ETHICS COMMITTEE FOR LANGUAGE MATTERS:

ANNUAL MONITORING REPORT

Please complete the form according to the following guidelines:

- *All researchers* need to complete Sections A and E.
- Section B is only completed if the research project is *quantitative* in nature.
- Section C is only completed if the research project is *qualitative* in nature.
- Section D is only completed if the researchers are making use of *previously collected biological samples or data.*

SECTION A: GENERAL INFORMATION AND PROGRESS

1. Project Head / Principle Investigator / Study leader Details						
Surname			**Initials**		**Title**	
Department						
E-mail						
Telephone	**Work**		**Cell**		**Fax**	
2. Student Details						
Surname			**Initials**		**Title**	
Department						
E-mail						
Telephone	**Work**		**Cell**		**Fax**	
3. Details of approved application						
Title						
Ethics Approval Number				**Risk level**	Low risk	
Approval date			**Expiry date**			

Are there any sub-studies/affiliated studies linked to this project?	Yes	◯	If yes, please indicate titles of the sub-study/affiliated study below and mark whether a report has been submitted.
	No	◯	

Titles of sub-studies/affiliated studies	Students/researchers included	Report in? (Please attach)	
		Yes	No
		◯	◯
		◯	◯
		◯	◯

4. Funding details (Where do you receive your funding from?)

Internal	☐	National (NRF/MRC)	☐	NIH/US Gov	☐
Industry	☐	International grant	☐	Self	☐

	Yes	No	NA
Were you able to fund your project as initially intended? If not, please indicate here in what way it has changed:	◯	◯	◯

5. Summary of progress to date

Shortly describe the overall progress to date of the project (500 words):

Please describe any ethical issues (both minor and/or major) that may have arisen during the past year (500 words):

Describe the research monitoring approach you followed:

	Yes	No	NA
Has the level of risk to the participants changed during the past year? If yes, please explain here (new level, reason, how ECLM was notified):	◯	◯	◯

Has any new conflict of interest occurred during the past year? **If yes, please explain here:**	◯	◯	◯
Have the research records produced (both hard and soft copies) been correctly maintained and secured as stated in the application? **Please explain your system here:**	◯	◯	◯
If the Ethics Committee for Language Matters (ECLM), has provided *provisional approval* for your project, have you fulfilled the conditions of the provisional approval e.g. approval from the Department of Health, goodwill permission from the school principal etc. and provided the ECLM with these? **Please give greater detail regarding the manner in which you *have/have not* adhered to the conditions of provisional approval provided by the ethics committee:**	◯	◯	◯
6. Adverse events/Serious adverse events/Incidents (if applicable)	**Yes**	**No**	**NA**
Has there been any adverse events/serious adverse events/incidents in the project during the past year? **Please give the following for each of the adverse events/serious adverse events/incidents: the date, a narrative overview, how it was managed and how the ECLM was notified.**	◯	◯	◯
If a data safety monitoring board was part of your planned research have they evaluated the adverse events/serious adverse events/incidents? **If yes, please attach a copy of the report.**	◯	◯	◯
7. External monitoring (if applicable)	**Yes**	**No**	**NA**
Has the study been externally monitored or audited? **If yes, please indicate the name of the agency:** **Please attach a copy of the report.**	◯	◯	◯

SECTION B: QUANTITATIVE STUDIES

8. Enrolment of participants	
Total number of participants planned to be included in the project.	
Actual number of participants enrolled in the project.	
Number of participants that withdrew from the project out of own choice. **Please provide reasons here for participants' withdrawal:**	
Number of participants withdrawn by primary investigator due to adverse events/serious adverse events/incidents/other reasons. **Please provide reasons here for these withdrawals:**	
Number of participants lost to follow-up (if appropriate). **Please explain here why they were lost:**	

SECTION C: QUALITATIVE ANALYSES

9. Methods used			
How many participants have been enrolled to date?			
	Yes	**No**	**NA**
Has data saturation been reached in this project?	○	○	○
Please give an overview of the methodology used to determine the indicated data saturation:			
Number of participants that withdrew from the project out of own choice. **Please provide reasons for participants' withdrawal:**			
Number of participants withdrawn by the primary investigator due to adverse events/serious adverse events/incidents/other reasons. **Please provide reasons for these withdrawals:**			
Number of participants lost to follow-up (if appropriate). **Please explain why they were lost:**			

SECTION D: USE OF PREVIOUSLY COLLECTED DATA

10. Databases	Yes	No	NA
Was the database you received anonymised? Describe the process:	◯	◯	◯
Was the database you received password protected?	◯	◯	◯

SECTION E: PROJECT AMENDMENTS AND STUDY STATUS

11. Amendments	Yes	No	NA
Has the study been amended or changed during the past year?	◯	◯	◯
Amendments	Date		

12. Status of study	Yes	No	NA
Has the study been completed and does this serve as your final report?	◯	◯	◯
Has this project been terminated? If so, please indicate the date, reason for termination and when the ECLM was notified:	◯	◯	◯
Does the project have to continue in the following year? Is this a request for extension of ethics approval? If YES, please add a cover letter to the report explaining the rationale for the request for extension of the ethics clearance as well as a motivation for the proposed new expiry date.	◯	◯	◯

13. Signature			
By signing this document, I certify that the information provided is accurate and complete.			
Signature by the primary investigator		Date	