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Navigating NHS Ethics

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Vice Chair NHS Ethics Committee (GG&C REC4)

2

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What does research ethics do?

Ensures the **rights** and **wellbeing** of people taking part are at the heart of all research

Reassures the public that health and social care research is designed and carried out in a way that responds to their needs

Enable participants to make **informed choices**

Ensures participants are **treated fairly**

23

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NHS REC Review : is this necessary for all NHS research activity?

Some of you may be familiar with the NHS guidance leaflet – outlining what is meant by:

- RESEARCH
- SERVICE EVALUATION
- CLINICAL/NON FINANCIAL AUDIT
- USUAL PRACTICE / HEALTH PROTECTION

Some of these activities may not appear to require NHS ethics review but they may still need UEC review

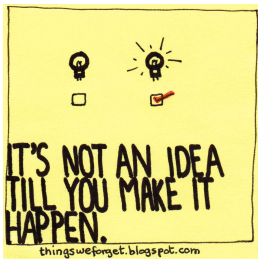
24

NHS REC Review : do I need this for all NHS activity?

Research	Service Evaluation	Clinical / Non financial audit	Usual practice (including health protection)
New knowledge	Define or judge current care	Informs delivery of best care	Investigate health issues in a population – health improvement or investigate outbreak or incident
Quantitative and/or quantitative research	What standard does service achieve?	Does the service reach a predetermined standard?	What are the health issues in this population and how do we address them? Or What is the cause of this outbreak or incident and how do we manage it?
Defined questions, aims and objectives	Measures service without reference to a standard	Measures against a standard	Systematic, quantitative or qualitative methods
Data collected is usually *additional to routine care*	Intervention is part of treatment as usual	Intervention is part of treatment as usual	Intervention is part of treatment as usual
Participants may be allocated to an intervention or a group	May include analysis of existing data but may include interviews or questionnaires	May include analysis of existing data but may include interviews or questionnaires	May include analysis of existing data but may include interviews or questionnaires or evidence review
May involve randomisation	No allocation to intervention – treatment as usual	No allocation to intervention – treatment as usual	No allocation to intervention – treatment as usual
Normally requires NHS ethics review but not always	Does not require NHS ethics review…but	Does not require NHS ethics review…. but	Does not require NHS ethics review… but

26

When should I start thinking about ethics?



27

THINK ETHICS

Do I have a sound justification for the project?

Do I know who my participants might be?

Do I know how I will recruit them?

Do I have a detailed outline of the project?

What permissions do I need?

28

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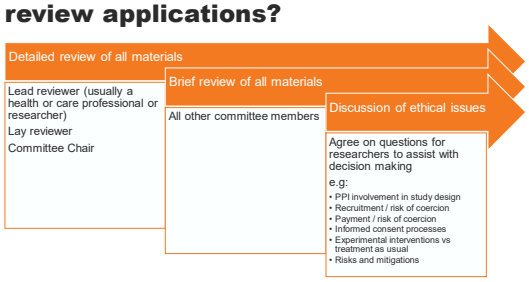
How do NHS ethics committees review applications?



29

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Some guidance from my ethics committee

- Social / Scientific value
- Recruitment
- Favourable Risk/Benefit Ratio
- Care and Protection of Research Participants
- Informed Consent
- Suitability of the Applicant
- Independent Review
- Suitability of Supporting Information

30

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Social and scientific value

- Is there a clear research question with justifiable purpose?
- Does the study build on what is known already?
- Will the study provide meaningful information of value?
- Does the planned method give us information that can be trusted and answer the research question?
- Are the numbers feasible and justified?
- Have you considered any input from a statistician and is there a clear analysis plan?
- Was there PPI input into the research design?

31

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Recruitment

Are the inclusion and exclusion criteria justifiable?

Sampling must provide meaningful and valid answers to the research question.

Is there exclusion of anyone known to be vulnerable to harm from the intervention? If not, fully justify their participation where necessary.

Is 'selection'/identification prone to bias or possibly coercive?

Who is making the approach and how will this be perceived?

Is it likely to be a 'cold' call?

Is the process 'opt in' i.e. potential participant denoting interest and not the researcher initiating this?

Provide a flow chart

32

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Favourable risk/benefit ratio

The benefits and risks should be fully explained in the protocol and to the participant through the participant information sheet and the consenting process.

If there in unlikely to be benefit to the individual but can answer an important research question this is okay but needs to be made clear

Where there is little or no benefit then there equally should be little or no risk involved.

Think about the burden to allowing a prospective research participant to make a fully informed choice.

33

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Care and protection of research participants

Do participants have the right to withdraw and is this clearly communicated?

How is their information/data being protected and what mechanism is in place to deal with data protection or possible distress?

Are participants and researchers adequately supported and there is relevant policy in place to ensure safety i.e. lone working policies.

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Informed Consent: a founding principle of research ethics

Human participants should enter research voluntarily fully informed about what it means for them to take part, and they give consent before a project or any research interventions take place.

The potential participant should be given adequate time to reflect on the information given and they should be under no time pressure to respond to the researcher.

During the consenting process it is normal for the researcher to reiterate the terms of the research, often as separate bullet points or clauses; the potential participant agreeing to each term (giving explicit consent) before agreeing to take part in the project as a whole.

35

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Suitability of the Applicant

The researchers CV(s) is checked for suitability to conduct the research.

This will include experience and knowledge of both the specialist area and research experience.

It is always useful for this to show evidence of GCP completion.

36

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Independent Review

All applications are expected to have been independently peer reviewed.

Often this has taken place for funding purposes.

Student level research is always considered proportionately to that expectation

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Suitability of Supporting Information

All questionnaires, diaries, interview questions should be suitable for the participant group. Where validated questionnaires are involved then ensure these are valid for the participant group.

Patient and public involvement entails research being carried out 'with' or 'by' members of the public, rather than 'to', 'about' or 'for' them.

The word public can refer to patients, potential patients, carers and people who use health and social care services as members of the public.

38

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Recruitment : tips to ensure ethical practice

Identification	How initially identified?
Approach	Is the right person doing that process?
Advertising or invitation letters?	Who is confirming eligibility?
Participant information sheet / Informed Consent	Who is assessing capacity to consent and when?
Contact with participants throughout study	Is selection fair and inclusive (e.g. EDI)

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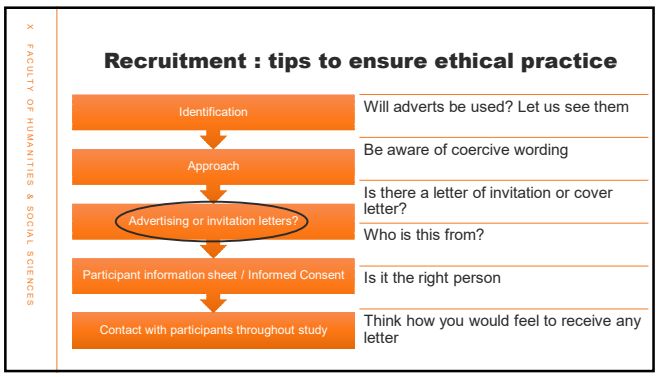
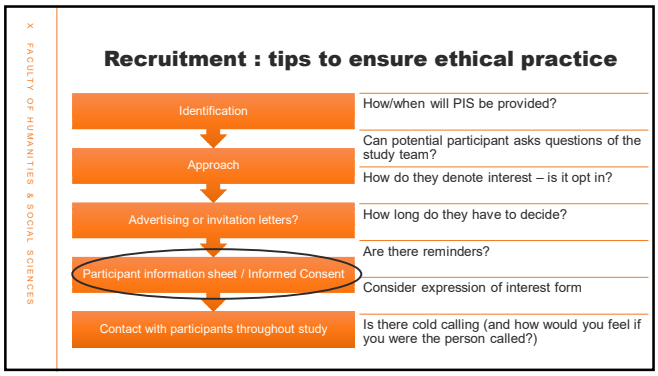
Recruitment : tips to ensure ethical practice

Identification	Who makes initial approach?
Approach	Is this appropriate?
Advertising or invitation letters?	Is this private and confidential?
Participant information sheet / Informed Consent	Does the routine clinical care team overlap with the research team
Contact with participants throughout study	

40


FACULTY OF HUMANITIES & SOCIAL SCIENCES
Recruitment : tips to ensure ethical practice
Identification
Approach
Advertising or invitation letters?
Participant information sheet / Informed Consent
Contact with participants throughout study
Will adverts be used? Let us see them
Be aware of coercive wording
Is there a letter of invitation or cover letter?
Who is this from?
Is it the right person
Think how you would feel to receive any letter

41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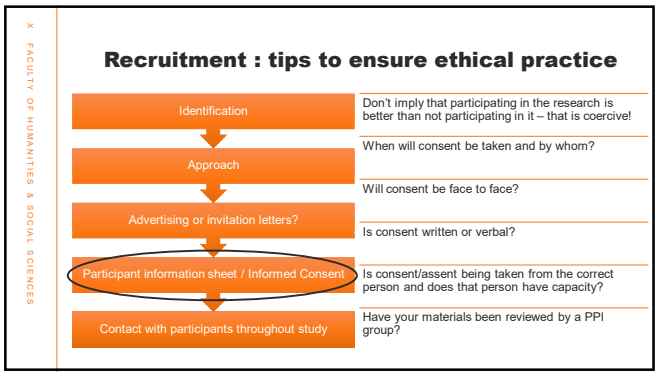
Recruitment : tips to ensure ethical practice
Identification
Approach
Advertising or invitation letters?
Participant information sheet / Informed Consent
Contact with participants throughout study
How/when will PIS be provided?
Can potential participant asks questions of the study team?
How do they denote interest – is it opt in?
How long do they have to decide?
Are there reminders?
Consider expression of interest form
Is there cold calling (and how would you feel if you were the person called?)

42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Recruitment : tips to ensure ethical practice
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Approach
Advertising or invitation letters?
Participant information sheet / Informed Consent
Contact with participants throughout study
Don't imply that participating in the research is better than not participating in it – that is coercive!
When will consent be taken and by whom?
Will consent be face to face?
Is consent written or verbal?
Is consent/assent being taken from the correct person and does that person have capacity?
Have your materials been reviewed by a PPI group?

43

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Recruitment : tips to ensure ethical practice

Identification → Approach → Advertising or invitation letters? → Participant information sheet / Informed Consent → Contact with participants throughout study

Will there be phone calls – when and what for?

Are particpants free to withdraw at any time?

If this is not possible – justify why and make this clear in advance

Normally study interventions should not take place before consent – has this been explained?

44

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Six HRA Design and Review Principles

- Involve **public contributors in the design and review process** to ensure that participant information is relevant and understandable for the intended audience
- Information provided should be **succinct**, and the quantity proportionate to the complexity of the study
- **Language should be as clear** as possible so that key points of information are easily understood
- Format of the information should be appropriate for the **intended audience**
- Written information should be formatted to **optimise comprehension**
- Participant information should always be tailored to the intended **study population**

45

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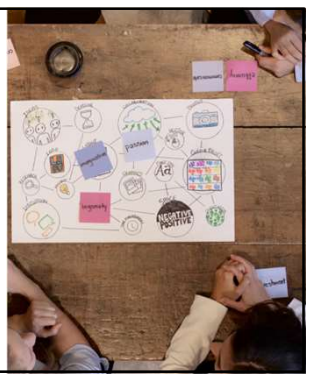
Involve public contributors in the design and review process to ensure that participant information is relevant and understandable for the intended audience

Four principles for public involvement:

- Involve the **right** people
- Involve **enough** people
- Involve **those** people **enough**
- Describe **how it helps**



46

Information provided should be succinct, and the quantity proportionate to the complexity of the study

- Too long: deters people from reading it.
- Quantity of information should be enough to make an informed choice about taking part and no more
- Explain research procedures and risks
- Length will vary depending on complexity.
- Public involvement helps you decide what sections need more detail
- How else can you present the information
- Use a lay summary at the beginning if it helps

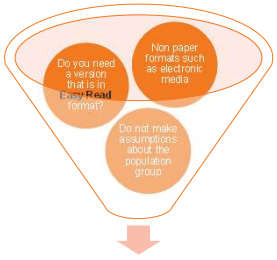
47

Language should be as clear as possible so that key points of information are easily understood

- Think about the **reading age and level** of potential participants
- Write in **plain language**. Check for UK spelling and terminology.
- Do not assume the reader will understand research, medical or legal terminology.
- Tools can assess how clear and useable your information is (Flesch-Kincaid, SMOG, Hemingway Editor), OR **test through public involvement as well**.
- **Visual aids** such as diagrams or pictures as well as words can help
- **Proof read** carefully – ideally someone not familiar with the subject
- Use personal pronouns and **active voice**

48

Format of the information should be appropriate for the intended audience



PPI

49

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Written information should be formatted to optimise comprehension

Accessibility	For the population group: think about dyslexic or neurodiverse readers
Font	Sans serif Minimum 12 point (larger where appropriate)
Text	Use bullet points instead of lists in continuous prose Use headings and subheadings
Important points	Use **bold text** and not text boxes

50

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Participant information should always be tailored to the intended study population

- One size does **not** fit all
- Templates across similar studies can work - tailor for each study
- What content do you need when working with people who will be making participation decision on behalf of others

51

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Ethics committee: validation questions relating to the HRA Quality Standards

- Have all acronyms and abbreviations been explained the first time they are used?
- Has British English been used throughout?
- Has an invitation to participate been included, explaining why the individual has been invited?
- Does the participant information describe what the study is about and the aims?
- Does the information explain who has been invited and why?

52

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Ethics committee: validation questions relating to the HRA Quality Standards

Have the following been included:

- What study participation will involve?
- How long participation will last?
- Where, when and how many times each study activity will be carried out?

Have the potential risks and benefits been described?

Does the information explain to those invited that they **do not have to take** part, they have the **right to withdraw** at a later date and how to do this?

Has a statement concerning **GDPR** been included?

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Ethics committee: validation questions relating to the HRA Quality Standards

Have the following contact details been provided for:

- Who can provide further information should a participant wish to discus the study further?
- Who a complaint or concerns can be reported to?
- A general contact point?
- NB At least one of these should be the Sponsor's Data Protection Officer

54

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Ethics committee: validation questions relating to the HRA Quality Standards

Where the sponsor has its own specific participant information template text (for use over multiple similar studies) make sure that information has been provided in the IRAS form to explain and justify **both** similarities and differences between the current project and those which have previously been approved using the same template text

55

Ethics committee: validation questions relating to the HRA Quality Standards

Where images or graphics have been used, have appropriate accessible alternatives such as captions or alternative text been provided to describe the images?

- Where use of a video has been proposed, has a transcript been included?
- NB: all video information should be subtitled. Scripts/storyboards in lieu of final content are encouraged

56

Ethics committee: validation questions relating to the HRA Quality Standards

Does the IRAS form include details of the patient and public involvement activities:

- Who was involved in the development of the participant information?
- How many people were involved?
- How feedback from public contributors was used to develop the information, including any sponsor-specific template text; and what changed as a result of the feedback

57

Some online examples to help you…

Example materials from https://www.hra-decisiontools.org.uk/consent/examples.html

58

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After NHS Ethics Opinion is provided

Research Governance:

- University? May need additional confirmation
- NHS R&D permission (this is different from ethics)
- IRAS materials
- Participant facing materials
- Legal framework

NHS Research Passport (for non-NHS employees):

- Staff: via HR
- Student: via Faculty Office

- Favourable
- Provisional
- Unfavourable

59

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Any questions?

60