enough to reach our required sample size in the time permitted in stage 1 (guided by statistics on ACCT levels provided by HMPPS). Data will be transferred securely to the Nuffield Department of Primary Care Health Sciences in Oxford (where the PI and statistical lead are based) for analysis and development of the RAT.

The second part of the project is qualitative in nature. This part of the study will be conducted by the Manchester and Durham co-applicants in select male and female prison establishments and involve monthly action learning groups held at the respective establishments over a three month period.

The third part of the study will involve prospectively testing the tool's predictive ability in a cohort of prisoners at the end of their ACCTs. We will sample prisoners who have closed ACCTs from a national sample of prisons, including women and men, remand and sentenced prisoners, all of whom will be aged 18 and over.

**Data collection**

For stage 1 we intend to collect data on a range of static and dynamic variables in developing the RAT. Data will be collected either one of two ways; the first option will be conducted in person by the researcher and involve a paper review of a selection of the ACCT documents, and electronic health records held inside the prisons, and NOMIS prison records. The second option will involve extracting data remotely with the support of a link person based at each prison. A list of prisoners who have had an ACCT closed within the previous 18 months of our census date will be generated by the identified link person. The link person at each site will arrange secure transfer, with remote support from the researcher, of unredacted ACCT documents to the researcher via a pre-approved secure courier service.

The researcher will extract the necessary data and record on a university of Manchester encrypted laptop, and in line with our original methodology the pseudo-anonymisation key will be held by the University of Manchester. Once the data has been extracted, the researcher will arrange for the ACCT documents to be returned to each respective establishment via the pre-approved secure courier service.

*For access to Prison-NOMIS data:*

The researcher will access NOMIS data one of two ways; the first option will be conducted in person by the researcher at the respective prison establishment, or, centrally via remote access. The data extracted will be securely stored on the researcher's University of Manchester encrypted laptop.

*For access to SystmOne data:*

Researchers will extract data from prison healthcare notes (SystmOne). Using the PIN, the researcher will locate the prisoner's healthcare notes on SystmOne remotely. Remote access to SystmOne will be facilitated by an identified host healthcare provider and will be accessed via a VPN.

For stage 2, monthly focus groups held either remotely, or in person over three months will be used to collect qualitative data on prisoner, clinician and prison staff views on important implementation and operational issues relating to the acceptability of the new tool. Data will be collected using an encrypted Dictaphone which will be sent to a University of Oxford Information Security Team (InfoSec) approved transcription service, Accuro Transcription Solutions Limited. A confidentiality agreement will be put in place and a secure file transfer system will be used.

For stage 3 a consecutive sample of prisoners who have had ACCTs closed a minimum of 3 months previously will be asked for consent, and then their ACCT documents and post-closure ACCT reviews used to score the RAT (independently of the prison staff and clinical teams). All self-harm episodes in the 3 months post-closure will be identified from central Safer Custody statistics (so that any prison transfers are accounted for). There will be no face-to-face interviews with individual prisoners as information for the tool will be collected from electronic records and ACCT documents already completed.

Further details on data collection are contained in section 12.3

## 8. PARTICIPANT IDENTIFICATION

### 8.1. Study Participants

For stages 1 and 3 the target population is prisoners placed on an ACCT document whilst in prison custody. The ACCT document, currently in version 6, is a series of forms held together in a folder. It is 'opened' by staff working in prisons in response to concerns that an individual prisoner is at risk of self-harm or suicide. There are several documents which make up an ACCT record; a 'CareMap Form' is completed in which a series of actions are considered to reduce the risk of harm occurring. An 'On-Going Record Form' records the conversations and observations of the person at risk. ACCT documents are 'closed' when an individual is no longer considered 'at risk'. The ACCT document is then typically held in a post-closure state for seven days during which it can be re-opened if further concerns arise, and a post-closure form is assessment is completed typically after 7 days. Due to a change from Version 5 to Version 6 of the ACCT document, we expect that some of our sample may be drawn from the version 5 document, as well as the current version 6. Our target population includes male and female prisoners, aged 18 and over, who are held in category A to C prisons. For stage 1 it is only the records relating to the prisoners that will be included with section

251 support for review without consent; for stage 3 the prisoners themselves will be recruited to provide informed consent; thereafter only their records will be accessed.

For stage 2: participants for qualitative research will be prison staff from safer custody, operational or managerial staff with experience of the ACCT, mental health healthcare staff; prisoners and peer supporters; and a range of other concerned individuals (carers, chaplaincy).

### 8.2. Inclusion Criteria

*For stage 1, paper and electronic records from prisoners with the following characteristics:*

- Male and female adult prisoners (age 18 years old and above).
- Have been on an ACCT which was closed within the previous 18 months and remain in the establishment at the point of data collection.
- Prison categories A to C.

*For stage 2*:

- Prison staff from safer custody, operational or managerial staff with experience of the ACCT, mental health healthcare staff; prisoners and peer supporters (e.g., listeners); and a range of other concerned individuals (carers, chaplaincy) that are willing to participate in monthly meetings of the action learning group.
- Prisoner representatives should have at least three months to serve so that they can attend and contribute to meetings.
- Good understanding of English (either native of second language)
- Willing and able to consent to take part in the study.

For stage *3:*

- Male and female adult prisoners (age 18 years old and above).
- Have been on an ACCT that was closed a minimum of 3 months previously.
- Prison categories A to C.
- Good understanding of English (either native of second language).
- Willing and able to consent to participate in the study.

### 8.3. Exclusion Criteria

Stage 1: It is not uncommon for an individual to have several ACCTs opened and closed in a short period of time. If we have already collected data on an individual and they are identified for inclusion again, they should be excluded only if this occurs within the 3 month follow-up period (on the advice of our statistician).

Stage 2: If an action learning group is over-subscribed, we will cap the group size at 10 and accept members on a ‘first come, first served’ basis.

## 9. PROTOCOL PROCEDURES

### 9.1. Recruitment

*Stage 1: Development of Risk Assessment Tool*. The RAT will be developed through the analysis of the records of prisoners who have had an ACCT closed in the previous 18 months and remain in the establishment at select prisons in the North of England. Where possible, researchers will work chronologically backward to collect the most recent data. We intend to collect data on a range of static and dynamic variables, see section 12.3, in developing the RAT through a paper review of the closed ACCT documents and SystmOne medical records and electronic prison records. Since this will be done without consent under section 251 support, an article in the Inside Times prison newspaper and posters in the select prison sites will be used to raise awareness of the research and provide channels for opting out.

*Stage 2: Qualitative study.* This part of the study will be conducted by the Manchester and Durham co-applicants in two-six prisons (four male; and two female prisons) and involve monthly action learning groups held remotely and within the prisons. Sites will be identified during stage 1 and will likely be prisons where the Manchester and Durham teams have experience of conducting research. The team will convene two stakeholder action learning groups (one male, one female) in each prison which will involve prisoners and peer supporters (e.g., Listeners). Up to two further action learning groups will be held virtually which will include prison and healthcare representatives from up to six prisons (four male, two female). Over three months, each group will convene monthly to address a particular aspect of implementation – e.g., training needs, defining the roles of each professional/peer withing the process, timing of administration, and processes for instigating support based on RAT scores. Each group member will canvass opinions from their peers to bring a consensus view to meetings.

The project will be advertised in prison via posters and through recommendations from staff members. If an individual expresses interest/is identified through staff, they will be approached by an identified point of contact and provided with an information sheet. If they give permission, they will be approached by the Manchester-based research team to provide and explain the information sheet.

Recruitment for staff will primarily be through the Safer Custody team, any staff member who expresses interest will be approached by the Manchester-based research team to provide and explain the information sheet. All participants will be given a minimum of 24 hours to consider, and consent will be obtained before the start of the first group; either on a separate study visit prior to the group commencing, or in a separate location to the group room on the day of a group session.

*Stage 3: Prospective Study.* We will recruit from a variety of Category A to C prisons from sample of prisons across England. We will not be interviewing prisoners. Our data will be extracted from the ACCT documents of prisoners that have been on an ACCT, which will be supplemented by information from medical and case files. A consecutive sample of prisoners who have had ACCTs closed a minimum of 3 months previously will be asked for consent, and then (following closure) their ACCT documents and post-closure ACCT reviews used to score the RAT (independently of the prison staff and clinical teams). All self-harm episodes in the 3 months post-closure will be identified from central Safer Custody statistics (so that any prison transfers are accounted for). We anticipate that this part of the study will require the Researchers to have access to the prison sites for 9 months each.

Prisoners who fit the inclusion criteria will be identified through the safer custody team (i.e. provide a list of suitable candidates) and will be initially approached by prison healthcare for permission to be approached by researchers. Researchers will attend on site over several days to provide additional information to those identified, allowing them time to consider (minimum 24 hours) before returning to obtain informed consent.

### 9.2. Screening and Eligibility Assessment

No screening procedure will be done (and the study is not a trial). Potential participants will have their notes reviewed for eligibility.

### 9.3. Informed Consent

Section 251 approval is being sought for stage 1 to extract data from ACCT documents, medical records and prison records. As the nature of stage 1 is developing a risk assessment tool, it is important that it includes the whole intended population. Seeking informed consent at this stage could introduce a bias to the sample given the sensitive nature of the topic (i.e. there may be some shared characteristics of those who choose not to consent). Section 251 approval would support equivalence between the study population in stage 1 and the intended population to which the tool would apply. Section 9.9 provides further details on how we will advertise through multiple channels that we are conducting the research in the specified sites, as well as providing ample opportunity for any prisoners wishing to opt-out.

For the stages 2 and 3 consent will be sought; the participant must personally sign and date the latest approved version of the Informed Consent form before any study specific activities are undertaken.

Written and verbal versions of the Participant Information and Informed Consent will be presented to the participants detailing no less than: the exact nature of the study; what it will involve for the participant; the implications and constraints of the protocol; any risks involved in taking part. It will be clearly stated that the participant is free to withdraw from the study at any time for any reason without prejudice to future care, and with no obligation to give the reason for withdrawal.

The participant will be allowed as much time as wished to consider the information (minimum 24 hours), and the opportunity to question the Investigator, their GP (where relevant) or other independent parties to decide whether they will participate in the study. Written Informed Consent will then be obtained by means of participant dated signature and dated signature of the person who presented and obtained the Informed Consent. The person who obtained the consent must be suitably qualified and experienced and have been authorised to do so by the Chief/Principal Investigator. A copy of the signed Informed Consent form will be given to the participant. The original signed form will be retained at the study site.

Specific differences between the two stages in relation to consent are outlined below.

In stage 2, participants are consenting to participate in audio recorded groups, which will be subsequently transcribed and used to inform development of the tool.

In stage 3, a consecutive sample of prisoners who have had ACCTs closed a minimum of 3 months previously will be asked for consent for the research team to access and extract data from their ACCT forms, medical and case records, and prison data.

### 9.4. Randomisation

This study does not involve randomisation.

### 9.5. Blinding and code-breaking

There is no blinding in this study, and no code breaking procedure is required.

### 9.6. Description of study intervention(s), comparators and study procedures (clinical)

There is no study intervention or comparator.

The aim of the study is to develop a risk assessment tool that will assess the risk of repeat self-harm within 3 months post-closure of any ACCT document. We will define self-harm to include any intentional self-poisoning or self-injury, irrespective of the degree of suicidal intent or underlying motive, which is used by the Prison Service. At the first stage of our proposed project, we will be developing the risk assessment tool from routinely collected information. At stage 2, we will be accessing the acceptability of the tool to prisoners, clinicians, and the prison service, and evaluating barriers to implementation. Throughout the development and evaluation (stage 3) of this risk assessment tool, we will be consulting with our advisory group that consists of the co-applicants, the PPI group (prisoners and family) and representatives of the prison service (Safer Custody, NOMS).

### 9.7. Study Visits and Data Collection

In Stage 1 we will not be interviewing prisoners. Our data will be extracted from the ACCT documents of prisoners that have been on an ACCT, which will be supplemented by information from medical and case files. Further information on the data points being collected is in section 12.3.

Stage 2 is a qualitative study using action learning processes. In one male and one female prison we will convene an action learning group with prisoners. Additionally, we will conduct two action learning groups remotely with staff members from up to six prisons. Over three months, each group will convene monthly to address a particular aspect of implementation - for example, training needs, defining the roles of each professional/peer within the process, timing of administration and processes for instigating support based on results of the tool. Researchers from the University of Manchester will conduct the groups, with co-applicant TW assisting with set-up and attending as a minimum, the first and last group. Groups will be audio-recorded on an encrypted device and transcribed by an approved external transcription service.

For Stage 3, the single point of contact with prisoners will be attaining informed consent for use of routinely collected information in this study. Our data will be extracted from the ACCT documents of prisoners that have been on an ACCT which will be supplemented by information from medical and case files. Data will be collected from the point of the ACCT closure, post-closure review, and all self-harm episodes in the subsequent 3 months will be identified from central Safer Custody statistics (so that any prison transfers are accounted for). Further information on the data points being collected in is section 12.3.

### 9.8. Sample Handling

No samples will be taken

### 9.9. Early Discontinuation/Withdrawal of Participants

Stage 1: Participants may become aware of the research through the Inside Times article or posters within the prison. Any prisoner who makes contact through the advertised channel can request to opt-out of the research and a note will be made to ensure their records are not accessed in the development of the tool. If their records have already been accessed, a researcher will ensure this is permanently deleted from the dataset on site at their next visit, therefore withdrawal from stage 1 will be possible at any point during the data collection period, where identifiable data is still stored securely within the establishment. After this point, identifiers are removed for a pseudonymised dataset to be sent to the statistician. Withdrawal at this stage will still be possible if requested, as a researcher in Manchester can access the pseudonymisation key to re-identify the person wishing to dissent and remove their data.

Stage 2: Participants wishing to withdraw at any point from the action learning groups can do so through the channels specified on the information sheets. Those who withdraw will not be invited to subsequent focus groups. We will not offer destruction of already collected data as it is important to retain discussion contributions for flow and context of transcripts, however, identifiable data will not be retained.

Stage 3: Participants wishing to withdraw at any point can do so through the channels specified on the information sheets. A pseudonymisation key will be securely stored at the University of Manchester to allow participants to change their minds at a later date should they wish to; study IDs will be used to re-identify the case and remove all records.

### 9.10. Definition of End of Study

The end of the study will be six months after recruitment of last prisoner for stage 3 of the study.

## 10. SAFETY REPORTING

This study involves observational analysis of routinely collected information and feedback from focus groups. There will be no change to standard care for participants and the study does not involve any interventions or clinical investigations. Therefore, we do not anticipate any adverse events and safety recording is not applicable.

## 11. STATISTICS AND ANALYSIS

### 11.1. Statistical Analysis Plan (SAP)

The plan for the statistical analysis of the study are outlined below. There is not a separate SAP document in use for the trial.

## 11.2. Description of the Statistical Methods

Details of data collection and independent variables are given in section 12

**Development of Risk Assessment Tool:**

We will create a statistical model to predict repeat self-harm based on a pre-specified list of predictors. These will include a core set based on face validity, population-based studies of self-harm in England and Wales (Hawton, 2014), systematic reviews (Fazel, 2009), and other factors if they are shown to improve the predictive performance of the multivariable model. We will pre-specify categories for low, medium, and high risk of self-harm recurrence to inform ways in which model predictions could be used in practice. We will follow the latest guidelines for prognostic research (Collins, 2015).

We will use time-to-event models to estimate the probability of an episode of self-harm following ACCT closure. Specifically, we will investigate using hazard rate model to allow for possible time-varying effects of dynamic risk factors (Thomas and Reyes, 2014). Risk estimates will be available at time of ACCT closure and subsequently. At the time of the post-ACCT interview (expected to occur between one week and one month after ACCT closure), additional dynamic variables will become available that may affect risk estimates even if not sufficient to trigger a new ACCT. We will therefore adapt our risk prediction model at the time of post-ACCT interview using model extension methods to incorporate additional covariates (Steyerberg, 2009, Chapter 20.2). Risk information will be presented numerically in the form of a probability of a self-harm episode within a fixed period of follow-up following closure of ACCT and following post-ACCT interview, and in relation to a probability threshold indicative of high risk (to be prespecified as part of the research project). Probabilities will also be expressed conditional on the length of the post-ACCT period that has already elapsed, to allow for the likely non-linear decline in risk over time, the initial 30 days after ACCT closure being a particular high-risk period for self-harm (Horton et al., 2014). This will also enable for the risk model to be used dynamically over time. Development of the RAT will use multiple imputation for missing risk factors and incorporate measures of internal validation to prevent model over-fitting, methodology we have implemented in previous work (e.g. Fazel et al., 2016).

**Qualitative Study**

Action Research principles involve the use of cycles of planning, observing, acting and reflecting to think through a problem and offer practical and implementable solutions (Zuber Skerritt, 2001, 2002). Members of the current team (JS, JJS, TW) have successfully used action learning in previous criminal justice system research as a tool for understanding and improving professional practice (Noga, 2016), including the development of an assessment/referral mental health pathway in police custody and a multi-disciplinary care planning tool for older prisoners. The action learning methodology has been considered a useful tool for encouraging multi-agency staff to critically reflect on their own service and on their working relationships with partner agencies (Ball, 2013; Dixon, 1998). We will aim to use multi-agency action learning groups to enable individuals in prison establishments, both professionals and peers (as well as the organisation itself), to learn from each other and develop more effective, practical solutions to the challenge of prediction of recurrent self-harm behaviours.

**Prospective Study:**

Our approach to prospectively assessing the performance of the tool will follow previously published guidelines (Royston and Altman, 2013, Su et al., 2016). The RAT will be administered, and its performance compared at two points – when the ACCT is closed and also at the post-closure ACCT reviews (to test

additional dynamic factors) - by researchers working independently from the ACCT team so that its performance will not be affected by changes to the management of prisoners based on the tool's score.

Individual-level diagnostic performance of the tool (without adjustment of the model coefficients for the new population) will be summarised at 3 months post-ACCT closure using measures of calibration and discrimination including sensitivity, specificity, the cindex, and the calibration slope and intercept. Missing predictors will be imputed using multiple imputation. We will follow published guidance on reporting validation study results (the TRIPOD checklist: http://www.tripod-statement.org/TRIPOD/TRIPOD-Checklist). As data will be already collected as part of routine ACCT processes and medical records, a separate reliability study is not envisaged.

### 11.3. Sample Size Determination

Stage 1: in order to develop a tool with adequate statistical power, we estimate that 10 'events' (or new self-harm episodes in the 3 months post-ACCT) will be required per predictor variable (Peduzzi et al., 1996), and we anticipate testing 15 predictors for possible inclusion in the tool (a total of 150 events). We estimate requiring 150 new self-harm episodes in the 3 months post-ACCT. Assuming a self-harm rate of 20% in the 3 months post-ACCT closure, we anticipate needing information on 750 prisoners who have closed ACCTs for the development of the tool. Sites will be selected with this sample sized in mind, targeting prisons with a high turnover of ACCT documents, based on statistics from HMPPS. The data will be extracted from ACCT documents, SystmOne medical records and prison core records.

Stage 2: Guidelines suggest that a group size of 4-8 is sufficient for rich discussion, allowing for enough breadth of role and experience without the limiting of individual contribution that sometimes comes in larger groups (Kreuger and Casey, 2002; Kitzinger, 2013). This should allow for the groups to contain all three target groups (clinicians, prison staff and prisoners).

Stage 3: Sample size estimates for the prospective study are likely to depend on the performance of the risk assessment tool during model development. A formal assessment of sample size requirements will therefore be made after this phase is complete; however, some indication can be given at this stage. A simulation study recommended ballpark minimum figures of 100 events for validating a clinical prediction rule derived using a logistic regression model (Vergouwe et al., 2005). This conclusion was broadly supported by another, more recent, simulation study (Collins et al., 2016). The factor that influences power is the number of self-harm episodes, rather than the total sample size. We therefore anticipate including enough individuals to obtain a minimum of 100 self-harm episodes to adequately assess the performance of the risk assessment tool prospectively. Assuming the same self-harm rate of 20% in the 3 months post-ACCT closure, this equates to a minimum of 500 prisoners who have closed ACCTs. The total sample size will be adjusted downwards should the self-harm rate be found to be higher than 20%. In the event that the self-harm rate is lower than expected (assuming as low as 10% in the 3 months post-ACCT closure), this would equate to a maximum of 1,000 prisoners with closed ACCTs.

### 11.4. Analysis populations

All participants will be used in analysis, we will use multiple imputation to address missing data. We do not anticipate participant withdrawal as the study involves use of routinely and previously collected data and there is one point of contact with participants to seek consent.

### 11.5. Decision points

Analysis will be performed during stage 1 and 2 which will inform specifics of study design for stage 3 (for example a formal sample size calculation for stage 3 will depend on the results of stage 1). Details are described in section 11.3. The CI will provide oversight of this process.

### 11.6. Stopping rules

Not applicable as this is not an interventional study.

### 11.7. The Level of Statistical Significance

Statistical analysis will be carried out in accordance with the pre-specified protocol described in section 11.2. We will follow published guidance on reporting validation study results (the TRIPOD checklist: http://www.tripod-statement.org/TRIPOD/TRIPOD-Checklist) and report a range of variables related to our risk assessment tool.

### 11.8. Procedure for Accounting for Missing, Unused, and Spurious Data.

Stage 1 and 3: Development of the RAT and the prospective study will use multiple imputation for missing risk factors.

### 11.9. Procedures for Reporting any Deviation(s) from the Original Statistical Plan

This will be discussed with the project management team, documented and reported in subsequent publications.

### 11.10. Health Economics Analysis

Not applicable, this study does not involve health economic analysis.

## 12. DATA MANAGEMENT

The plan for the data management of the study is outlined below. In addition to this, a Data Transfer Agreement (DTA) will exist between the Universities of York, Manchester and Oxford to cover the transfer of data from collection sites to university storage. Additionally, where necessary other appropriate agreements between relevant parties will be arranged.

### 12.1. Source Data

Source documents are where data are first recorded, from which participant data will be obtained. For stage one and three, these include ACCT documents, (e.g. CareMap forms, Ongoing Record Forms, post-closure forms), medical records and prison case files. For stage 2, this will include transcripts from focus group sessions. All documents will be stored safely in confidential conditions.

### 12.2. Access to Data

Direct access will be granted to authorised representatives from the Sponsor and host institutions for monitoring and/or audit of the study to ensure compliance with regulations.

### 12.3. Data Recording and Record Keeping

**Data collection**

Stage 1: The RAT will be developed through the analysis of ACCT documents, SystmOne medical records and electronic prison records. We intend to collect data on a range of static and dynamic variables in developing the RAT. The static variables include age, index offence, duration of imprisonment, nature of current self-harm, medical diagnoses, medications, and the number and recency of prison transfers during the current prison stay. Regarding healthcare information, medications may act as a proxy for diagnosis or severity but will be assessed carefully due to the increased risk of medication diversion in prison and off label prescription. Data will also be extracted to establish whether details of the respective ACCT are detailed in SystmOne notes.

Dynamic variables will include the length of time that a prisoner was on an ACCT document; the case reviewer's score of the patient's risk after specified reviews (low, medium, or high); how many ACCT reviews were held; and the reason the ACCT document was initially opened (contained in the Concern and Keep Safe Form). The latter will be compared with the Post Closure Review form that has an item asking whether the problems leading to the opening of the ACCT have been resolved. We will also look at whether the individual has been referred and seen by mental health services during the ACCT process by examining SystmOne medical records. There are dynamic variables in the Post Closure Form but these are not collected earlier in the ACCT process in a structured manner and hence it is not possible to know if they have changed during the process. This also applies to the CAREMAP Form, part of the ACCT document, which includes information on the problems, resources, goals, and level of risk. Based on preliminary discussions with prison officers, dynamic variables that typically are addressed in this form include family support, financial problems (including debts to other inmates), immigration issues, and the prisoner's mental health, but it remains unclear whether there is a structured and reliable way to investigate them for the purposes of this study. Nevertheless, we will investigate the possibility of using these variables by looking at a small subsample of ACCTs and seeing if this information is reliably collected in a form that can be used for tool development.

Researchers will either attend establishments or remotely access information from ACCT documents, prison records and healthcare records. On the basis the researcher visits the prison in person, data will be inputted into a database on a University of Manchester encrypted laptop which will contain the prison unique identifier (prison number) and an associated study ID. A researcher will physically look through a hard copy of the ACCT document and will electronically search SystmOne for healthcare records. For prison records, it has been requested that researchers are granted direct access to NOMIS (electronic prisoner database). The dataset used by the researchers will remain electronically stored and password protected at each establishment for the duration of the data collection period in that prison.

In the instance we need to access prison and healthcare data remotely a link person at each prison will identify eligible ACCT records from the ACCT database, which is held in safer custody. Subsequently ACCT documents selected will be sent to the researcher via secure courier. The researcher will extract the necessary data and record on a university of Manchester encrypted laptop and in line with our original methodology the pseudo-anonymisation key will be held by the University of Manchester. All ACCT

documents will be securely stored when not in use. Once the data has been extracted, the researcher will arrange for ACCT documents to be returned to each respective establishment via secure courier.

*For access to SystmOne data:*

Researchers will extract data from prison healthcare notes (SystmOne). Using the PIN, the researcher will locate the prisoner's healthcare notes on SystmOne remotely. Remote access to SystmOne will be facilitated by an identified host healthcare provider and will be accessed via a VPN.

*For access to Prison-NOMIS data:*

The researcher will access NOMIS data centrally. The data extracted will be securely stored on the researcher's University of Manchester encrypted laptop.

Following this, identifiers will be removed and the pseudonymised dataset will be transferred securely to the Nuffield Department of Primary Care Health Sciences in Oxford (where the PI and statistical lead are based) for analysis and development of the RAT. We anticipate that the data extraction and linkage will require two FTE trained Research Assistants (based in the North of England) and one in Oxford (to do the analyses).

Stage 2: Monthly focus groups will be facilitated either virtually, or in person. Those groups conducted in person will be recorded using an encrypted Dictaphone and permission will be sought from each establishment to bring in. Audio files will be securely transferred to a university approved company (Accuro Transcription Solutions Limited) for transcription. Those groups conducted virtually will be recorded using the virtual software available.

Stage 3: A consecutive sample of prisoners who have had an ACCT closed at least 3 months previous will be asked for consent, and then their ACCT documents and post-closure ACCT reviews used to score the RAT (independently of the prison staff and clinical teams). All self-harm episodes in the 3 months post-closure will be identified from central Safer Custody statistics (so that any prison transfers are accounted for). We anticipate that this part of the study will require the Research Assistants to have access to the prison sites for 9 months each. These data will be transferred to Oxford for analysis.

## 13. QUALITY ASSURANCE PROCEDURES

The study will be monitored, or audited in accordance with the current approved protocol, relevant regulations and standard operating procedures.

### 13.1. Risk assessment

For Part 1 the risks are minimal as there is no direct contact with prisoners. This part involves reviewing of prisoner records. In the rare case that a RA feels upset due to reading records about self-harming incidents, this will be addressed in supervision. All RA supervisors are clinical academics, with experience in working in prisons, experience working with populations that self-harm and experience in supervising. They will address the issue in supervision at first and refer to occupational health if the issue persists or severity is such that indicates need for professional help.

While Part 1 does not involve direct contact with prisoners, and therefore presents no direct risk to them, we will follow relevant data protection procedures and confidentiality practices in order to look after the data being collected.

Parts 2 and 3 involve contact with prisoners and prison attendance. We will ensure all meetings occur in healthcare or prison boardrooms rather than the wings so that risks are minimised. All prison establishments have zero tolerance to violence and this will be part of each meeting's agenda, as a reminder. If any of the participants has presented with risks in the days prior to the meeting, they will be risk assessed and if needed notified that they will be excused from the meeting.

There are minimal risks for participants in the group meetings; they will be reminded at the start of the limits of confidentiality (as laid out in the information sheets) and staff will be on hand to ensure the safety of all participants. While we ask participants to be open with their comments in the group meetings, they will only share what they are comfortable with sharing. If anyone shows signs of distress then the researchers will ensure their wellbeing before proceeding, giving them the option of withdrawing if needed.

As with Part 1, researchers will treat the data being collected from participant's records with the upmost care. During the consent process for prisoners to Part 3 of the research, we will remind participants of the limits of confidentiality (as per the information sheet) and prison staff will be on hand to ensure the safety of everyone there.

### 13.2. Study monitoring

No GCP monitoring will be undertaken as this is an observational study and not a trial, and no interventions will be made on participants.

To check reliability of data extracted from paper files, we will extract a subset of 20 files by two people (one of them the research assistant and the other co-applicant AP).

### 13.3. Study Committees

A Study Management Group consists of the co-applicants and meets every 6 months.

An external advisory committee has been formed and has met once (and intends to meet every 12 months) made up of Dr Tim Amos (chair), Dr Nigel Eastwood, Dr Amanda Taylor, Lucy French, Jake Shaw and Dr Huw Stone.

The CI (SF) will be responsible for the overall Project Management, with some responsibilities being delegated to co-applicants. The CI will be responsible for the research governance, organising and facilitating advisory group meetings. The CI will monitor progress and achievement of milestones. The CI and co-applicants involved will be in monthly contact via meetings, teleconferences, and email. For stages 1 and 3, Jenny Shaw and Jane Senior will coordinate the development of the RAT and validation study. TW will supervise the qualitative part (stage 2).

## 14. PROTOCOL DEVIATIONS

A study related deviation is a departure from the ethically approved study protocol or other study document or process (e.g. consent process or administration of study intervention) or from Good Clinical Practice (GCP) or any applicable regulatory requirements. Any deviations from the protocol will be documented in a protocol deviation form and filed in the study master file.

Any delays or change of plans will be discussed with the research team at first and subsequently brought to the advisory group meetings prior to notifying the NIHR. The CI will arrange an introductory meeting with the team, which will allow for agreed allocation of tasks and timelines.

## 15. SERIOUS BREACHES

A "serious breach" is a breach of the protocol or of the conditions or principles of Good Clinical Practice which is likely to affect to a significant degree –

(a) the safety or physical or mental integrity of the trial subjects; or

(b) the scientific value of the research.

In the event that a serious breach is suspected the Sponsor must be contacted within 1 working day. In collaboration with the C.I., the serious breach will be reviewed by the Sponsor and, if appropriate, the Sponsor will report it to the approving REC committee and the relevant NHS host organisation within seven calendar days.

## 16. ETHICAL AND REGULATORY CONSIDERATIONS

### 16.1. Declaration of Helsinki

The Investigator will ensure that this study is conducted in accordance with the principles of the Declaration of Helsinki.

### 16.2. Guidelines for Good Clinical Practice

The Investigator will ensure that this study is conducted in accordance with relevant regulations and with Good Clinical Practice.

### 16.3. Approvals

Following Sponsor approval, the protocol, informed consent form, participant information sheet will be submitted to an appropriate Research Ethics Committee (REC), HRA (where required) and HMPPS National Research Committee. For stage 1 section 251 support will be sought. Additionally, the research team will request written approval from host institutions.

The Investigator will submit and, where necessary, obtain approval from the above parties for all substantial amendments to the original approved documents.

### 16.4. Other Ethical Considerations

An additional ethical consideration for stage 3 is whether the scores from the RAT will be shared with the care team. The decision not to inform the care team is influenced by two main factors; firstly, the tool will not yet be validated at this stage so it would be inappropriate to use any scores to inform prisoner care. Secondly, in order to collect data on self-harm incidents in the follow-up period, we will wait until 3 months post-closure to collect the data, after which point the period for which the tool assesses risk will have passed.

### 16.5. Reporting

The CI shall submit once a year throughout the study, or on request, an Annual Progress report to the REC Committee, HRA (where required) host organisation, Sponsor and funder (where required). In addition, an End of Study notification and final report will be submitted to the same parties.

### 16.6. Transparency in Research

The study is registered on ISRCTN, number 41021444.

### 16.7. Participant Confidentiality

The study will comply with the General Data Protection Regulation (GDPR) and Data Protection Act 2018, which require data to be de-identified as soon as it is practical to do so. The processing of the personal data of participants will be minimised by making use of a unique participant study number only on all study documents and any electronic database(s). All documents will be stored securely and only accessible by study staff and authorised personnel. The study staff will safeguard the privacy of participants' personal data.

For Stages 2 and 3 where consent forms will be collected, these will be transferred from the prison to the University using a locked bag, with signed witnesses at both the establishment and on return to the University to evidence compliant transfer of documents.

### 16.8. Expenses and Benefits

Not applicable. All participants are assessed at baseline in their prisons.

## 17. FINANCE AND INSURANCE

### 17.1. Funding

HTA funded, project reference 16/159/09.

### 17.2. Insurance

The University has a specialist insurance policy in place which would operate in the event of any participant suffering harm as a result of their involvement in the research (Newline Underwriting Management Ltd, at Lloyd's of London).

### 17.3. Contractual arrangements

Appropriate contractual arrangements will be put in place with all third parties.

## 18. PUBLICATION POLICY

We are planning to publish two journal articles – one on the qualitative study, and one based on the development and validation of the tool. We have included open access costs in our application so that our findings are accessible to criminal justice (who will not have academic journal subscriptions). We intend to make conference presentations at one prison health conference and one suicide research meeting so that the findings are disseminated to individuals and organizations involved in prison health and suicide prevention. We also will present our findings to prison charities in one event for third sector organizations in the UK (e.g. Prison Reform Trust, Howard League). SF, KH and JS have existing links with the Independent Advisory Panel on Deaths in Custody, and presented to the panel previously – we will do so again. In addition, our PPI representatives will disseminate our results to POPS, prison charities and via newsletters to involved prisons.

We will also present the main findings to the prison service via the annual Training College seminar (where SF and KH have presented previously). This meeting is attended by many prison governors and prison officers. SL will present the results to internal events at the Ministry of Justice and Safer Custody. We will disseminate the validation findings and the tool via the Royal College of Psychiatrists Quality Network, which will provide one route to inform prison psychiatrists in England and Wales about the tool. We will use social media (Twitter, LinkedIn) to enhance dissemination. We endeavour to present interim results to local academic meetings, in Oxford, London, and Manchester. We will liaise with the NIHR communications team for advice on other means of dissemination that could increase the impact of our research and we will also work with the University of Oxford press office.

## 19. DEVELOPMENT OF A NEW PRODUCT/ PROCESS OR THE GENERATION OF INTELLECTUAL PROPERTY

Ownership of IP generated by employees of the University rests in the University. The University will ensure appropriate arrangements are in place as regards any new IP arising from the trial.

## 19. ARCHIVING

New information gathered from the participants will be stored for 3 years after end of the project to allow sufficient time for data cleaning and analysis. They will be stored on an encrypted USB site, in a locked filing cabinet in a locked office, in the Department of Psychiatry.

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## 21. APPENDIX A: STUDY FLOW CHART

Stage 1: **Development of risk assessment tool**

Duration: 9 months

Process: Based on routinely collected information. Using a pre-agreed list of variables, we will extract data from ACCT documents, prison records and healthcare records for around 750 current prisoners. We will consider all demographic, criminological and clinical factors that are associated with risk of self-harming/suicide.
We will create a statistical model to predict repeat self-harm based on this pre-specified list of predictors that will include a core set based on face validity, population-based studies of self-harm in England and Wales and systematic reviews, and other factors if they improve the predictive performance of the multivariable model. We will also pre-specify categories for low, medium and high risk of self-harm recurrence to inform ways in which model predictions could be used in practice, following the latest guidelines for prognostic research.

Outcome information: Self harm (first episode) in the 3 months post-ACCT closure

Prisoner numbers: 750 (assuming 15 predictor variables being tested in the final model, 10 prisoners per predictor variable and 20% event rate post-ACCT)

Stage 2**: Qualitative research to assess acceptability to prisoners, clinicians and prison service**

Duration: 3 months

Methodology: Action learning processes. This part of the project will assess acceptability of the new tool to relevant stakeholders including prisoners, clinicians and prison staff and examine barriers to implementation. This process has been previously used successfully by members of the current team to operationalise a newly developed health and social care planning procedure in prison and a mental health and risk assessment tool in police custody. In two prisons (one male and one female), we will convene two action learning groups which will include prisoners and peer supporters (e.g. listeners). We will also conduct two further action learning groups virtually comprising frontline and managerial prison officers and healthcare staff; and a range of other concerned individuals (carers, chaplaincy etc.) from select prisons. Over three months, each group will convene monthly to address particular aspects of implementation - for example training needs, defining the roles of each professional/peer within the process, timing of administration and processes for instigating support based on results of the tool. Each group member will canvass opinions from their peers, bringing a consensus view to meetings to ensure agreed processes reflect new ways of working likely to be acceptable to the wider workforce, thus increasing the likelihood of successful implementation. We will develop pathways based on different risk assessment scores so that those using the tool will know how to link the tool's outcomes with best practice.

Stage 3: **Prospective cohort study to evaluate predictive performance of the tool**

Duration: 9 months (Start at month 50 of the project, i.e., 3 months after the start of Stage 2)

Methodology: Prisons to participate: select prisons across England. These prisons cover male and female prisoners, both adult and adolescents/young adults, that are either on remand or sentenced. The sample size will be guided by the results from the development of the tool (Part 1 of the project).

Data collection: 5 Research Assistants for 9 months

Data analysis: Tool administered independently on ACCT post-closure reviews and for the subsequent 3 months from Safer Custody self harm data. Measures of discrimination (incl. sensitivity, specificity, positive and negative predictive value, C-index) and calibration will be reported. Finalise instrument according to prospective study and final report to be written.

Total duration of the project: 59 months

## 22. PROTOCOL VERSION CONTROL TABLE

PROTOCOL VERSION CONTROL TABLE

| Document History* | | | |
|---|---|---|---|
| Version | Date | Editor | Comments |
| 1 | 05.04.17 | SF, AI, TM | Initial protocol submitted in full application |
| 2 | 29.08.17 | SF, AI, TM | Incorporated changes recommended by NIHR |
| 3 | 30.04.18 | SF, AI | Version agreed by NIHR panel |
| 4 | 21.11.19 | SF, AI | Some discrepancy. Marked as 24/10/2019 v5 AND 17/09/2019 V4 on the document. |
| 4 | 17.03.20 | SF, AD | Approved by REC version. |
| NO VERSION 5. | | | |
| 6 | 29.10.20 | SF, LH | Version agreed by NIHR panel |
| 7 | 01.06.21 | SF, LH | Version submitted in relation to substantial amendment (1). Version control table inserted. Version approved by REC. |
| 7.2 | 24.03.22 | SF, LH | Version submitted to REC & CAG in relation to substantial amendment 2. |
| 8 | 05.04.22 | SF, LH | Version agreed by NIHR panel, in relation to substantial amendment 2. |
| 8.1 | 16.06.22 | LH, SF, JSe, JSh | Version relates to stage 2 amendment and pending NRC application |
| 8.2 | 29.07.22 | NW | Version relates to amendments made by Nigel Wellman (NW) from the University of Oxford sponsor office. |
| 8.3 | 11.08.22 | LH | Version relates to addressed comments from NW. |
| 8.4 | 23.08.22 | LH | Version relates to the amendment of transcription service for stage 2 data on the advice of NW. |
| 8.5 | 31.08.22 | LH | Version relates to merging of comments from NW and Carole Cornelius (CC) from the University of Oxford sponsor office. |
| 9 | 21.09.22 | LH | Version relates to REC favourable opinion for stage 2. Pending NIHR panel agreement. |

*As of version 7 please use sub numbers for amendment versions that are undergoing consultation and review (i.e. v2.3, v2.4), with only whole numbers used for the final versions.