UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

How to prepare successful ethics clearance applications

Monday, 29 July 2019

Purpose of presentation is to

- Assist researchers to prepare ethics clearance applications that will be successful after their first submission.
- Thus save time and allow research to proceed
- This invention focuses on the practical details related to submitting an application to HREC-Medical

What this session is NOT about

- A philosophical debate of the ethics of medically orientated research

Please remember no research that places people, animals or the environment at risk of harm, either directly or indirectly, can be conducted without prior approval of the ethics of the proposed research.

Retrospective ethics approvals are NOT allowed.

Context in which ethics are considered

- HREC stands for Human Research Ethics Committee. There are two of them:
  - Medical: focus on work done in hospitals, work done on patients, medical procedures, etc.
  - Non-medical: focus on questionnaires, interviews, etc. outside of hospitals
- Animals Research Ethics Committee (AREC)
- Biobanks – approve ethics of 'sample' storage
- Institutional Biosafety Committee (IBC) – for GMOs etc.

Modus operandi of RECs

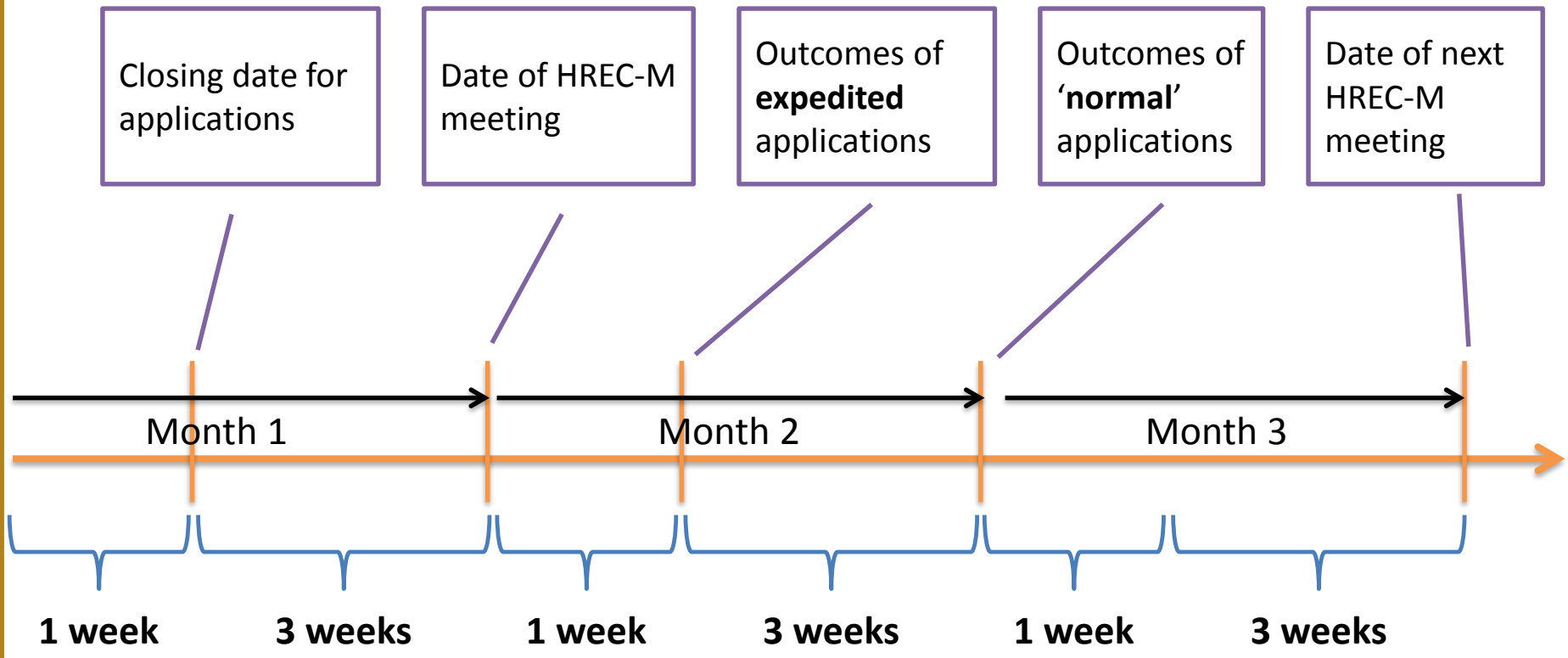
- Make decisions based on peer review
- Peer review relies on the opinion of independent experts
  - Independent implies they have no interest in the outcome of decisions made
  - Experts mean they are knowledgeable about the field of research being contemplated, if not specifically, generally

HREC-Medical Context

- HREC-M sits every month of the year bar December
- Applications are accepted up to 3 weeks before the meeting – why because reviewers need time to prepare
- The committee reviews between 70 and 100 applications every month
- The reviewers do the work as part of their service to academic citizenship
- Their workload is high

Duration of the process

- **You should expect a minimum turnaround time of 7 weeks from submission to outcome for 'normal' applications**



This assumes your protocol is approved on the first attempt.

Please plan well in advance

Re-emphasising the duration of the process

Assume you submit an application which gets returned for minor amendments (which is the case in 85% of applications. How long will this take?

- **Submit original 3 weeks before a HREC-M meeting**
- **Outcome of 'normal' application due within 4 weeks**
- **You have 1 week to make amendments and resubmit before closing date**
- **3 week delay before next meeting**
- **Outcome of expedited application due within 1 weeks**

- **Total time = 3 + 4 + 1 + 3 + 1 = 12 weeks (3 months)**

Make sure your application only needs one turn at the committee

Thus it is important to strive to avoid getting this result …

Approved subject to amendments!

Well this is better than not approved, but these are surprisingly rare, maybe less than 1%

3 TIPS TO AVOID HAVING TO MAKE AMENDMENTS

Help the reviewers to declare your proposed research ethical: #1

- Describe the science carefully but simply:
  - Do not assume the reviewer knows the details of the science,
  - Explain the detail without talking down to the reviewer,
  - As Albert Einstein said, if you cannot explain it to your grandmother, it probably means you do not understand it yourself.

Help the reviewers to declare your proposed research ethical: #2

- Make sure that questions you ask in the study participants are appropriate:
  - Think of age, education level, social circumstances,
  - Test your questions with a colleague or some other (non-vulnerable) independent person

Help the reviewers to declare your proposed research ethical: #3

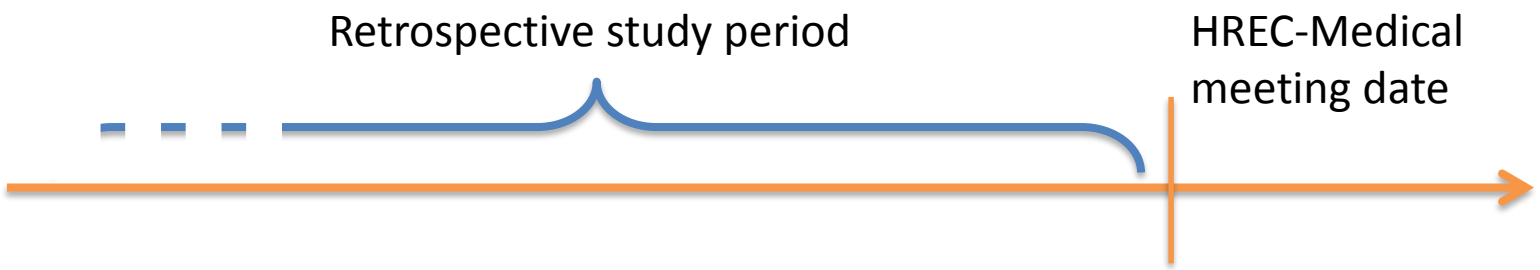
- Check your application before submitting it:
  - Does it have all the signatures?
  - Are all the sections completed?
  - Have you included all the attachments?
  - Use the check list provided to assist with this.
  - Use the check list provided on the website (https://www.wits.ac.za/research/researcher-support/research-ethics/ethics-committees/).

- Delay by a day to check all is in order rather than rushing and having to wait for a month

AVOID THESE COMMON ERRORS

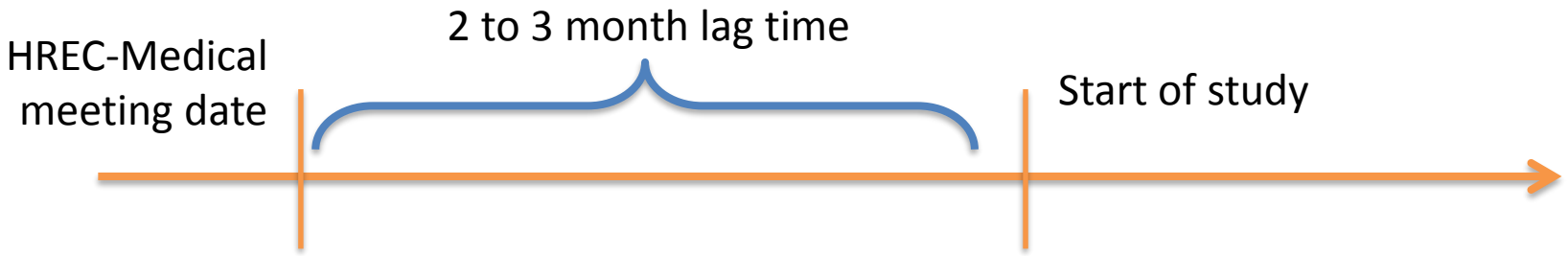
Errors related to timing issues

- Retrospective studies are studies that use previously collected material, e.g., previously captured medical records
- And therefore the period of the study cannot extend beyond the date of the HREC meeting



More errors related to timing issues

- Prospective studies
  - Studies in the future, collecting future material
  - Therefore, can only schedule data collection after the approval of ethics, that is award of the certificate
  - Turn around time, if the application is perfect, will be between 7 and 28 days
  - Better to prepare 2 to 3 months in advance



Data Collection

- Remember when collecting data to make sure you do not collect any unique identifiers
  - make sure that the data is anonymous
  - Do not say things like “we will endeavour to keep participant data confidential.”

- If this is not possible take care that your data and the identifying elements are stored separately, with a link to the data file

Forms

- Data collection form – make sure it is clear, complete and fully descriptive of all the data to be collected
- Information sheet – this is used to inform subjects, use the template provided on the website: https://www.wits.ac.za/research/researcher-support/research-ethics/ethics-committees/
- Consent form – this is signed by the subjects
- Do not use overly technical language in any of these forms

Signatures

1. The following signatures must appear on the application forms:
   - Applicant
   - Supervisor (where applicable)
   - Head of Dept. / Head of Entity / Dept. Re
     Coordinator

Without these the application will be sent back for signing

Other typical mistakes to avoid

- Use of very technical language in a participant information sheet
- Typos in the participant information sheet
- Typos in the consent form
- Use of one consent form for different interventions, please separate them

More typical mistakes to avoid

- Statements like, “we will make an effort to keep your data confidential”

- Use of very long questionnaires – think about your participants

Remember to

- Complete all sections of the application form
- Arrange a pre-screening

WE WISH YOU GOOD LUCK