

Ethics Committee for Language Matters (ECLM)

STANDARD OPERATING PROCEDURES OF THE ECLM

ETHICS OFFICE		Standard Operating Procedure	
Title	Standard Operating Procedures		
SOP no	1	Version no	2
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Web address	Not applicable	Page no	1 - 11

1 COMPILATION AND AUTHORISATION

Action	Designated person	Signature	Date
Compiled by:	Chairperson ECLM: Prof AS Coetzee-Van Rooy		
Checked by:	ECLM committee members		
Authorised by:	SCRE		

2 DISTRIBUTION

Department/Unit	Name	Signature	Date
ECLM members	See membership list		
UPSET Director	Prof HG Butler		
RULL Director	Prof D Scott-Macnabb (until 30 June 2021)		
RULL Director	Prof P Van Schalkwyk (from 1 July 2021)		

3 DOCUMENT HISTORY

Date	Version no	Reason for revision
January 2020	1	Not applicable, first version of the SOPs
May 2021	2	Alignment of ECLM Procedure document & SOP to clarify decision making processes; improving the layout of the SOP by e.g. adding numbers instead of bullets

4 PURPOSE OF THE SOP

- 4.1 **Purpose:** These terms of reference provide guidelines and a minimum standard of procedure for the ECLM operational management of the ethics process within the Faculty of Humanities. It ensures the core purpose of the ECLM to protect the dignity, rights, safety and well-being of all human participants in language related research done by staff and registered students of the NWU in the Faculty of Humanities.
- 4.2 **Status:** The Ethics Committee for Language Matters (ECLM) is an independent committee of the Faculty of Humanities of the North-West University, functioning in collaboration with the Human Social Sciences Research Ethics Committee (HSSREC) and HREC.

5 SCOPE

- 5.1 The ECLM will review, for ethics approval purposes, studies within the broad field of humanistic disciplines that research human language use in social, political, institutional, cultural and historical environments and developmental contexts, that are of minimal risk and do not involve vulnerable groups, children and health or health-related research.
- 5.2 Each of the eight Faculties of the North-West University have Research Ethics Committees (REC's) responsible for overseeing and managing compliance with the requirements of ethical research in *minimal risk studies*.
- 5.3 The ECLM is not mandated to review research:
- Should the study involve *vulnerable participants* and/or be a *greater than minimal risk study* (medium or high). The ethics applications should then be referred to an appropriate National Health Research Ethics Council (NHREC)-registered REC, based on the focus of the study. The relevant REC within the Faculty of Humanities is the registered NWU Human Social Sciences Research Ethics Committee (HSSREC).
 - Should the study be "health or health-related", statutory regulations require that review is done by a NHREC-registered Health Research Ethics Committee, or the NWU-HREC.
 - Should the study topic otherwise fall outside the expertise of a particular Faculty REC, the ethics application should be referred to a REC with appropriate expertise.
- 5.4 All research proposals/protocols must be evaluated and approved by a Scientific Research Committee within the different schools/research entities of the Faculty of Humanities prior to applying for ethics approval of projects/studies (A-rule 4.9.4 of 2019).
- 5.5 Research proposals should be provisionally classified according to risk levels (no; low/minimal; medium; high) by these Scientific Research Committees and the ECLM will verify this classification. All proposals pertaining to human participants must be approved by ECLM prior to any research commencing.
- 5.6 Proposal/protocols of projects/studies with apparently no risk (systematic literature reviews, postal surveys with validated questionnaires, unidentifiable electronic surveys and public observation without identification or intervention, etc.) must also be sent to the ECLM for confirmation of no risk and for ethics clearance and noting.
- 5.7 All ethics applications for new projects/studies, sub-study inclusion under approved umbrella projects and amendments to or extensions of approved projects/studies must be evaluated and approved by the ECLM and signed by the ECLM chairperson.
- 5.8 ECLM will follow a collective decision-making process, including:
- The ECLM chair aggregates the individual reviews of an application by at least two ECLM academic members.
 - The ECLM chair considers the ethical implications implicit in the contents of these two reviewers' reports.
 - The ECLM chair distributes a compilation of these reports to students and supervisors.

- The ECLM chair engages in analogue reasoning with the reviewers, students and supervisors with the aim to achieve consensus. This could involve a series of conversations facilitated by the chair between the reviewers and the applicants (students or staff).
 - In instances where consensus is not reached, a decision is reached via secret ballot with the full ECLM. Should the votes be equal, the Chair has the deciding vote.
 - After ratification the ethics approval letter is sent to the applicants by the chair.
- 5.9 Written ethics approval from the ECLM followed by an Ethics Approval Certificate from the North-West University SCRE (Senate Committee for Research Ethics) must be obtained before commencing any project/study.
- 5.10 The ECLM will, in line with NWU research ethics policy, not consider research studies for approval if it is apparent that the data collection for the research has been completed or has been started. Such retrospective projects/studies will immediately be terminated.
- 5.11 ECLM-members are required to have the necessary/relevant expertise about the subject matter and about research ethics principles.

6 ABBREVIATIONS AND/OR DEFINITIONS

Abbreviation/definition	Description
ECLM	Ethics Committee for Language Matters
NWU SCRE	North-West University Senate Committee for Research Ethics
REC	Research Ethics Committee
SOP	Standard Operating Procedure
HSSREC	Human and Social Sciences Research Ethics Committee
HREC	Health Research Ethics Committee
FoH	Faculty of Humanities

7 RESPONSIBILITIES

Table 1 below sets out the responsibilities of applicants and of the various members of the ECLM.

Person	Responsibilities
Researcher	<p>Attend at least one session of NWU or Faculty-facilitated ethics training or, in the case of students, verify that this was provided by study leader. As far as possible, students are encouraged to attend such training.</p> <p>For own research projects, timeously submit a completed, participant-respecting application that includes all necessary documents.</p> <p>Timeously and diligently responding to recommendations for revision</p> <p>Inform ECLM in writing as soon as any part of protocol/research design changes.</p> <p>Report all adverse events relating to your study's participants to ECLM (even if these do not apparently relate to your research).</p> <p>Provide annual written and/or verbal feedback to ECLM on ethical aspects of your research, particularly ethical issues/risks that were not predicted beforehand.</p>
	<p>Convene meetings as needed.</p> <p>Facilitate ECLM meetings and optimal turnaround time for applications.</p>

Chairs	<p>Declare all conflicts of interest.</p> <p>Assign reviewers.</p> <p>Review all applications and peruse all reviewers' reports (i.e., note all ethical red flags not identified by reviewers).</p> <p>Facilitate deliberation about and final approval of applications.</p> <p>Sign off on all approved applications within one week of their final approval.</p> <p>Monitor that ECLM only review ethics applications as specified by its scope of practice.</p> <p>Train or arrange for training of faculty-affiliated researchers/students to submit efficient applications.</p> <p>Be a whistle-blower about unethical research practices within the faculty.</p>
ECLM academic members	<p>Attend all scheduled meetings.</p> <p>Be available for extraordinary meetings as needed.</p> <p>Declare all conflicts of interest.</p> <p>Review applications, as requested, within 10 working days and submit reviews to the Chair and Administrator.</p> <p>Engage in deliberation about and final approval of applications.</p> <p>Finalise further review requested within 3 calendar days.</p> <p>In the case of major revisions, re-review application and present findings to ECLM Chair.</p> <p>Continuously sensitize colleagues and students to the importance of ethical research.</p> <p>Be a whistle-blower about unethical research practices within the faculty.</p>
ECLM community members	<p>Attend scheduled meetings.</p> <p>Be available for extraordinary meetings as needed.</p> <p>Declare all conflicts of interest.</p> <p>Review applications, as requested, within 10 working days and submit reviews to the Chair and Administrator.</p> <p>Engage in deliberation about and final approval of applications.</p> <p>Be a whistle-blower about unethical research practices within the faculty.</p>
Administrator	<p>Facilitate all correspondence between applicants and ECLM, including:</p> <ul style="list-style-type: none"> • Checking completeness of applications and requesting outstanding documents from applicants. • Forwarding all complete applications to chairs. • On chairs' advice, sending applications to reviewers, including review report templates. • Sending letters of feedback to applicants as advised by the chairperson. This is done on ECLM template. • In cases of minor revision, forwarding applicant revisions to reviewers for approval and facilitating further exchanges as needed. • In cases of major revision, forwarding applicant revisions to reviewers for re-review. • Once approved, formulating an ethics approval letter, which will be signed off by the chairperson or vice chairperson (if applicable), and sending this to applicant and SCORE administrator. <p>Record the dates of all of the above and include this record in agendas/minutes.</p> <p>Finalise agenda prior to scheduled meeting date.</p>

	<p>Facilitate signing when necessary, of confidentiality, conflict of interest, and permission to audio-record meeting by all ECLM meeting attendees at the beginning of the meeting (and as applicants enter the meeting).</p> <p>Take the minutes. Send minutes to chairs for approval one week prior to scheduled ECLM meeting.</p> <p>Keep a clear document trail (electronic and paper copy) for 10 years.</p> <p>Store audio-records of ECLM meetings in password-protected computer for 10 years.</p> <p>Prepare draft annual reports for the ECLM that are also reviewed by the Faculty Board and SCRE.</p>
Ad-hoc member(s)	<p>Review applications where additional subject/professional expertise is required to fully comprehend the ethical implications of an application.</p> <p>Submit written review to ECLM Chair within 10 working days.</p>
Study leaders	<p>Support student to submit a complete, effective application. To this end study leaders need to attend at least one NWU or Faculty-facilitated ethics training session and train their students in research ethics as part of their supervisory responsibilities.</p> <p>Support student to timeously and diligently respond to recommendations for revision.</p> <p>Ensure that student informs ECLM in writing as soon as any part of protocol/research design changes.</p> <p>Ensure that student reports all adverse events relating to study's participants to ECLM (even if these do not apparently relate to study).</p> <p>Support student to provide annual written and/or verbal feedback to ECLM on ethical aspects of their research, particularly ethical issues/risks that were not predicted beforehand.</p> <p>Take ultimate responsibility for students conducting ethical research.</p>

8 PROCEDURE/S

STANDARD OPERATING PROCEDURES (SOP) of the ECLM

8.1 PURPOSE OF THIS SOP

- This SOP supports processes for speedy approval of all ethics applications by the ECLM.
- This SOP promotes understanding of the responsibilities of the ECLM chair, co-chair, 10 committee members (academics, potential community members), potential ad-hoc members, administrator, and applicants.
- This SOP will explain the requirements for all ethics applications.
- The purpose is to establish a clear line of responsibility for submitting, evaluating and approving ethics applications.
- This SOP will be approved by the ECLM and reviewed every 1-2 years where necessary amendments will be made.
- In the case of administrative support not being available, the ECLM chair or another appointed ECLM member, will fulfil all activities ascribed to the Administrator in the following documents.

8.2 MEMBERSHIP

ECLM consists of a chair, a vice-chair (if applicable), 10 committee members (academics) and an administrator. Where applicable, research interns may be invited to sit on the committee (for the duration of their internship) with observer status as part of their training, after they signed confidentiality agreements.

The term of ECLM membership is five years, depending on the agreement with and availability of the committee member and the NWU SCREs regulations for terms.

New ECLM members are approved by the ECLM, the Faculty Board and SCRE and on appointment, will sign an appointment letter, confidentiality clause and a code of conduct. New members will also submit an updated CV to the ECLM administrator. The appointment of academic members must reflect in their task agreements as staff members.

8.3 MEETINGS

ECLM meetings will be held once a month or electronically when necessary to prevent undue delay of finalization of applications.

All ECLM meetings will be guided by a complete agenda.

The ECLM chair, committee members (academic and community), and the administrator will attend all the meetings to ensure a 60% quorum. The Administrator and intern/interns will not be part of the 60% quorum. Members must inform the Chair/Administrator prior to the meeting if they will not be able to attend.

Ad-hoc ECLM members will be requested to attend meetings as the need for their expertise may arise.

If applicable: Applicants (or their delegate if not available – i.e. someone involved in the study) could (as applicable) be invited by ECLM to a specific meeting. Applicants (or their delegate) may be asked to address ethics issues that might arise from an application during the meeting. Following the meeting, applicants could be asked to repeat the answers given, in writing, and/or to correct/amend an application and send these together with a cover letter explaining the corrections/amendments, to the ECLM administrator as soon as possible.

ECLM members will disclose conflict of interest and agree to uphold confidentiality of all discussions and decisions about ethics applications during meetings.

Minutes will be taken by the Administrator at every meeting and approved at a following meeting. Permission will be asked to audio-record face-to-face meetings and the Administrator will archive the recordings for 5 years. In the event of online meetings, permission will be asked to record the meeting and the Administrator will archive the recordings for 5 years. In the event of electronic / email meetings, the written records of participating members will be archived by the Administrator for 5 years.

8.4 CORRESPONDENCE

All correspondence with regards to new applications, amendments to or extensions of approved projects/studies, sub-study inclusion under umbrella projects as well as responses to recommended amendments and inquiries must be sent to the ECLM Chair/administrator.

The ECLM Chair/administrator will ensure that all correspondence reaches the relevant parties. The supervisor is the main relevant party. If email details of the students are known, they will also be included in the correspondence.

ECLM will enter into no correspondence with sponsors/funders of research projects. ***All correspondence is with applicant and study leader/promoter.***

The ECLM chair will correspond with research participants who have comments / queries /concerns/ complaints about ECLM-approved studies or studies by researchers affiliated with the FoH that relate to human participants.

8.5 NWU ETHICS APPROVAL CERTIFICATES

All Ethics Approval Certificates will be issued by the North-West University SCRE secretariat after approval by the ECLM, final approval by the ECLM chair and receiving an official approval letter from the ECLM.

The project title, project leader, ethics number, approval date and expiry date will be indicated on the Ethics Approval Certificate.

8.6 ETHICS APPLICATIONS FOR NEW PROJECTS/STUDIES

It is the responsibility of the researcher/project leader/study leader/promoter to submit ethics applications, using the official NWU ethics application form as available on InfoEd or the ECLM- approved form available from the ECLM Chair/Administrator. *Students should complete ethical applications under supervision of study leaders/promoter. The final responsibility remains that of the study leaders/promoter because the student works under her/his supervision.*

All ethics applications must be submitted to the ECLM Administrator and include the official, fully-completed application form, the completed NWU checklist, a Scientific Research Committee approved research proposal/protocol (with a letter from the chair of such committees as proof of the aforementioned), an abbreviated CV for applicant/team of applicants and *language edited* informed consent documents using ECLM's template (obtainable from Chair/administrator). If questionnaires/recruitment documents (e.g., flyers, posters) are going to be used they should also be included. If interview protocols will be used, these should be included too. If gatekeeper clearance has already been secured, all gatekeeper approval documents should be included. If the application for gatekeeper clearance follows after ethics clearance, applicants are reminded to apply for relevant gatekeeper clearance after they secured ethics approval. Applicants must notify the ECLM Chair/administrator that their application has been submitted.

The ECLM Chair/administrator will ensure that all the relevant documentation is included with every application before sending the approval request to the ECLM chair for reviewer selection and placing it on the agenda for the next meeting. The ECLM administrator will print the application and open an application ledger.

If applicable, the ECLM administrator advises the applicant (or delegate if not available) at which meeting the application will be evaluated. Where applicable the applicant (or delegate) could be invited to attend the ECLM meeting and represent the application should reviewers have questions. Attendance also has educative potential.

The ECLM chair assigns two reviewers to each application. Reviewers will evaluate applications and present their evaluation (using the ECLM reviewer form) to the Chairperson who will steer a feedback process. Thereafter the ECLM will engage in a process of noting, ratification and/or discussion and consensus, culminating in a decision to either approve with minimal/minor corrections, defer because of major corrections, or disapprove the applications.

A rebuttal report by the applicant should be returned as soon as possible to the ECLM Chair/administrator, along with written response to the feedback document (explaining where and what corrections/amendments were made). The administrator will pass these on to the original reviewers. Reviewers have 5 working days to review, confer and approve, or confer and request further minor revisions (the latter speaks to the teaching mandate of the university: reviewers support applicants to perfect application). Should reviewers not have consensus, the chair and vice-chair (if applicable) will arbitrate. Should approval be recommended, the final information/consent documents must be forwarded (via the administrator) to the chairs to be signed off. Once approved by the appointed committee members (the chair and the original reviewers), the ECLM administrator will formulate an ethics approval letter, which will be signed off by the chairperson or co-chairperson (if applicable). The ECLM administrator will send the ethics approval letter to the applicant and to the North-West University SCRE secretariat and request a NWU certificate of approval.

Major revisions may require ECLM review at a formal, scheduled ECLM meeting. After amendments have been submitted to the administrator, along with response to the feedback (rebuttal) letter, the application is placed on the relevant next ECLM agenda. The administrator sends the revised documents and applicant response to the Chairperson and the same reviewers for re-evaluation. This is followed by presentation of the application process to date at the relevant ECLM meeting by the chair or the applicant or her/his delegate, and a debate to reach a consensus decision follows (i.e., approve, approve with minimal/minor corrections, defer again because of major corrections, or disapprove).

It is also the responsibility of the researcher/project leader/study leader/promoter to support the necessary corrections/amendments to ethics applications. Students should be guided in this process.

Once approved by ECLM, the applicant must submit a set of completed, updated, corrected study documents (proposal, informed consents, and participants' information leaflets) to the ECLM administrator. These documents must indicate the final ethics approval number and respective date in a header or footer format. If the informed consent letters will be used in a language other than English, the translated versions (designed for Gr 8. readership level) must be submitted to ECLM at this final stage too.

The North-West University SCRE secretariat will issue and send an official NWU Ethics Approval Certificate to the applicant after receiving the ethics approval letter.

The North-West University SCRE secretariat will send a copy of the official NWU Ethics Approval Certificate to the ECLM administrator as proof of issue.

Table 2: ETHICS APPLICATIONS FOR NEW PROJECTS/STUDIES**(Summary of process)**

1	Submit ethics application on the appropriate application form together with all the relevant forms.	Applicant
2	Applicant to notify ECLM administrator once the application is submitted.	Applicant
3	Administrator to ensure inclusion of all relevant documents before sending approval request to ECLM chair.	Administrator
4	Administrator print complete application and open application ledger for every application	Administrator
5	ECLM chairs to assign two reviewers to every application. Administrator notifies reviewers and sends them the full documentation	ECLM chair Administrator
6	Reviewers submit finalised reports on ECLM report forms no later than seven (7) calendar days.	Reviewers/administrator
7	Administrator collates reviews as recommended by the Chair and sends letter of feedback to applicant.	Administrator
8	Applications with revisions and a rebuttal letter to be returned to administrator as soon as possible.	Applicant
9	Applications with major revisions to be reviewed again by a formal ECLM meeting after amendments were completed by applicant.	Applicants/reviewers
10	Approved applications must be submitted to administrator together with complete set of corrected study documents.	Applicant
11	ECLM to submit ethics approval letter to NWU SCORE.	Administrator
12	NWU SCORE secretariat to issue official NWU Ethics Approval Certificate to applicant.	NWU RERC secretariat
13	NWU SCORE secretariat to send copy of NWU Ethics Approval Certificate to ECLM administrator	NWU RERC secretariat
14	ECLM to monitor research ethics care via Annual Monitoring reports.	ECLM chair and administrator

8.7 ETHICS APPLICATIONS FOR SUB-STUDIES TO BE INCLUDED UNDER UMBRELLA PROJECTS AND/OR AMENDMENT/EXTENTION OF SUB-STUDIES UNDER UMBRELLA PROJECTCS

All ethics applications for sub-studies to be included under umbrella projects must be submitted on the ECLM *Application for approval of sub-studies under umbrella projects* application form, available from the ECLM administrator.

A written permission letter must be obtained from the umbrella project researcher/project leader/study leader/promoter to include additional studies and be submitted with the application.

The remaining steps/processes are exactly the same as for new project/single study applications.

See Table 2 Ethics Applications - Summary of process

8.8 APPLICATIONS/REQUESTS FOR AMENDMENTS TO OR EXTENSIONS OF APPROVED PROJECTS/STUDIES

All applications/requests for amendments to already approved projects must be submitted in writing (via email) to the ECLM administrator. The written application must include the existing ethical clearance certificate, the original ethics application and informed consent documents, and a letter tabulating all the proposed changes with explicit comment on the ethical implications of each change. If the changes imply the need for re-consent, the adapted informed consent documents must be included.

Applications/requests for extensions of ethics approval periods are submitted on the ECLM Annual Monitoring form with an additional cover letter motivating the request for extension and proposing a motivated end date for ethics approval in the case of the specific project.

For preparation of the next meeting, the ECLM administrator will email the application/request for evaluation to the ECLM chair as soon as all the relevant information has been received.

The ECLM administrator will include the application/request on the agenda for the next relevant meeting. The remaining steps/processes are exactly the same as for new project/single study applications.

REQUESTS FOR AMENDMENTS TO OR EXTENSIONS OF APPROVED PROJECTS/STUDIES (Summary of process)		
1	Send application/request in writing to ECLM administrator	Applicant
2	Send application/request to ECLM chair	Administrator
3	Place application/request on agenda for next meeting	Administrator

8.9 APPLICATIONS FOR SECONDARY DATA ANALYSES STUDIES

All secondary data analyses studies after Scientific Committee approval require ECLM clearance (unless these were conceptualised and ECLM-approved as part of an umbrella/single study). Meta-analyses of published studies and reputable public archives will be excluded from this process, but still requires approval by the Scientific Committee.

The ethics surrounding the use of secondary data include that the current analysis is absolutely compatible with the aim of the original study, or, in the original informed consents, participants were made explicitly aware how data would be shared with others for secondary data analyses purposes, what these purposes would be, and if this would entail data being sent out of the country where it was generated. If this is not so, re-consent procedures must be followed before submitting an application to ECLM.

If re-consent is not needed, the application must include the fully completed application form, the completed checklist and all of the following:

- i. Proof that the study in which the data were generated was ethically cleared (e.g., copy of ethics clearance certificate).

- ii. The research protocol of the previous study (and, where relevant, the instruments used to collect the data).
- iii. The informed consent documentation of the previous study.
- iv. A letter of permission from the principal investigator of the original study granting permission for secondary data analysis unless open access.

If the data constitute published findings (which will be meta-analysed) or data obtained from reputable research archives/public data-bases then i-iv are not required. However, applicants are to provide proof of permission to use data from reputable archive/data-base, or proof of purchase of such data (i.e., applicants need to prove legitimacy of their access to these data).

8.10 APPEALS PROCESS

If an applicant believes that ECLM did not evaluate his/her/their application fairly, or within reasonable turnaround time, then applicants are advised to:

- Send a letter of appeal to the ECLM chair, via the ECLM administrator. The ECLM chair will then set up an appointment with the applicant/s to consider how the appeal could be addressed.
- Should the above not facilitate resolution, send a letter of appeal to the chair of the NWU SCORE, who will attempt to facilitate resolution.
- Should the above not facilitate resolution, direct an appeal to the NHREC (www.nhrec.org.za)

8.11 MONITORING PROCESS

Researchers/students whose applications are ECLM-approved need to provide annual monitoring reports on the ethics processes as applicable to the approved project/s on the ECLM Annual Monitoring form.

In addition, the ECLM chairs will randomly monitor the ethics process of a representative sample of applications approved by ECLM from time to time (in cycles of 3 years). This could include asking to see the stored consent forms, and/or asking to speak with study participants about their experience of being part of the study, etc.

8.12 EXPEDITED APPLICATION PROCESS

ECLM will have extraordinary committee meetings to facilitate **urgent** ethics applications/amendments to existing applications. Such a meeting will not consist of standing members, but will be convened from available members. 'Urgent' does not include applications that were not submitted timeously.

9 REFERENCE DOCUMENTS

NWU Ethics Policy.

10 ADDENDA

No	Document name
1	ECLM application form
2	ECLM procedures
3	Informed consent form
4	Reviewer's report form
5	ECLM appointment letter
6	ECLM code of conduct
7	ECLM confidentiality agreement

8	ECLM Annual Monitoring form
9	ECLM Sub-project application form
10	UPSET research project proposal for staff projects

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