

Post Approval Submission: Renewal

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IRB Number: [08-0800](#) PI: [David Teqnal](#)
Study Title: Human Resource Factors Related to Organizational Growth in Peruvian Microfinance Institutions

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>> **Renewal Action Requested**

ALERT: Modifications proposed as part of this renewal must be accomplished by editing the individual answers to the questions and data elements that make up the application. The modifications cannot be processed until the actual changes have been made throughout the application.

1. Renewal action requested by Principal Investigator (choose only one):

- Study has always involved only analysis of existing data or specimens. Continue as approved.
- Study involves(ed) direct interaction/intervention or contact with subjects:
- Continue as approved: Enrollment of new subjects continues.
- Enrollment of new subjects closed; interaction/intervention with previously enrolled subjects continues.
- Direct interaction with subjects completed but subsequent monitoring or follow up continues.
- Subjects' involvement completed but renewal is requested for data analysis.

Note: if you affirm that your subjects' involvement is complete and that you are in data analysis, or if your study has always involved only data analysis, you will be re-directed to a substantially abbreviated application.

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>> **Progress Report**

1. Number of Subjects involved through direct contact or use of their data (for multi-site studies, include only subjects covered by this IRB) (Note: b+d should not be larger than a)

A. Total projected number as approved by IRB: *

B. Total number of subjects involved to date (for clinical trials include 'screen failures') *

C. Number of subjects added since last renewal: *

D. Number to be included in upcoming year *

2. Have any subjects withdrawn voluntarily or been withdrawn from the study? Yes No

3. Have there been any complaints about the research from subjects or others? Yes No

4. Have there been any findings (e.g., publications, new information) that alter the risk/benefit ratio or otherwise impact the study? Yes No

5. Have there been any relevant multi-site reports? Yes No

6. Does this study have a Data and Safety Monitoring Committee (DSMC or DSMB)? Yes No

7. Have there been any deviations since the last renewal? Yes No

8. Have there been any reportable unanticipated problems that have not already been reported since the last renewal? Yes No

9. Have there been any individual IND safety reports or adverse events since the last renewal (that were not reportable under UNC-CH policies)? Yes No

10. Have there been any modifications to the study protocol that were not previously submitted to the IRB for approval? Yes No

11. Are you requesting any changes to the study or consent documents? Yes No

12. Has this study been audited by external sponsor or monitor since approved or last renewed? Yes No

13. Will you be obtaining consent (initial or re-consent) from subjects in the upcoming approval period? Yes No

You may modify a study you are currently renewing (that is, you may combine these two actions into a single renewal submission). Click "yes" at question #11, and detail your modifications in the associated text box. Then edit your initial IRB application to reflect these changes.