Research governance: getting all the right approvals in place.

What is the difference between Research and Clinical audit?

Audit	Research
Never involves experiments, whether on healthy volunteers, or patients as volunteers	May involve experiments on human subjects whether patients, patients as volunteers or healthy volunteers
Is a systematic approach to the peer review of medical care in order to identify opportunities for improvement and to provide a mechanism for bringing them about	Is a systematic investigation which aims to increase the sum of knowledge
Never involves allocating patients randomly to different treatment groups	May involve allocating patients randomly to different treatment groups
Never involves a completely new treatment	May involve a completely new treatment
Never involves a disturbance to the patients beyond that required for normal clinical management	May involve extra disturbance or work beyond that required for normal clinical management
May involve patients with the same problem being given different treatments, but only after full discussion of the known advantages and disadvantages of each treatment. The patients are allowed to choose freely which treatment they get	May involve the application of strict selection criteria to patients with the same problem before they are entered into the research study
Measures against a standard	Usually involves an attempt to test a hypothesis

http://www.gain-ni.org/index.php/resources/clinical-audit/auditvsresearch

- **RESEARCH** - is designed and conducted to generate new knowledge and should follow the systems for approval of NHS Research
- **AUDIT** - is designed to answer the question "Does this service reach a predetermined standard?"
- **EVALUATION** - is designed to answer the question "what standard does this service achieve?"

Clinical Audit, Service Evaluation or Research?

There is a flow diagram that is quite useful on the link below:

Ref: Developed from the NRES Defining Research leaflet.

http://www.apcrc.nhs.uk/governance/is_it_research.htm

What is research Governance and why do we need it?

Definition: Research Governance can 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.

Why do we need it?:

- Safeguard participants in research
- Protect researchers/investigators (by providing a clear framework to work within)
- Enhance ethical and scientific quality
- Minimise risk
- Monitor practice and performance
- Promote good practice and ensure lessons are learned

HRA Flow chart link:

http://www.hra.nhs.uk/resources/applying-to-recs/nhs-rec-application-process-flowchart/

Top Tips

1) Contact your R& D early on in the process
2) Talk to your R & D department and find out what the process is , what forms are required and an approximate time it will all take ***– this will help you to manage your expectations.***

Sign up for Good Clinical Practice (GCP) training (1 day free training or 2 hours on line) http://brtc.org.uk/

3) Set yourself a ***realistic*** timeline to get through this process i.e. don't contact your R&D department when you need to start your research in 2 or 3 week's time!!! Also allow enough time for data collection and also for data analysis and writing it up, (however long you think it will take – add half that amount of time on top).
4) Think about how you will record and save data, do you need to pass data to colleagues within the organisation or outside of the organisation?
5) You may need to get advice from your Information Governance team for questions such as:
    - Do you need a safe-stick ?
    - Where and how are you going to store information, is it secure and in compliance with your organisations rules?
    - Do you need to share data? – get advice from your Caldicott Guardian
    - How long will you need to keep documents after the study has ended.
6) Will you need any public engagement (PPI) - to contribute to the design your study or perhaps to have a representative sit in and contribute to your meetings?
7) Register on IRAS (Integrated Research Application System) and do the 15 min trial to familiarise yourself with the system. Note: there is a way to save a PDF copy of your form if you need to forward it to anybody for checking.
8) If you follow the first two sections (blue and green) 'Stages of Research' then the research approval section will be easy.
9) Allow your Research and Development department to guide you through this stage.

All the very best with your future research!!!

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