

Research Ethics Committee (REC)
The Aga Khan University
Nairobi, Kenya
AGA KHAN UNIVERSITY

P R O G R E S S R E P O R T

PROJECT ID
GRANT CODE

Ref: 2013/REC-04(vS)

REPORT DATE
FROM AND TO

2nd dec 2013-1st dec 2014

☐

URC

☐

Seed Money

External Funded:

☐

Local

☒

Overseas

PROJECT TITLE:

The role of elastography in the diagnostic algorithm of
accurate quantification of liver fibrosis

PRINCIPAL INVESTIGATOR

Dr Joyce Sande

OR REPORTED BY

¹PLEASE COMPLETE AND RETURN THIS FORM NO LATER THAN:

1. PROJECT COMMENCEMENT DATE: 2nd dec2013

2. IF THE PROJECT HAS NOT COMMENCED, OR COMMENCEMENT DELAYED, ADVISE WHEN THE PROJECT IS EXPECTED TO COMMENCE OR WHETHER THE PROJECT IS TO BE WITHDRAWN OR WHAT IS THE REASON FOR DELAY IN STARTING THE PROJECT WORK

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3. IS THE PROJECT COMPLETE ?

YES

IF, YES, GIVE DATE

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NO

¹ Submit Progress Report to Research Support Unit via email

4. GIVE A BRIEF REPORT OF PROGRESS AND RESULTS TO DATE, IF ANY, Problems encountered actions taken to solve the problems, IF ANY AND INCLUDE A LIST OF PUBLICATIONS, IF ANY(ATTACH A SEPARATE PAGE IF NECESSARY).

More detailed progress report attached.

5. THIS REPORT COVERS THE PERIOD BETWEEN Dec 2013 TO Dec 2014

6. DETAILS OF PROGRESS REPORTS (IF ANY) SUBMITTED EARLIER.

REPORT NO	PERIOD COVERED	PHASE WISE COMPLETION OF THE WORK PLAN	DATE OF SUBMISSION	REMARKS

7. HAS THE PROJECT BEEN CONDUCTED IN ACCORDANCE WITH THE PROTOCOL APPROVED BY THE RESEARCH COMMITTEE AND HEALTH ETHICS COMMITTEE

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Yes

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No

IF NO, PLEASE GIVE DETAILS.

8. HAVE YOU MADE ANY MODIFICATION IN THE ORIGINAL PROTOCOL OR METHODOLOGY, OR WORK PLAN?

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Yes

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No

IF YES, PLEASE DETAIL REASONS FOR MODIFICATIONS. (add extra rows if needed and attach revised proposal)

Item	Original Text	Modification made	Explanation for Change

9. HAS THE REC APPROVAL PERIOD EXPIRED?

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Yes

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No

IF YES, DO YOU WISH TO APPLY FOR AN EXTENSION OF THE APPROVAL PERIOD?

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Yes

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No

IF YES, PLEASE STATE THE NEW EXPIRY DATE REQUESTED AND THE REASON FOR REQUEST FOR EXTENSION.

New expiry Date Requested	Reasons for Extension
December 2015	To complete data collection. Analyse the data. For write-up.

PLEASE REMEMBER THAT ANY AMENDMENTS TO THE APPROVED PROTOCOL REQUIRE FURTHER SPECIFIC APPROVAL BY REC.

I CONFIRM THAT THIS RESEARCH PROJECT IS IN CONFORMITY WITH THE SPONSOR² AND THE APPROVAL OF THE ETHICAL REVIEW COMMITTEE AND (AND SUBJECT TO ANY CHANGES SUBSEQUENTLY APPROVED) AND THAT ALL AMENDMENTS ARE ALREADY REPORTED TO THE RESEARCH SUPPORT UNIT

ALL FINANCIAL MATTERS ARE DEALT ACCORDING TO THE GRANTS & CONTRACTS OFFICE GUIDELINES.

Principal Investigator

Dr Joyce Sande

Name

Radiology

Department



Signature

22/1/15

Date

Department Chair's
Signature & Date



W. M. MACKAY

²Sponsor is referred to as the funding agency for e.g. (URC, Seed Money or External funding agency)

E-MENTORING RESEARCH PROGRAM – MONTHLY PROGRESS REPORT

2013

Names of Mentee/Mentor: Mentee Dr Joyce Sande

Title of Project:

Aim/Objective of your research project

Analyze the accuracy of shear wave elastography in the diagnosis of liver fibrosis as compared to liver biopsy.

PROGRESS

- 1) Sample size currently 125. Aim to get to 130 (total needed) by end of feb.
- 2) Proposal comments on sample size. Currently, approximately 100 biopsies are carried out in each radiology department in a year thus we chose a figure of 110 having factored in the AUROC and standard error. Shear wave elastography has been shown to have a lower operator error technique than transient elastography (3-16%); therefore, just as a precautionary measure we have raised the sample size from 110 to 130. A sample size between 110 and 130 would be sufficiently large to provide a good estimate of the AUROC even if the actual AUROC is lower than expected and therefore could result in a larger standard error. The sample sizes proposed are based on a single diagnostic test. When we combine tests to identify patients with significant fibrosis or cirrhosis, the AUROC should improve leading to an even smaller sample size being needed.
- 3) I have sent an initial data set to biostatistician with pertinent analysis questions that need to be addresses with his statistical help
- 4) I have also drafted A' live' word document on ongoing observations during the study of important discussion points that will need to be addresses after the analysis
- 5) I aim to send statistitian final data set by feb 28th Godwilling. Without his feedback and advice I will not be able to progress!!!!!!

How often have you been communicating with your Mentor
As the need arises

How much time have you allotted for your research (weekly)

Approx. 1-2 days per week (not yet formally agreed)

Accomplishments this research period A repetition of prior (ie number of patientss enrolled in study/surveys completed)

- .1. Recruitment- From end of Feb to 52to 81 patients thus far
- .2. Online research course to finesse research skill
- .3.Started live document of study observations
4. Formal approval letter from KNH in addition to the AKU one for the collaborative research
- .5. Continued patient recruitment from aku, knh and st mary's

Challenges this research period

- 1) Starting to think about the data
- 2) Collaboration withBiostatistician. Lack of feedback on almost complete data set and corresponding analysis we need to do based on questions we can answer from the data set.
- 3) Time needed to complete the research

I will now need to move from a less formal time protection to formal time protection for the data analysis and write up. Even at least 1 day week minus clinical interruptions.



THE AGA KHAN UNIVERSITY

Faculty of Health Sciences
Medical College

Ref: 2013 /REC-04(v5)
25th November 2013

Dr. Joyce Sande
Senior Instructor-Radiology
Aga Khan University -EA, Nairobi

Dear Dr. Sande,

**Re: THE ROLE OF ELASTOGRAPHY IN THE DIAGNOSTIC ALGORITHM OF ACCURATE
QUANTIFICATION OF LIVER FIBROSIS**

In reference to the Ethics Committee letter dated 18th Sept. 2013_Ref:2013/REC-04(v4), the Aga Khan University Faculty of Health Sciences Research Ethics Committee reviewed the revised proposal and related documentation submitted to the RSU and noted that all ethical concerns earlier raised have been conclusively addressed.

The committee in a meeting held on 22nd November, 2013 granted approval for this project based on core ethical standards which have been fully instituted in the protocol. This proposal is also in compliance with the Aga Khan University Research Ethics Regulations.

You are authorized to conduct this study from **02nd December 2013**. This approval is valid until **01st December 2014**.

The study should be conducted in full accordance with all the applicable sections of the R&EC guidelines and you should notify the R&EC immediately of any changes that may affect your research project. You should report any unanticipated problems involving risks to the participants to the R&EC. You must provide an interim report before expiration of the validity of this approval and request extension if additional time is required for study completion. As the principal investigator you must advise the R&EC when this study is finished or discontinued and a final report submitted to the RSU. Further approval from the Hospital should be sought before publishing the results.

If you have any questions, please contact Research Support Unit - kamanda.ciru@aku.edu or 020-366 2148.

Sincerely,

Dr. Ameen Lakhani
Chair, FHS AKU (N) - Research Ethics Committee



THE AGA KHAN UNIVERSITY

Ref: 2013/REC-04(V3)
20th August 2013

Faculty of Health Sciences
Medical College

Dr. Joyce Sande
Senior Instructor
Aga Khan University –EA, Nairobi

Dear Dr Sande,

**RE: THE ROLE OF ELASTOGRAPHY IN THE DIAGNOSTIC ALGORITHM OF ACCURATE
QUANTIFICATION OF LIVER FIBROSIS**

This is to notify you that that the Aga Khan University Faculty of Health Sciences Research Committee deliberated on the responses and revised protocol you submitted for the above mentioned study.

The Committee is satisfied that this is a proposal of scientific merit, the responses satisfactorily answer the concerns earlier raised and hence your study was approved for onward submission to the Ethics Committee.

Further, this being a mentorship programme, the committee opines that you may consider incorporating a local mentor since most of the work as proposed will be undertaken locally.

You will be notified of the Ethics Committee's decision by the Research Support Unit (RSU) in due course. If you have any questions, please contact RSU through - kamanda.ciru@aku.edu or 020-366 2148.

Yours sincerely,

Dr. Gunturu Revathi
V. Chair, AKU (EA) - Research Committee