OHRN Toolkit

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Title: Researchers' Handbook: A Guide for Researchers in Offender Health

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The **Offender Health Research Network** is funded by Offender Health at the Department of Health, and is a collaboration between several universities, based at the University of Manchester. It was established in 2004 to develop a multi-disciplinary, multi-agency network focused on offender health care innovation, evaluation and knowledge dissemination.

Ethics and Governance

The various processes of approvals required for research with offenders can be complex. The Offender Health Research Network has produced the 'OHRN Toolkit' which aims to clarify the procedures and to offer guidance on gaining the relevant approvals. Interactive flowcharts with detailed drop down guidance for each question or approval category are shown below.

The main question which determines the types of approvals required for a particular project is;

- "In which area of the criminal justice system is the project going to be conducted?", "Is it **police**, **courts**, **prison** or **probation** By clicking on which area your project will be conducted you will be taken directly to the flow-chart.
  (**NB**: If more than one area then click on each area separately. Researchers must consider all approvals).

Figure 2: Approval process for police research

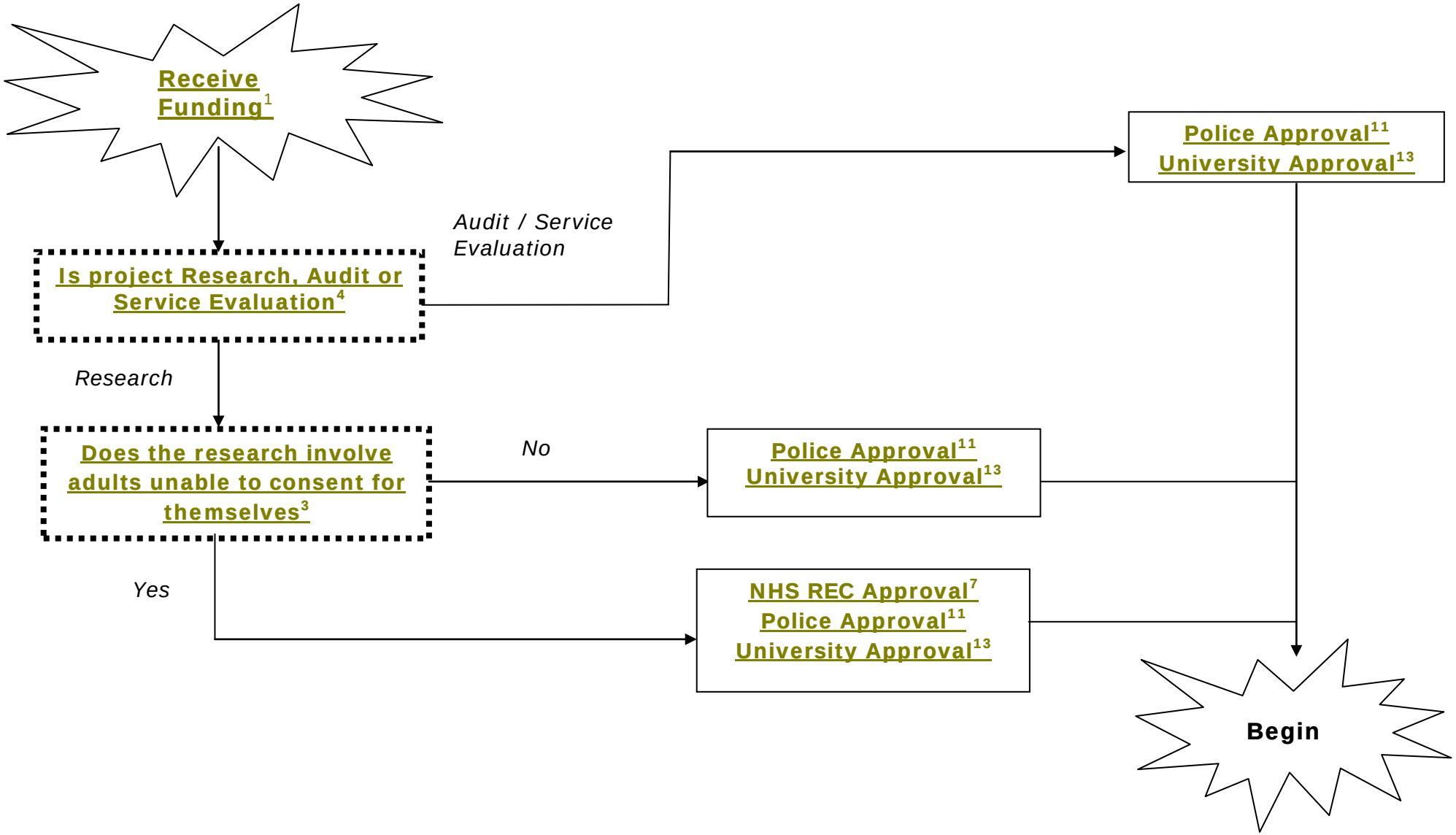


Figure 3: Approval process for court research

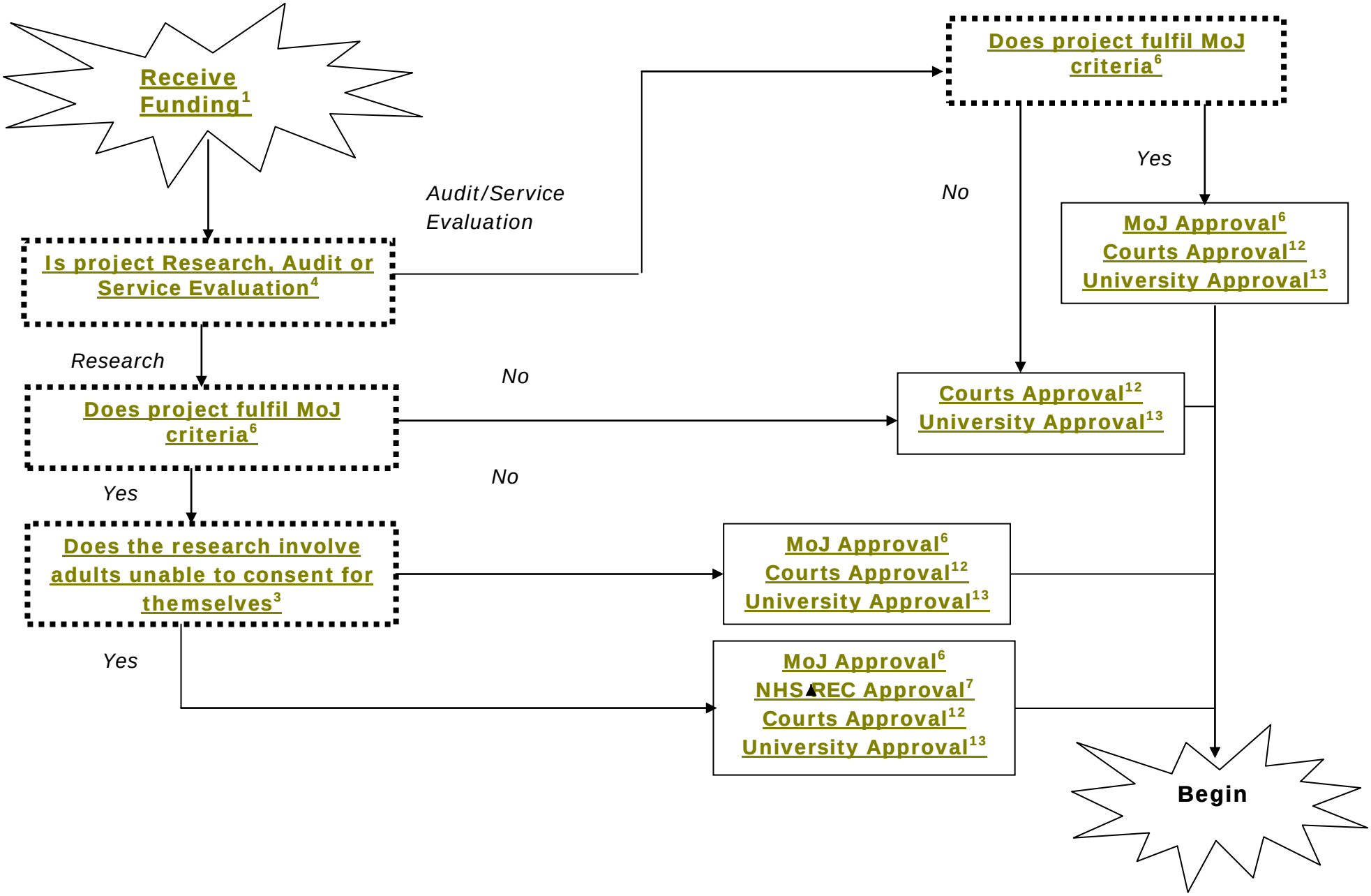


Figure 4: Approval process for prison research

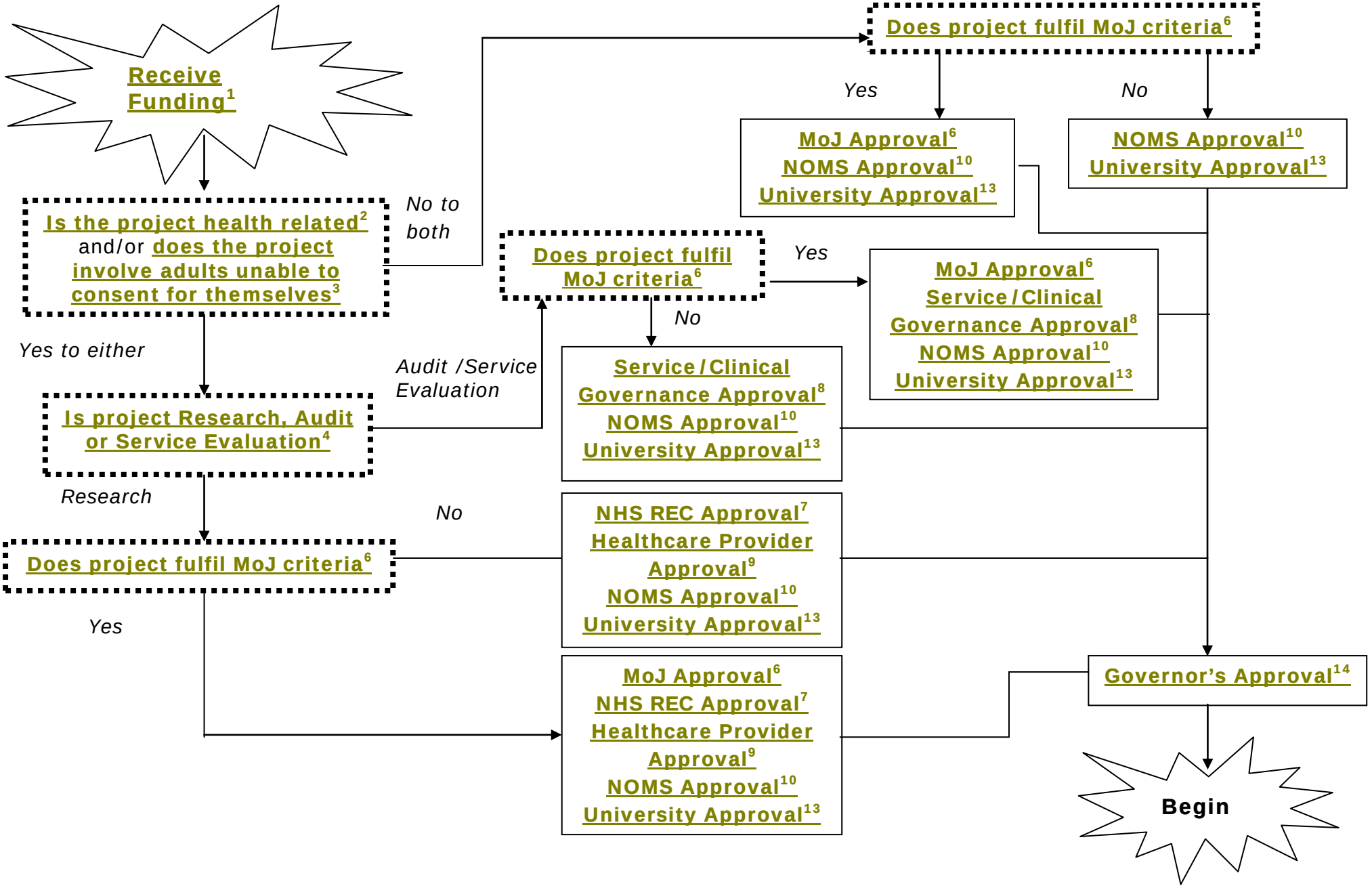
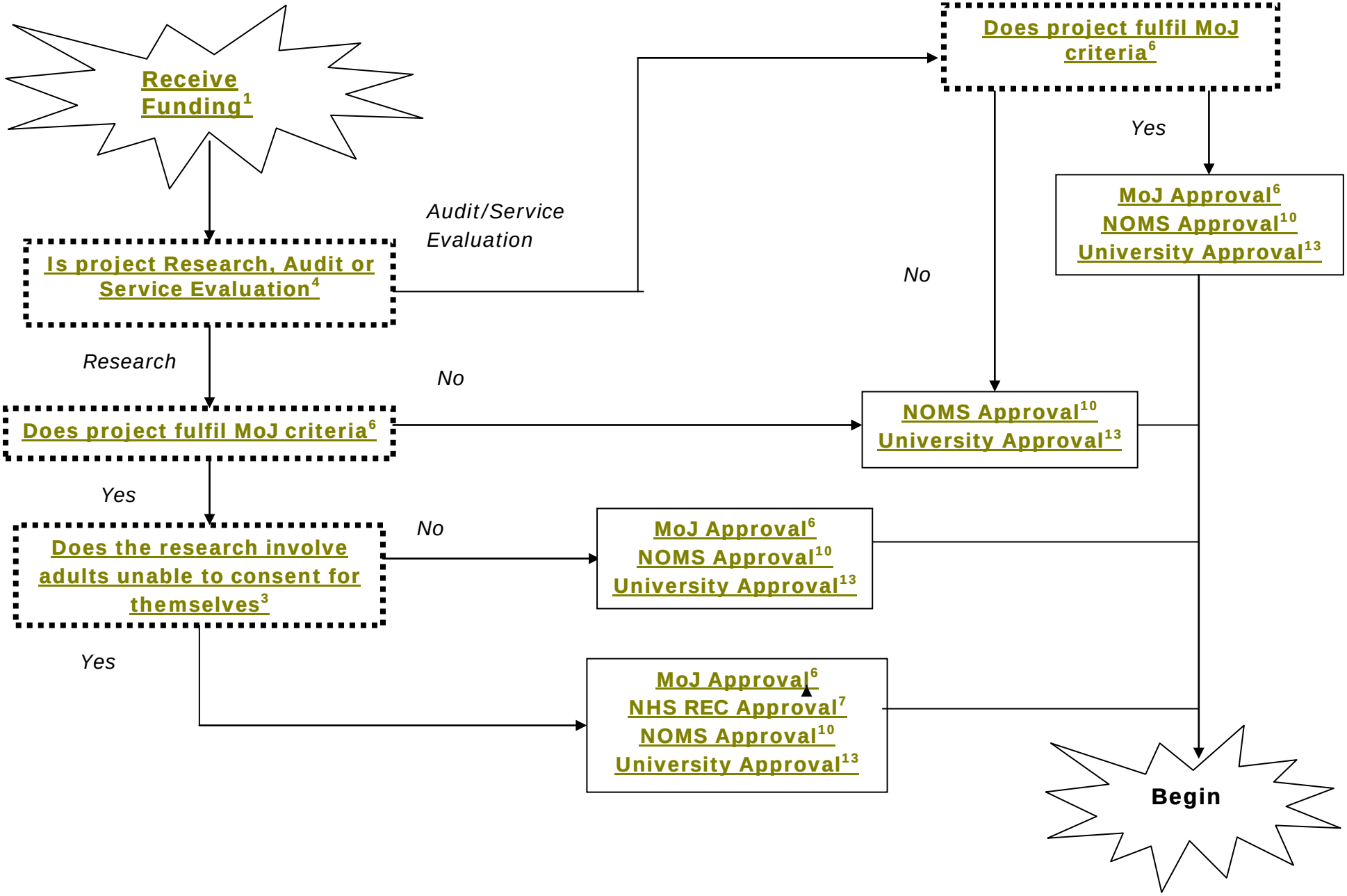


Figure 5: Approval process for probation research



For any assistance or advice on these procedures, please contact Charlotte Lennox at the Offender Health Research Network at charlotte.lennox@manchester.ac.uk

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1: Receive Funding

Projects requiring funding can only receive ethical approval once funding has been approved. However, NHS Trust R&D Departments may be able to help locate funding so it may be worth contacting them for advice. The OHRN regularly publishes details of new funding available; **www.ohrn.nhs.uk/funding**

2: Is the project health related?

Research projects conducted within a prison and that are health related will require NHS REC Approval (Section 7) and NHS PCT / Healthcare Provider Approval (Section 9); however all prison projects need NOMS Approval (Section 10) and Governor's Approval (Section 14).

NB: If the project involves adults unable to consent for themselves (Section 3) then the project will require NHS REC Approval (Section 7) even if not health related.

NB: The responsibility for deciding whether a study should be presented as research, audit or service evaluation lies with the Sponsor in consultation as appropriate with the institutions responsible for the governance of the project. Where doubt arises, advice can be sought from a R&D office or from NRES (Section 4).

What is the definition of prison health related studies?

The term “health research” encompasses a broad range of activities all aimed at improving or maintaining health.

The main outcomes from health related research are health outcomes, these can be the assessment, identification or diagnosis of health or health related issues, an improvement in a person’s health or wellbeing, or knowledge gained to improve service provision, assessment, identification or diagnosis.

Research defined as health related should encompass at least one of the following categories:

1. Human participation: studies with a health outcome that requires *face-to-face* contact and may involve use of health records as well.

- *Investigating the impact of a substance misuse service on people in prison*
- *Assessing mental health issues for people in prison*
- *Evaluating a psychological intervention with people in prison*
- *Interviewing prisoners about any health related issue i.e. physical, mental, psychological, behavioural*

2. Records based studies: studies which require access to *personal data* on health or lifestyle *without* involving face-to-face contact with any people e.g., epidemiological studies, health economic studies, public health interventions, health services research and meta-analyses – information may be obtained by telephone, postal questionnaires/surveys or electronic/manual data retrieval.

- *Study of records of those who have died in prison or on release from custody, i.e. suicide.*
- *Access to health data from OASys*

3. Clinical samples: studies that involve *laboratory studies* on *human material* which are specifically designed to understand or treat a disease/disorder.

- *Examination of urine/blood to ensure that medication is being taken appropriately, ie treatment for TB, epilepsy, etc.*

4. Intervention development: development or adaptation of interventions.

- *Examination of the effectiveness of a Offender Behaviour Treatment Programme in prison*
- *Examination of the effectiveness of a new Cognitive Behavioural Therapy with prisoners.*

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3: Does the project involve adults unable to consent for themselves?

All research projects which come under the Mental Capacity Act 2005 will require NHS REC Approval (Section 7).

The Act applies to any intrusive research (research that would legally require consent if it involved people with capacity) within England and Wales, wherever it takes place, except for clinical trials of investigational medicinal products. This research may include research in healthcare, social care, criminal justice and other settings. It is not limited to research undertaken within NHS organisations or other public bodies.

More information on the Mental Capacity Act can be found on the NRES website;
www.nres.npsa.nhs.uk/applications/apply/ethical-review-requirements/

On 1st October 2007 parts of the Mental Capacity Act came into force that are relevant to research. The Mental Capacity Act is relevant to research involving adults over the age of 16 in England and Wales, except Clinical Trials of Investigational Medicinal Products (CTIMPs).

What is capacity?

Capacity is the ability to make a decision. Capacity can only be assessed in relation to a particular decision and a particular time – a person may have the capacity to make some decisions but not others, or capacity may vary over time.

How is capacity assessed?

The Act contains a two-stage test of capacity:

- Is there an impairment of, or disturbance to, the functioning of the mind or brain?

and if so,

- Is the impairment or disturbance sufficient that the person is unable to make that particular decision?

Lack of capacity can be due to a range of causes, including dementia, mental illness, learning disability, brain damage, intoxication, any condition causing confusion, drowsiness or loss of consciousness (e.g. concussion, stroke, heart attack, epileptic fit, serious accident, delirium).

4: Is the project Research, Audit or Service Evaluation?

Prison projects which are “research” and are health related require approval from a NHS REC (Section 7) and permission for research from the Healthcare Provider (Section 9). Prison projects which are “audit” or “service evaluation” do not require NHS REC approval or permission for research from the Healthcare Provider but still require service/clinical governance approval from the PCT (Section 8), if health related. Research, audit and service evaluation in prisons and probation **all** require NOMS approval (Section 10) if undertaken by external staff and require MoJ approval if they come under the MoJ criteria (Section 6).

Research, audit and service evaluation would require Police approval (Section 11) if undertaken by staff external to the Police Service and Court approval (Section 12) if undertaken by staff external to HM Court Service. Court projects would require MoJ approval if they come under the MoJ criteria (Section 6).

The NRES publishes a leaflet “Defining Research” with broad criteria for distinguishing between ‘research’, ‘audit’ or ‘service evaluation’.

Table 1: Differentiating clinical audit, service evaluation, research and usual practice/surveillance work in public health

RESEARCH	SERVICE EVALUATION	CLINICAL AUDIT
The attempt to derive generalisable new knowledge including studies that aim to generate hypotheses as well as studies that aim to test them.	Designed and conducted solely to define or judge current care.	Designed and conducted to produce information to inform delivery of best care.
Quantitative research – designed to test a hypothesis. Qualitative research – identifies/explores themes following established methodology.	Designed to answer: "What standard does this service achieve?"	Designed to answer: "Does this service reach a predetermined standard?"
Addresses clearly defined questions, aims and objectives.	Measures current service without reference to a standard.	Measures against a standard.
Quantitative research – may involve evaluating or comparing interventions, particularly new ones. Qualitative research – usually involves studying how interventions and relationships are experienced.	Involves an intervention in use only. The choice of treatment is that of the clinician and patient according to guidance, professional standards and/or patient preference.	Involves an intervention in use only. The choice of treatment is that of the clinician and patient according to guidance, professional standards and/or patient preference.
Usually involves collecting data that are additional to those for routine care but may include data collected routinely. May involve treatments, samples or investigations additional to routine care.	Usually involves analysis of existing data but may include administration of interview or questionnaire.	Usually involves analysis of existing data but may include administration of simple interview or questionnaire.
Quantitative research – study design may involve allocating patients to intervention groups. Qualitative research – uses a clearly defined sampling framework underpinned by conceptual or theoretical justifications.	No allocation to intervention: the health care professional and patient have chosen intervention before service evaluation.	No allocation to intervention: the health care professional and patient have chosen intervention before audit.
May involve randomisation.	No randomisation.	No randomisation.
Normally requires REC review. See **http://www.nres.npsa.nhs.uk/applications/apply/**.	Does not require REC review.	Does not require REC review.

The table from the NRES website:
(**http://www.nres.npsa.nhs.uk/applications/apply/is-your-project-research/**)

Further guidance on categorising projects is also available from the NHS R&D Forum website; (**www.rdforum.nhs.uk/docs/categorising_projects_guidance.doc**)

Although guidance is available, it is recognised that the boundaries between Research, Audit and Service Evaluation are difficult to define precisely. Issues of interpretation may arise in deciding how a project should be presented. Some projects on the borderline raise significant ethical and governance issues. Where it is decided that a project should be reviewed by a Research Ethics Committee and managed under research governance frameworks, it should be presented as research.

If having considered the published guidance you and your sponsor are unsure whether your project should be presented and reviewed as research, please seek advice from your R&D office in the first instance. Advice can also be sought from the R&D offices of other institutions responsible for governance of the project.

If after seeking R&D advice you require further advice from the NRES, please email an A4 summary (one side only) outlining your proposal to the co-ordinator of a prison flagged REC (**www.nres.npsa.nhs.uk/contacts/find-your-local-rec/**) or the NRES Queries Line (**queries@nres.npsa.nhs.uk**). For ease of reference please include your request in the covering email.

5: Integrated Research Application System (IRAS)

The Integrated Research Application System (IRAS) is a single online system for applying for permissions and approvals for health and social care/community research in the UK, including offender health projects. It builds on the functionality of the previous NRES on-line application system, which is now no longer available.

IRAS streamlines the application process by allowing researchers to enter all the information needed by different approval bodies in an “integrated dataset”, which then populates the application forms used by each body. It avoids the researcher having to re-enter the same information separately in multiple forms.

IRAS can be used for applications to NHS RECs and NHS R&D offices for review of health-related research. It can also be used where required for any application to the Ministry of Justice, whether for research, audit or service evaluation. In 2010 it is planned to include all NOMS applications, whether for research, audit or service evaluation.

Guidance for Applicants

- IRAS can be accessed at **www.myresearchproject.org.uk**
- Log in using your previous account details from the NRES on-line form system (if available) or go to Create Account. Anyone can create an IRAS account for training purposes even if they are not ready to make an application.
- Guidance on how to use IRAS can be found here IRAS help (**www.myresearchproject.org.uk/Help/Contents/IRASHelp_UserManual.pdf**) and IRAS e-learning (**www.myresearchproject.org.uk/Help/ELearning/index.html**). The e-learning module is a useful starting point for new users.
- Click on New Project to create your project. You can do this for training purposes even if you do not have a particular project in mind.
- Complete the Project Filter to generate the integrated dataset for your project. It is important to answer the Filter questions correctly as this generates all sections and questions relevant to the type of project and the approvals required.
- Complete the dataset using Question Specific Guidance (available using 'Help' or by clicking on the information buttons).
- When you have filled in all the questions, each of your application forms will be complete and ready for submission.
- Go to the Submission tab for each application form for guidance on how to submit the application. Each approval body will have its own arrangements for submission. Note that it is not yet possible to make submissions electronically.

6: Does project fulfil Ministry of Justice criteria?

The Ministry of Justice (MoJ) Research Quality Assurance (RQA) applies to projects taking place within the National Offender Management Service (HM Prison Service and HM Probation Service), HM Courts Service or any other agency within the responsibility of the MoJ for England and Wales and meeting any of the criteria in Box 1:

Box 1: Criteria for RQA

- national in scope
- intended to be published
- results to be sent to Ministers
- a study of outcomes of policy or operational changes

NB: Projects defined as audit or service evaluation rather than research will still be subject to RQA if they meet any of the above criteria.

The application form for MoJ RQA approval is contained within the Integrated Research Application System (IRAS) application form (Section 5).

Guidance for Applicants

- For advice on the RQA process at the Ministry of Justice, please contact Analytical Services (Offender Management and Sentencing) in MoJ. The main contact point is David Brown; **David.brown@cjs.gsi.gov.uk**
- The completed MoJ application form should be submitted electronically by sending as a file attachment to David Brown at the above email address. Hard copy is not required and the form does not need to be signed. No additional documentation is required unless requested.

7: NHS REC Approval

Approval is required from an NHS Research Ethics Committee (REC) for 'health related' research conducted within prison settings and **any** research involving adults unable to consent for themselves.

RECs are required to provide independent, competent and timely review of health related research. A REC's duty is to protect participants from harm and, secondly to facilitate good quality research.

Certain REC's are 'flagged' to specifically review these types of research. Details of flagged RECs are available on the NRES website (**www.nres.npsa.nhs.uk/contacts/find-your-local-rec/**) or you can seek guidance from the Central Allocation System when booking your application.

For guidance on whether your project is research, audit or service evaluation, see Section 4.

The application form for ethical approval by a NHS REC is contained within IRAS (Section 5). There is help and advice for applicants on the NRES (**www.nres.npsa.nhs.uk**) and IRAS (**www.myresearchproject.org.uk**) websites and also in IRAS help (**www.myresearchproject.org.uk/Help/Contents/IRASHelp_UserManual.pdf** and IRAS e-learning (**www.myresearchproject.org.uk/Help/ELearning/index.html**)

Common Issues

Sponsor's Role

The study sponsor is the person who takes on ultimate responsibility for the initiation, management and financing (or arranging the financing) of the research. The sponsor satisfies itself that appropriate checks have been undertaken to ensure that the study meets the relevant standards, and makes sure arrangements are put and kept in place for authorisation, management, monitoring and reporting.

All research falling under the remit of the Secretary of State for Health must have a formal sponsor. This includes all research in health and social care that involve NHS patients, their tissue or information, etc. There are similar

requirements for research involving social care practitioners, clients and resources, where this falls under the Secretary of State for Health's remit.

Any organisation that is a legal entity may declare itself as a sponsor. While the Clinical Trials Regulations allow for individuals to become sponsors, many institutions do not permit their staff to take personal responsibility in such areas because of the risks and legal liabilities involved.

A sponsor can delegate specific responsibilities to any other individual or organisation that is willing and able to accept them. However, the sponsor should ensure that the delegation of responsibilities to another party is formally agreed and documented.

In some cases, a co-sponsorship agreement may be reached. If so, you should nominate one body as the lead sponsor for the purposes of the ethics application and a sponsor letter should be provided describing the responsibilities of each sponsor. In particular, this should clarify the agreement about compensation and indemnity in the event of harm to research participants.

It should be noted that co-sponsorship is an arrangement that is not recognised in EU states other than the UK and is therefore not applicable to multi-national studies within the EU.

Indemnity

Indemnity is an assurance that payment will be made to cover the legal liability of another person in the event of a claim. Legal liability may arise from fault in the management, design or conduct of the research. The liabilities may fall on different parties in each case. It is the sponsor's responsibility to ensure that arrangements are in place before the study starts to cover the potential legal liabilities of the various parties arising from the research. The main REC must be assured that there are appropriate arrangements to compensate participants in the event of harm due to fault in the management, design or conduct of the research. The REC will not expect to see full details and proof of all

arrangements. However, applicants must be clear about all the arrangements for compensation before making an application to the REC. In general, such arrangements will normally be in place through NHS indemnity, and/or employer's liability insurance, and/or professional indemnity and/or clinical trials insurance, as appropriate. In certain circumstances, e.g. high-risk research activities or vulnerable participants, additional arrangements may need to be made. Employers and sponsors must be made aware of such situations in sufficient time to make necessary arrangements.

Liability arising from the management of the research

The liabilities of the sponsor relate to the overall management of the study, i.e. the systems and processes through which the sponsor meets its responsibilities. This could include responsibilities for monitoring and training, for example. Normally the sponsor(s) will hold insurance or provide indemnity to cover their liabilities as sponsors. Where the sponsor is the employer of the Chief Investigator this is likely to be covered through insurance or indemnity for employer's liability. Where there is more than one sponsor, details for all sponsors should be provided. You should make sure that you have discussed the study with the sponsor and that they have agreed, in principle, to act as sponsor.

If an NHS organisation is a sponsor, then indemnity is provided through NHS schemes. If a university or higher education institution is a sponsor a copy of the relevant policy must be provided. Where sponsor activities are delegated to sites or sub-contracted to another party, the contract or agreement between the organisations should set out the responsibilities of the parties and the arrangements for covering any liabilities. The sponsor is responsible for ensuring that these arrangements are in place.

Liability arising from the design of the research

The design of the research is the responsibility of the author and any co-authors of the protocol. Employers are responsible for the actions of their staff who design research studies as part of their employment. Normally the employer(s)

of the author(s) will hold insurance or provide indemnity to cover their liabilities for the design of the research. The main author will usually be the Chief Investigator in the UK. Where the employees of an NHS organisation are responsible for designing the study, indemnity is provided for harm arising from the design of the study through NHS schemes. If the author is employed by a university, or the design of the research has been undertaken in the course of an honorary arrangement with a university, give details of the insurance or indemnity arrangements. This situation applies to researchers employed by a university, regardless of whether or not they hold any honorary contract with an NHS organisation. The university is likely to hold insurance that is additional to normal employer's liability insurance, to cover CTIMPs or other interventional trials. For other non-interventional clinical research, employer's liability insurance is likely to be sufficient. A copy of the relevant policy must be provided. If the author is employed by a company, is self-employed or is an independent contractor, give details of the insurance or indemnity arrangements, a copy of the relevant policy must be provided.

Liability arising from the conduct of the research

The conduct of the research refers to the study procedures, as described in the protocol or proposal, which are conducted by the research team with participants, data or tissues. Employers are normally responsible for the actions of their staff who conduct research procedures as part of their employment. However, where the research involves NHS patients under the care of NHS organisations (including independent contractors), indemnity for harm to participants resulting from clinical negligence is provided either through NHS schemes or through professional indemnity. Formal permission from the NHS organisation (R&D approval) must be obtained in writing before the start of the research. Independent contractors, e.g. GPs, should ensure that their professional indemnity provides cover for the activities they will be undertaking. Where the research involves private patients under the care of an independent contractor, the main REC requires assurance that appropriate indemnity

arrangements will be in place before the study starts. A copy of the relevant policy must be provided. Where the investigator is an employee or contractor of a university or Higher Education Institution (HEI) and the research involves members of the public taking part in research outside the care of the NHS, the HEI should have insurance or indemnity to meet the investigator's liabilities. Such research may take place in the HEI, in the community or in other private or state institutions. In some cases, the HEI may need to arrange additional insurance. A copy of the relevant policy must be provided. Where the investigator is an employee or contractor of a Contract Research Organisation or Site Management Organisation and the research is taking place through a commercial organisation, the company should have insurance or indemnity to meet the investigator's liabilities. A copy of the relevant policy must be provided.

Guidance for submission

- Ensure documentation is complete (See **Annexe 1**: Provides information on common themes/issues from reviews of prison studies).
- Check the guidance under the *Submission* tab for the REC application form in IRAS before you proceed to submission. Note that if you are using e-authorisation in preference to ink signature this must be done **before** you save and print the form otherwise the authorisation will not be visible. E-authorisation can be used for all declarations except the Chief Investigator's declaration for a clinical trial of an investigational medicinal product.
- When you are ready to submit, click on *Proceed to Submission*, save and print the form and arrange for ink signatures where required.
- Ring Central Allocation System (0845 270 4400) for allocation to a REC. Further guidance on booking is at **www.nres.npsa.nhs.uk/applications/booking-your-application/**
- Enter details of the REC at the top of the form.
- Check that the submission code appears at the foot of each page of the application form before sending.

- Send one hard copy of the application form to the REC office by the agreed submission date, together with the submission checklist and all relevant supporting documentation.
- The researcher will be invited to attend the REC Meeting to answer any questions of clarification the committee may have. **Advice:** Ensure a member of the research team (preferably the Chief Investigator) can attend.
- Correspondence and REC decision will be issued within 10 days of the REC meeting.

8: Service / Clinical Governance Approval

If the project is audit or service evaluation, or some other type of non-research activity such as case study, system/equipment testing or satisfaction survey, an application must be made to the service/clinical governance office for that NHS organisation. You must also check with them what other review arrangements or sources of advice apply to the project. For example, there may be standard guidelines on the conduct of clinical audit. The Caldicott Guardian will be a source of advice on the use of patient data. It should be possible to reach this nominated person through the main NHS organisation switchboard.

9: Healthcare Provider Approval

For prison research that is health related, permission of the healthcare provider is also required. This is usually the PCT and is required where the research is related to the provision of care provided by the care organisation. This approval provides management permission and reviews the governance arrangements. 'Research governance' which be defined as the broad range of regulations, principles and standards of good practice that exist to achieve, and continuously improve, research quality across all aspects of healthcare in the UK and worldwide.

Research & Development Departments at local NHS trusts will assess research governance issues, including the need for NHS resources from the proposed study sites. These will include an assessment of the study design and ascertainment of whether the study includes vulnerable groups and the impact of this. Further information on research governance can be found in the Research Governance Framework at the following link:

http://www.dh.gov.uk/PolicyAndGuidance/ResearchAndDevelopment/ResearchAndDevelopmentAZ/ResearchGovernance/ResearchGovernanceArticle/fs/en?CONTENT_ID=4002112&chk=PJlaGg

Final approval will only be given after NHS REC approval, but applications can be made in parallel to NHS REC approval, and this is encouraged.

Guidance for applicants

- Check which Healthcare Provider (**www.dh.gov.uk/assetRoot/04/10/75/10/04107510.pdf**)
- Access RDForum (**www.rdforum.nhs.uk**)for contact details of R&D Department for each Healthcare Provider
- All applications should be made using IRAS (**www.myresearchproject.org.uk/**). See Section 5.
- Using IRAS complete the R&D form and Site Specific Information. One form per site is required
- **NB** Final approval can only be granted when NHS REC approval letter has been forwarded to R&D department but application can be made at any time

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10: NOMS Approval

All prison and probation based research must be approved by NOMS. Investigations coming under the category of 'Audit' or Service Evaluation' conducted by external staff must still be approval by the following procedure.

Guidance for applicants

- **Advice:** For prison health research the application process will be faster if already approved by NHS REC, but may be made at any time.
- Access HM Prison Service website (**www.hmprisonservice.gov.uk/**) and go to 'Resource Centre', 'Research'.
- Complete 'Research Application Form'.
- Submit to:
    - Research contact if project to take place at one establishment or one probation office
    - Regional Psychologist if project to take place at several establishments or probation offices in one Prison Service Area
    - National Research Committee if project to take place at several establishments in more than one Prison Service Area or probation offices nationwide. Contact for the National Research Committee (**national.research@noms.gsi.gov.uk**)
- Correspondence and Decision

NB: NOMS procedures state that offenders involved in research are not to be given incentives for taking part in research if located in prison, and only voucher incentives if located in the community.

11: Police Approval

For projects conducted within the Police Service, initial contact must be made through the Chief Constable for each police service. Some police services (e.g. the Metropolitan Police) have a specific research application to complete, others do not. Therefore the Chief Constable will advise who best to contact. Applicants should provide as much detail as possible, including a methodology and information on what is the likely impact of the research on police resources.

12: Court Approval

Information on approval for court based projects can be found at HM Courts Service website (**www.hmcourts-service.gov.uk/infoabout/information_for_researchers/index.htm**).

13: University Approval

University approval may be required for university staff, or for those studying for higher degrees; Research & Development/Governance department or University Ethics Committee. Approval may be important to ensure indemnity. (For other researchers, check indemnity issues with employer.)

14: Governor's Approval

Prison governors have the final say whether research may take place in their establishments. No project may take place without the Governor's approval.

BEGIN RESEARCH!

Annexe 1: REC REVIEW – Hints & Tips for Researchers

There are a number of core elements which a research ethics committee will consider during the review of a research application. The following information is intended to guide and prompt researchers when designing their project/protocol and in preparing an application for submission to a REC. (Please note that the list is not exhaustive).

General Advice:

The NRES Website: **www.nres.npsa.nhs.uk** holds a considerable amount of guidance in the FAQ's section and on specific topics.

The REC application form is accessed through the Integrated Research Application System (IRAS) via: **www.myresearchproject.org.uk**. Before submission, please check that all the questions in the REC application form have been completed.

The application will need to be booked to a "flagged" REC, recognised to review applications from the prison & probation services via National Research Ethics Service – Central Allocation System (CAS) on: 0845 270 4400 (9.30am - 4.00pm weekdays)

The information provided in *all* papers submitted to the REC should be written in lay language. This is particularly important for information sheets which potential participants will receive (Note: the national reading age in the UK is around 9 years of age).

Abbreviations should be avoided, or at least explained.

References to drugs, especially in questionnaires should use the street drug names.

Occasionally, a researcher may think of introducing a slightly different methodology to what is considered to be usual. In such cases, the researcher will need to justify its use.

The REC will consider a variety of aspects and will need to be satisfied that:

The applicant and supporting staff are suitable and appropriate to undertake the study:

- The researcher is competent to undertake research in the prison environment and will consider the knowledge and expertise of the Chief Investigator.

- If the research is part of an education qualification, the committee will require reassurance that there is appropriate supervision and support of the student.
- The safety of the research team has been considered.

The facilities are suitable:

- Is the setting appropriate for the interviews, investigations or treatment to be undertaken. Could safety or confidentiality be compromised for either the participant(s) or the researcher? Demonstrate knowledge of the regulations, and systems for protection of staff/visitors within the prison. It may be advisable for the researcher to have a strengthened regimen in place for their own protection, similar to a loan working policy.

The relevance of the research and research design are acceptable:

- Is the study design scientifically sound? It would be unethical to conduct poorly designed research. Will the methodology answer the research question.
- Is the research worthwhile and that the results are likely to lead to a tangible benefit.
- Is the proposed research intended to benefit the target population and or society as a whole.
- If the research could be undertaken in a group other than the prison population, a sound justification for researching on prisoners would be required.
- Ideally, questionnaires should be validated for use in the study population.
- If non-English speakers are being excluded from participation, justification is required.

The researcher has:

- **anticipated the benefits and risks for the individual trial subject:**
- **the care and protection of the research subject have been considered:**
- **any Hazards, discomfort and distress of subjects are identified:**

The researcher should acknowledge potential problems and demonstrate how they will safeguard against them. What rescue/damage limitation

mechanisms or processes would be available? Areas to think about would include:

- Demonstrate knowledge of the rules & regulations within the prison environment. When would confidentiality for instance need to be broken and how would this be dealt with. An example would be if a participant intends to self-harm, harm others or pose a threat to security.
- Consider whether the participant may be at risk of anxiety or distress. How these issues would be addressed, minimised or avoided. Would referral to a health professional or counsellor be required? Causes may arise from:
    - In-depth questioning and exposure of sensitive personal information.
    - Inappropriate identification of participants.
    - Confidentiality breeches, including publishing of findings. Permissions should be sought for use of quotations. How will participants' anonymity be maintained?
- Would advocacy services be required and if so, who will fulfil this role?
- Exploitation – possibly examples include: coercion, inducements and manipulation.
- Know the rules regarding rewards for participants, particularly prisoners.
- Is there potential for conflicts of interest and if so, how can these be avoided or eliminated.
- How will the protection and confidentiality of the participant be maintained. Would the methodology you wish to use expose them to any danger such as bullying or blackmail if in particular, other prisoners were to know of a their participation.
- Although in a controlled environment, how will participants' dignity, privacy, autonomy etc., be upheld.
- How will burdens or harms be avoided or minimised (particularly: vulnerable or sick participants). Loss of earnings would not be acceptable.
- For some studies it may be appropriate for follow-up care to be provided during or at the end of the study. What provisions will be in place.
- Who can the potential participant approach/be referred to should they wish to discuss their possible participation with an independent person.

Selection & Recruitment arrangements:

- The exact process for identifying potential participants, approaching and recruiting them into the study should be explained step by step. Details as to who will do what, where and when will need to be included.
- Ideally, potential participants should initially be approached by someone who knows them or provides their care. They should be invited to respond by contacting the researcher, via a suitable mechanism to indicate their interest in participating. However, staff should not act as gatekeepers in selecting possible participants to avoid the possibility of introducing bias to the study.
- The researcher should be mindful that some potential participants will be more vulnerable than others. (e.g.: their health & general status) and therefore different requirements for the differing levels may be necessary. Recruitment material is a good example of adapting to the needs of the population - would it be better to use posters/pictures rather than written texts as some people have a limited degree of literacy.
- For some studies, the staff may be participants themselves – has this been acknowledged and their participation built into the study design.

The written information to be given to potential participants and the procedure to be followed for obtaining informed consent is adequate and complete:

NOTE: The NRES website: **www.nres.npsa.nhs.uk**/guidance provides information & Guidance on Information sheets & Consent forms which include information on how to assess readability of documents using the Flesch Reading Ease score or Fog Score.

- Comprehension may be impaired for a variety of factors including language, culture, education level, mental and emotional state, situation and age.
- In order for potential participants to be able to process and understand what they are being asked to do, information should be delivered in a format suitable to their needs. For instance, the researcher could consider using pictures to explain the study or test information sheets on lay people to ascertain the level of understanding.
- RECs will look to see that the language in information sheets is simple, clear and suitable for the population to be researched. Information and consent processes are considered to be a whole and therefore evidence of an adequate consenting process will be

considered. Would potential participants whom literacy is compromised, require more time or help in understanding the study.

- Coercive terminology should be avoided. Examples of this would include: important/valuable/special/vital…… "the Governor would like you to participate" etc.
- At this stage it cannot be assumed that someone has agreed to participate, therefore potential participants should be thanked for "considering" taking part.
- Are any risks & discomfort involved clearly explained?
- What would happen if the participant wishes to withdraw at any time? It should be clearly explained that it is acceptable to say no, or to withdraw at any stage without any consequences and that their parole, care or stay in prison will not be affected. Where applicable, what would happen to results already collected.
- Remember, staff may also be participants. They should be reassured that they will not suffer if they decide not to participate or withdraw from the study at any stage and that their employment rights will not be affected. To avoid bias and cohersion etc., careful consideration should be given to situations where the line-manager is the researcher and is asking a member of the team to be a participant – ideally this relationship should be avoided.
- The time a participant is expected to invest in the study should be realistic and explained.
- Information regarding the use of audio tapes or digital recordings needs to include details as to how the data will be stored and destroyed (& when).

Consent of the research subject including justification for research on persons incapable of giving consent *(where appropriate).*

The consent template on the NRES website, gives an outline of the clauses required. This document should be amended to suit the actual study.

- Is the person who is going to take consent appropriate, trained and in the right place at the right time?
- Does the participant have an opportunity to ask questions & have them answered?
- If access to mental health records is required, specific consent to do so will be needed.
- Specific consent to audio taped/digitally recorded discussions should be included.

Confidentiality including the rights of the subject to physical and mental integrity, to privacy and to the protection of data.

- Reassurance as to how data will be handled will be required along with information on how the participants confidentially will be protected.
- Confirmation should be given to participants to advise them that information collected during the study will not be shared or used by the prison/probation authorities in order to disadvantage them in any way.
- A summary of the study results should be offered to the participants at the end of the study. How would these results be published and how will participants receive the report to maintain confidentiality.

The provision of Governance, Indemnity and Compensation:

- Does the study have the required (provisional) approvals, sponsorship, funding and indemnity?
- Who will be responsible for Governance of the study? Often, this is the Primary Care Trust, but not always. Further information is provided in the main document.
- What is the appropriate system for compensation should a participant wish to make a claim for negligence or harm?

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