

3 May 2024

## **HREC-Medical Timelines and Communication Processes**

The Wits University Research Office and the WHC HREC Administration Team are very conscious of the pressures on students, both undergraduate and postgraduate, and researchers to initiate their research projects as soon as possible. In this context apparent delays in the HREC approval of research can be frustrating. However, it must be remembered that the process of approval rests jointly with the administration and the applicant. It is, therefore, important that the administration adhere to strict timelines, but equally important that applicants know and follow these timelines.

Thus, to ensure a smooth and efficient review process, the HREC Administration wishes to share the following timelines and communication processes with the research community in the Faculty of Health Sciences and the University as a whole. These timelines and processes will be implemented from June 2024 to help ensure a smooth ethics approval process for everyone.

We kindly ask all applicants and reviewers to adhere to these processes.

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# 1. Review of Commercially and/or Grant Funded Studies including Clinical Trials (WHC):

#### 1.1 The Timelines

The timeline is illustrated in Figure 1 for the months of June and July, as an example, and is described below in general terms.

- 1. **Deadline for the submission of applications**: The third Friday of the month before the HREC-Med Clinical Trials meeting.
- 2. Time for applications to be allocated to selected HREC-Med Reviewers: Within 7 days.
- 3. **Reviewing of applications**: 14 days with the deadline second Friday of the month (i.e., 7 days before the HREC-Med Clinical Trials meeting).
- 4. **Meeting preparation**: 7 days.
- 5. **WHC section of the HREC-Med Clinical Trials Meeting**: Third Friday of the month.
- 6. **Outcomes sent to applicants**: within 14 to 21 days after the meeting depending on workload.

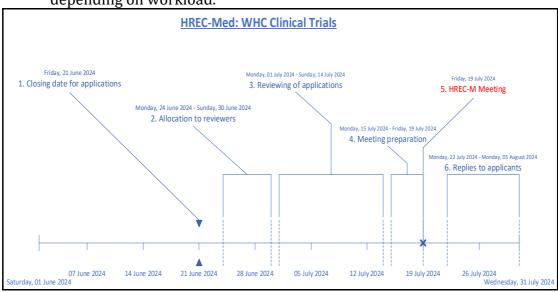


Figure 1: Timeline for WHC HREC-Med Clinical Trials

Thus, for a perfect application proposing ethical research that requires no alterations, the turnaround time from submission to certificate is more than six weeks (45 days).

#### 1.2 Communication Channel

Contact Mrs Jennifer Palmer:

<u>ipalmer@witshealth.co.za</u> or <u>jennifer.palmer@witshealth.co.za</u>

## 2. Review of Wits Undergrad and Postgrad degrees, studies not for degree purposes, and case reports

#### 2.1 The Timeline

The timeline is illustrated in Figure 2 for the months of June and July, as an example, and is described below in general terms.

- 1. **Deadline for the submission of applications**: The third Friday of the month before the HREC-Med research meeting.
- 2. Time for applications to be allocated to selected HREC-Med Reviewers: Within 7 days.
- 3. **Reviewing of applications**: 14 days with the deadline third Friday of the month (i.e., 7 days before the HREC-Med research meeting).
- 4. **Meeting preparation**: 7 days.
- 5. **HREC-Med Research meeting**: Last Friday of the month.
- 6. **Outcomes sent to applicants**: within 14 to 21 days after the meeting depending on workload.

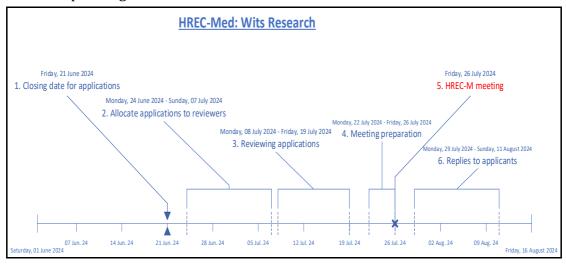


Figure 2: Timeline for Wits HREC-Med Research Office

Thus, for a perfect application proposing ethical research that requires no alterations, the turnaround time from submission to certificate is more than seven weeks (51 days).

#### 2.2 Communication Channels:

Contact: Wits Research Office Research Team:

HREC-Medical.ResearchOffice@wits.ac.za or iain.burns@wits.ac.za

### 3. HREC-Med Scoring System

The scoring system used to code the outcomes of the review process is based on a six-point scale as described below. Please look out for the score assigned to your application as this has an impact on the turnaround time.

- 1. Approved unconditionally (also referred to as full approval).
- 2. Approved subject to minor revisions delegated to the Secretariat and chair to complete.
- 3. Pending approval subject to response to comments provided by the Reviewers, to be resolved by the original Reviewers.
- 4. Not approved as requires major revision and/or Reviewer comments to be resolved. Will require review at the next HREC-Med meeting
- 5. Rejected in the current form. Must be resubmitted and will receive a new application number and review timeline.
- 6. Rejected due to substantive ethical concerns, will not be reviewed again.

#### Note:

- Turnaround time for applications with scores from 2 to 4 will be extended and will depend on Applicant's timeous responses to HREC-Med meeting decisions.
- Applicants should respond to HREC-Med decisions within 7 days, but this may be extended on request if the Applicant needs more time.
- Category 2 replies will be assessed in-house as soon as possible.
- Category 3 responses go back to the original reviewers who have 7 days to reply.
- Category 4 studies which need to be discussed at the next HREC-Med meeting will result in delays in approval.

## 4. Applicant's Concerns

Any concerns held by an Applicant are best dealt with through email to the Secretariat using the email addresses provided above.

Impasses and major concerns may be addressed by face-to-face or virtual meetings between Applicant(s) and HREC-Med Chair, Co-Chairs, Reviewers, and/or Secretariat as applicable to expedite the review and approval process.

Requests for such meetings may come from either the HREC-Med or from the Applicant(s) and will be arranged expeditiously depending on all parties' availability.

## 5. Principles to Govern All Correspondence:

All correspondence should be cordial, collegiate, and professional.

Rude or threatening emails or letters will not be accepted and will do nothing to speed up turnaround times.