



Strategic approaches for training Stakeholders in Ethics Policy & Procedures

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Strategic Approaches for Research Ethics

- n Background
- n Development of University Ethics Policy
- n Structure of Research Ethics approval system
- n Strategy for roll-out
- n Suggestions for the future



Legislative Background & Issues

- n Research involving NHS
- n Human Tissue Act
- n Research involving animals
- n Data protection legislation
- n Screening of researchers working with vulnerable subjects
- n Professional standards
- n ESRC Research Ethics Framework
- n Emerging Ethics policies of other Research Councils & Foundations



Development of University Ethics Policy

- n Codes of Practice and principles of new Ethics Review Process developed by Committee for Ethics in Research
 - n Research Governance & Quality Assurance – Code of Good Research Practice
 - n Code of Practice for Ethics in Research
- n Essential to have *visible* PVC / Senior Mgmt support
- n Key principles – widely consulted upon:
 - n Applies to all research – Self-regulation check list
 - n Light touch – but rigorous & rapid
 - n Comprehensive review by Ethics Panels of cognate researchers
 - n Transparent & proportional
 - n Underpinned by Monitoring & Audit
 - n Training / communication of best practice



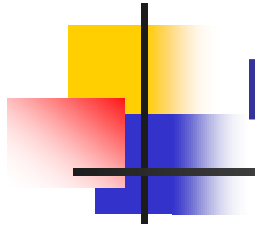
New Ethics Review Process

- n Self-regulation of all research by annual Ethics Checklist
 - n “Nil return”
 - n Light overview by local Ethics Rep
 - n Central storage by Ethics Administrator
 - n Ethical issues arise
 - n Ethics Administrator expedites review via relevant cognate Research Ethics Panel (meets monthly) and 2 expert reviewers
 - n Amendment as appropriate
 - n Approval (or otherwise)
 - n NHS involvement – patients, staff, facilities –
 - n Proposal submitted to local NHS REC
 - n Approval and any conditions logged by Ethics Administrator
- n Processes for: Training/Communication/Monitoring/Audit
- n Policy development / overview by CER



Committees

- n Research Ethics Panels receive from Principal Researchers and/or local Ethics Reps contentious / difficult projects (inc cross-disciplinary projects)
- n Research Ethics Panels
 - n Groups of researchers from cognate research areas
 - n REP membership is Cross-Faculty
 - n REPs replicate existing good practice across HEI
 - n REPs facilitate subject-specific expert guidance
- n REPs review projects with delegated authority from Committee for Ethics in Research
- n Report all actions to CER
- n CER is responsible for policy and overview



Ethics Committee Structure



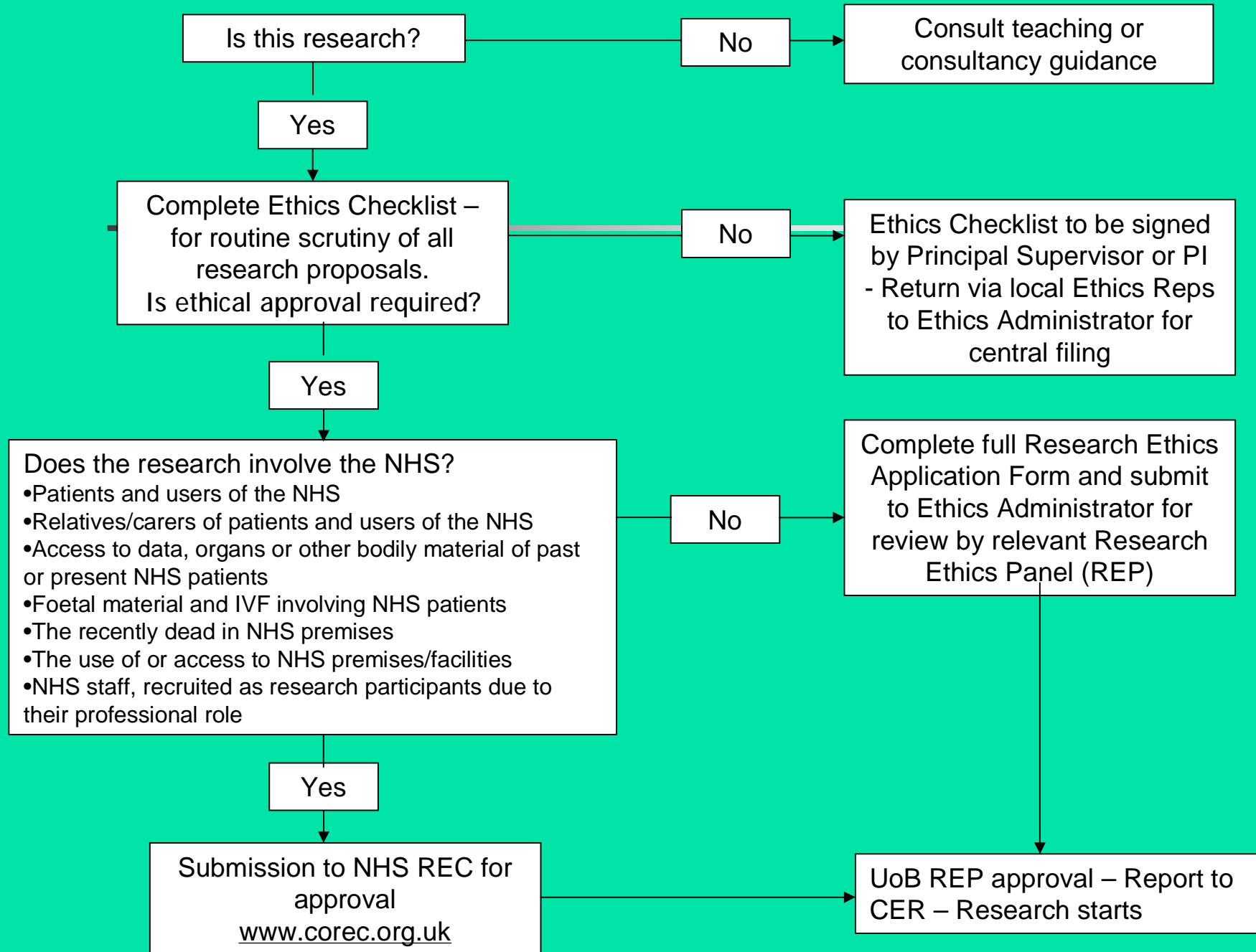
Research Ethics Checklist & Review

- n To be completed for every research project
 - n By Principal Supervisor for Masters and PGRS
 - n By PI for every research programme
 - n Light overview by local Ethics Representative
 - n If negative for ethical implications: signed off by local Ethics Rep and filed by Ethics Administrator for audit purposes



Examples of Self-Regulation

- n Examples of “Nil return” check list:
 - n Research not involving human subjects
 - n With no impact on other areas of society eg environment
 - n Non-confidential or sensitive questionnaires and interviews with non-vulnerable subjects
 - n Research already granted permission by other ethics committees
 - n Procedures authorised as appropriate for self-regulation
- n If positive for ethical implications: Research Ethics Application Form submitted to Ethics Administrator for rapid review by REP





Standard Research Ethics Application Form

- n Standard form – for consistent consideration and audit
- n UB example (selection of 15 categories):
 - n Principal Investigator's and other researchers' details
 - n Type of project –
 - n PGRS or Post-Doc involvement
 - n Involves children or vulnerable subjects
 - n Involves Human Tissue
 - n Lay description of project aims, objectives, duration, funding
 - n Risks and hazards, personal safety issues
 - n Identification & recruitment of potential participants
 - n Informed consent issues & arrangements for confidentiality
 - n Special arrangements for those without English as first language
 - n Safeguards/procedural compliance
 - n "Sponsorship" – Indemnity for negligent or non-negligent harm



Strategies for Training/Communication [1]

- n New process launched across HEI September 2009
 - n Package of info sent to all staff via Deans' Offices
 - n Aim to roll out to all research-active staff / PGRS and achieve compliance in 2 years
 - n Remind Supervisors of their role in ethics training of PGRS
- n All University CER members received prior training
 - n Keele University Research Ethics package – 2 stages
- n All members of 2 Research Ethics Panels received training on new process via Staff Dev package
- n Training package delivered to Research Supervisors and PIs in mixed groups
- n Training package delivered to Departments/Faculties involving local Ethics Reps as presenters



Strategies for Training/Communication [2]

- n Research Ethics package for PGRS – already part of Induction Course (ca 12 years) and ESRC Social Science Training Programme (ca 10 years)
 - n Updated with details and explanation of new process
- n New internet self-evaluation package on Research Ethics – under development
- n Internet and printed communications:
 - n University Staff Handbook – section on Research Ethics
 - n Research Ethics webpages
 - n Research Bulletin
 - n Staff Briefing – weekly email bulletin
 - n Latest news on University intranet home page



Suggestions for the Future

- n Revise both Codes of Practice (triennial requirement)
- n Evaluate impact of Ethics Review processes across University – Questionnaire via eg local Ethics Reps (or Deans/Associate Deans)
- n Review operation of both Research Ethics Panels – sample experience of applicants – and reviewers
- n Establish effective mechanisms for audit against approved Research Ethics Application / NHS COREC
 - n Frequency and depth should be proportionate and recorded
 - n Any actions should be agreed by REP / CER – and PI
- n Review the whole process after 3 years' operation



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