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# Ethics Committee application

- Common Pitfalls and Misunderstandings

*Sue Blowey*  
*Vice-Chair CPREC*

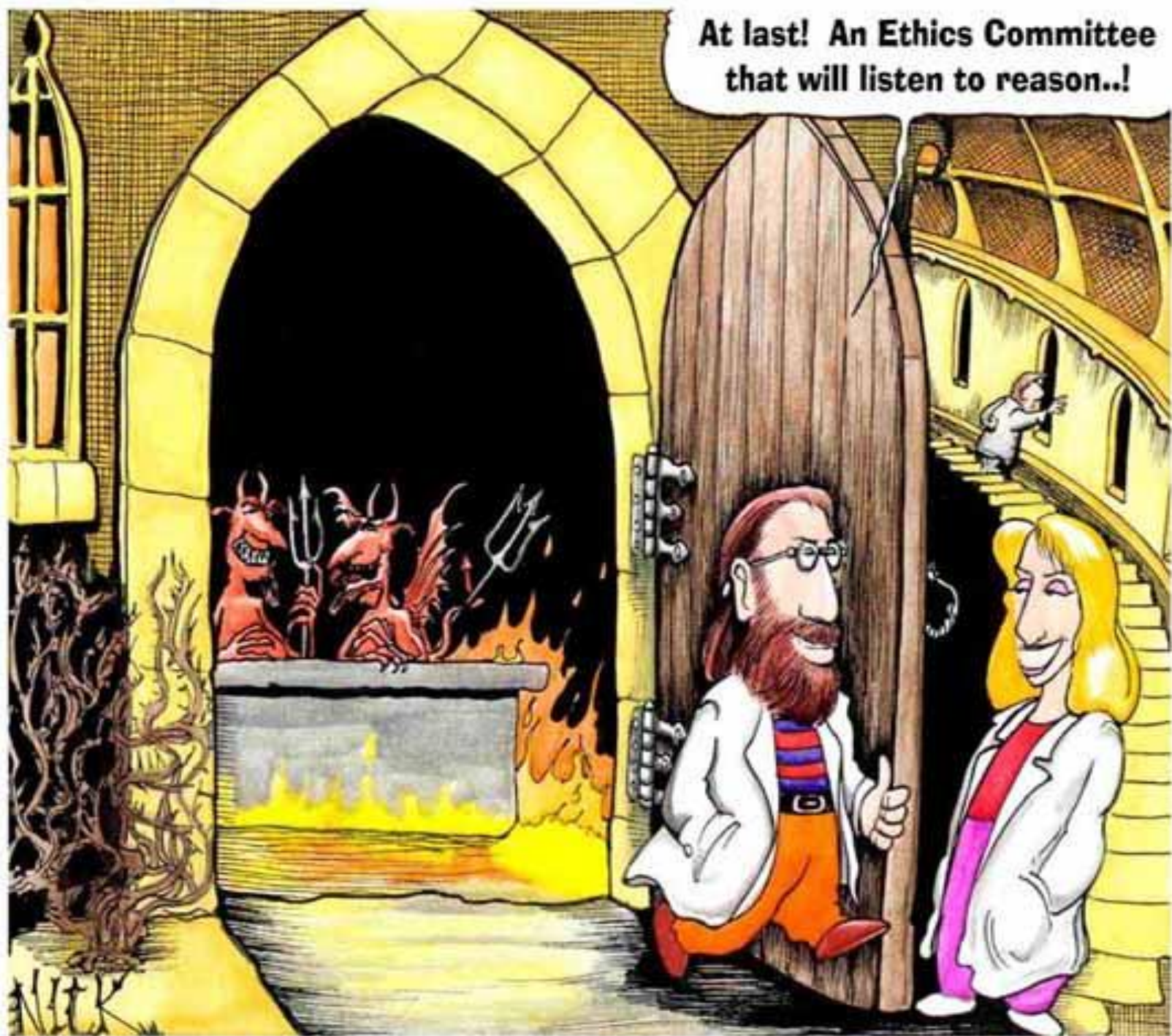


DON'T TRUST HIM,  
DAVID - HE'S AN  
AUTHORITY FIGURE.

Chris  
Madden.

STRANGE MATTER

by nick d. kim [strange-matter.com](http://strange-matter.com)



At last! An Ethics Committee that will listen to reason..!

NICK



# Definition

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- A Research Ethics Committee is defined as a multidisciplinary, **independent** body charged with viewing research involving human participants to ensure that their dignity, rights and welfare are protected.
- **The independence of a REC is founded on its membership, with strict rules regarding conflicts of interest,** and on regular monitoring of and accountability for its decisions.



# Purpose

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- An REC exists to promote and foster good “ethical” research.
- To act as a “critical friend” and not to set itself up as a hurdle for researchers for new projects.
- Not a question of “getting it past” ethics committee!



# Aims

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- Protection of the research participant
- Protection of the researcher
- Protection of the good name of the research institution and research generally.



# Composition

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- Members are not delegates! Each sits as an individual.
- Ideal qualities:-
  - Committed to ethical research
  - Not intimidated by the professionals
  - Team players
  - “Experts” should not predominate – every member has expertise in something.



# Process

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- “Ethos” of a committee can be all important and only partially defined by accreditation and monitoring processes.
- Balance between understanding powers and limitations on its activities - and common sense
- Importance of offering a decision with confidence after due and documented process
  - (but just allowing for the possibility that, on some occasions, a committee **might** have got the wrong end of the stick!)





# Composition

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- Important to use and respect the roles of Coordinator and Chair.
- Ability to separate unimportant detail from substance and to identify main ethical issues. Courtesy to all who use the committee's services. A good committee should not be a "soft touch".
- If necessary, it is important for a committee to be steady "under fire".



# Decision

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- Differences of opinion in the committee are dealt with by discussion and consultation. Votes are only taken rarely.
- The process of discussion is clear and duly recorded.
- Research ethics develops rapidly and new questions and procedures have to be addressed. Ethics committees undergo regular training and updating of individual members.



# Forward working

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- Importance of networking and having ongoing contact with the research community.
- Identify together potential areas of difficulty and possible ways of moving forward together.
- Collaboration need not be collusion!



# REC application – filter page

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- Title of research should match throughout the application
- Ticking the right category box at this stage is important
  - if unsure which category – re due to mixed methods check with Ethics Co-ordinator
- If it is a project that is educational – tick the box



# REC application – summary

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- Cutting and pasting from your protocol at this stage is not advisable
- Lay/expert members who have potentially not understood your protocol will need a clear explanation of your intentions
- This part of application should ‘mirror’ the purpose section of the PIL

# REC application – summary main issues



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- Do not leave blank – if you genuinely believe there are none – say so
- Raise the main ethical issues that you have identified – this allows you to demonstrate your ‘integrity’
- On discussing your project with an appropriate patient body reflect their main concerns?

# REC application – purpose and design



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- Again do not cut and paste from protocol
- Be clear about primary and secondary research objectives
- Scientific justification – present relevant evidence only
- Summary – what is the actual intervention in a paragraph

# REC application – risks and ethical issues



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- Do not to leave blank
- Use language clear
- Put a relative through your proposed intervention / questionnaire – what would you want them to be aware of before they signed up
- Timing of intervention, especially questionnaire – be honest



# REC application – potential research participant



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- Are they in your direct care
- Not in your direct care
- NHS staff
- General Public



# REC application – recruitment

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- Direct approach
- Via invitation letter
- Via poster
- Online
- Timing

# REC application – informed consent



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- Ongoing process
- Context
- Quality of information provided
- Cooling off

# REC application – confidentiality

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- Data
- Overseas
- Paperwork
- Anonymity

# REC application – incentives and payment



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- Is there potential benefits to participants?
- Clear that there may be no benefit
- Payments especially travel
- Is budget is available?
- Vouchers are preferred over cash



# REC application – scientific and stats review

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- All RECS qualified statistician
- Aims and objectives – are they achievable with the methodology chosen?
- Total number of participants – how has this been calculated?
- Pilot?



# REC application – management of research

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- Indemnity and insurance
- Sponsorship
- Governance
- Local R+D



# Research - Protocol

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- Current title and version
- REC application should mirror protocol
- References up to date and relevant
- Protocol should contain more background information than REC application





# Research - CV

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- CV Supervisor
  - Demonstrate expertise clinical area
  - Demonstrate able to supervise previous students
- CV investigator
  - Educational qualification
  - Demonstrate working in the field
  - Demonstrate prior research experience or ICH GCP training



# Research - PIL

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- Use the REC template
- Usually reviewed by Lay members
- Demonstrates your ability to communicate to potential research participants
- Ensure that you explain your methodology and concepts such as randomisation
- Thank the participant at the end



# Research Consent Form

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- Use standard REC template
- Correct title not acronym
- Right version for the right protocol
- Date and signature – same page
- Don't copy and paste from other studies
- Genetic study - should be separate consent



# Research Invitation Letter

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- Sent to the right person to avoid coercion
- Should not be a mini-PIL
- Clear in whom to contact
  - Telephone rather than personal mobile
  - Access 24 hours/day
  - Have you tried this number your self?



# Feedback to include

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- Scientific expert in the field
- Own local peer group
- Patient group
- Feedback R+D submission
- Correspondence with co-ordinator if relevant



# REC meeting

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- Attend
- If unable to attend ensure your availability on the phone
- Take your supervisor if possible – especially if it is their proposal
- Take some support if English is not your first language
- Register question and be clear in your answers



# REC applications – colleagues

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- Nurture in surgery
  - Project - Learning within the operating department
    - Coercion, Conflict of interests/roles, Action poor practice identified.
- Barriers to talent management in Hospital
  - Project – Concept succession planning senior nurses
    - Recruitment, Potential coercion, Action poor practice identified, Docs – not standard REC docs, data storage, poor supervision.



# REC applications - clarity

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- Cell salvage

- Project – vaginal blood loss suitable for re-infusion

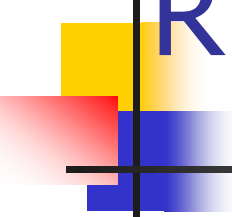
- Scientific rationale – arbitrary volume decided
- Recruitment – several months before intervention
- PIS – not standard, scanty details purpose study, not clear risks and benefits to participants

- Intra-operative GDT

- Project – micro-vascular imaging prior to induction

- PIS – written clearly to establish what is standard and what is





# REC application – ‘hobby horse’

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- Routine urinary catheterisation prior to Caesarean
  - Project – pilot study
    - Protocol not complete version
    - Prior evidence outside UK– proposed against NICE guidelines
    - Data collected would not meet primary objective
    - No independent external review
    - Not clear on participants involvement following discharge
  - Unfavourable opinion
    - Fundamental study changes



# REC application – ‘hobby horse’

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- Routine urinary catheterisation prior to Caesarean
  - Project – resubmitted
    - Data collection tool still did not meet primary objective
    - Review submitted – within department
    - PIL and consent – still not in standard REC format
  - Unfavourable opinion
    - Seek help from a senior colleague