APPLICATION FOR EXEMPTION

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1. PROJECT TITLE
Behavioral Approaches to Treatment Adherence for Diabetes in Maya Municipalities of Highland Guatemala: A Pilot Study

Proposed Project/human subjects involvement Start and End Dates (Cannot commence prior to IRB review and approval determination)
From: November 1, 2013 To: August 30, 2014

2. PRINCIPAL INVESTIGATOR (or Faculty Sponsor)

<table>
<thead>
<tr>
<th>Name (Last, First, MI):</th>
<th>Degree(s):</th>
<th>University Academic Title:</th>
<th>School:</th>
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<tbody>
<tr>
<td>Goldin, Liliana R.</td>
<td>PhD</td>
<td>Professor</td>
<td>Silver School of Social Work</td>
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<td>NYU E-mail address:</td>
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<td><a href="mailto:goldin@nyu.edu">goldin@nyu.edu</a></td>
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<tr>
<td>Phone:</td>
<td></td>
<td>3052999650</td>
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3. NYU CO-INVESTIGATOR or Student Investigator

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<th>Name (Last, First, MI):</th>
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4. Additional CO-INVESTIGATOR(S)

Are there any additional NYU Co-Investigators on this protocol?
☐ Yes → Complete Appendix A
☒ No

Signatures of Co-Investigator(s) are required.

5. Other PERSONNEL

Are there any other NYU personnel on this protocol?
☐ Yes → Complete Appendix A
☒ No

Other personnel should include individuals who recruit participants, obtain consent, or who collect or analyze personally identifiable study data.
6. EXTERNAL CO-INVESTIGATOR(S) & Other PERSONNEL

Are any external (non-NYU) investigators or personnel engaged in the NYU research? ☑ Yes ➔ Complete IRB Review Certification for NYU Research Involving Non-NYU Affiliated Sites

☐ No ➔ Go to Question #7

“Engaged” individuals are those who intervene or interact with participants in the context of the research or who will obtain individually identifiable private information for research funded, supervised, or coordinated by NYU. See OHRP Engagement Guidance or contact the UCAIHS for more information.

External (non-NYU) personnel may be subject to their own institutional review and/or local oversight requirements. Investigators are responsible for determining if other requirements apply and are encouraged to maintain documentation of any additional approvals/determinations for this study.

7. ADDITIONAL CONTACT(S)

If further information about this application is needed, specify the contact person(s) if other than the PI (e.g., study or regulatory coordinator, research assistant, etc.). ☐ N/A

Name (Last, First, MI): Phone:

E-mail: Fax:

Name (Last, First, MI): Phone:

E-mail: Fax:

All NYU individuals listed on this protocol will have access to information about protocol actions and the completion status of each individual's administrative and training requirements (NYU, CITI, COI disclosure). Personal financial information provided in COI disclosures is not included.

8. EDUCATION

Educational requirements must be satisfied prior to submitting the application for review. See Collaborative Institutional Training Initiative CITI Training or NYU Online Tutorial and Exam. If you have taken different training, please contact the UCAIHS.

Note that human subjects courses completed for RCR may not provide adequate training for human subjects research.

Have all NYU investigators and key personnel completed the appropriate web-based course (CITI or NYU) in the protection of human research subjects? If no, please complete prior to submission. See CITI or NYU. ☑ Yes ☐ No

9. FINANCIAL CONFLICT OF INTEREST

All NYU Investigators (defined as individuals who are responsible for the design, conduct or reporting of research) must have a current COI disclosure (updated as necessary for the proposed research) review. Examples of financial interests that must be disclosed include (but are not limited to) consulting fees or honoraria; stocks, stock options or other ownership interests; reimbursed travel and patents, copyrights and royalties from such rights. For more information, see Academic Conflict of Interest and Conflict of Commitment.

a. Have all NYU Investigators completed the required COI disclosure? ☑ Yes ☐ No

If no, please complete COI disclosure now.

PHS investigators

Non-PHS investigators

b. Does any NYU Investigator (including principal or co-investigator), or their immediate family members have a financial interest (including salary or other payments for services, equity interests, or intellectual property rights) that could affect or reasonably appear to affect the research, or a financial interest in any entity whose financial interest would affect or reasonably appear to affect the research? ☐ Yes ☑ No

If yes, such conflicts must be reviewed and managed by your Dean prior to submission to the UCAIHS.

10. FUNDING OR OTHER SUPPORT

a. Is the research funded or has funding been requested? ☑ Yes ☐ No
If Yes ▶ Specify sponsor: Office for Research SSSW
Type: □ Federal □ Non-Federal

Provide a complete copy of the grant application or funding proposal. The University is required to verify that all funding proposals and grants (new or renewals) have been reviewed before funds are awarded.

b. Is any support other than monetary (e.g., materials, equipment, etc.) being provided for the study?
   □ Yes □ No

If Yes ▶ Specify support and provider:

11. SCREENING QUESTIONS FOR EXEMPTION ELIGIBILITY (Please check appropriate boxes)

a. Does your study need UCAIHS review? 1) Does it involve research AND 2) use human subjects as defined by the federal regulations at 45 CFR 46.102, AND 3) will it be carried out under the auspices of NYU Washington Square Campus? □ Yes or □ No. If you answered no, please do not complete this form. Please use the form entitled Checklist for Determining Whether a Project Involves Human Subjects if you need a written record and review our FAQs. If you have further questions, please contact the UCAIHS Office at 212-998-4808 or via email at ask.humansubjects@nyu.edu.

b. Will the research expose participants to discomfort or distress beyond that normally encountered in daily life?
   □ Yes □ No

c. Will research be conducted in a location currently or recently experiencing significant unrest, warfare or repression (e.g. riots, rebellions, political or religious repression)? This includes research in a context (e.g., organization or nation) that restricts individual liberties or freedom of speech.
   □ Yes □ No

d. The research design might contradict the ethical norms of the local culture (e.g., males speaking with single women in Muslim countries).
   □ Yes □ No

e. Could disclosure of participants’ responses outside the research reasonably place participants at risk of criminal or civil liability or be damaging to participants’ financial standing, employability, or reputation?
   □ Yes □ No

f. Does any part of the research require the use of deception or incomplete disclosure of information to participants?
   □ Yes □ No

g. Will prisoners (or their data and/or specimens) be participants in the research? Prisoner means any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.
   □ Yes □ No

h. For research proposed under category 1, will the research be conducted outside of commonly accepted educational settings or deviate from normal educational practices?
   □ Yes □ No or N/A

i. For research proposed under category 1, will the researcher be adding an activity or exercise for research purposes?
   □ Yes □ No or N/A

j. For research proposed under category 1, will the researcher be modifying the curriculum for research purposes?
   □ Yes □ No or N/A

k. For research proposed under category 1, will the researcher be participating in classroom activities with his/her students?
   □ Yes □ No or N/A

l. For research proposed under category 2, will the research involve surveys or interview procedures with children? Children are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted. In New York State, the legal age of consent is 18.
   □ Yes □ No or N/A

m. For research proposed under category 2, will the research involve observations of the public behavior of children, during which an investigator participates in the activities being observed?
   □ Yes □ No or N/A
n. For research proposed under category 4, will any of the data, documents, records, or biological specimens be collected or created after the date of this application for exemption?
  - Yes
  - No or N/A

o. For research proposed under category 4, will any of the information obtained from private sources of data, documents, records, or biological specimens be recorded by the investigator in such a manner that participants could be identified directly or through identifiers linked to the participants?
  - Yes
  - No or N/A

p. For research proposed under categories 1-5, is the research subject to FDA regulations?
  - Yes
  - No or N/A

If you checked YES to one or more of the questions b-p above, your research is NOT EXEMPT. Do not complete this application. Submit an Application for Review by the University Committee on Activities Involving Human Subjects. For more information on what qualifies as exempt research, see Exempt Status.

12. EXEMPT CATEGORIES OF RESEARCH at 45 CFR 46.101 (b) Paragraphs 1-6

Please check the categories of exemption for which you are applying. You may check more than one box.

Category 1 ☐ Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Category 2 ☒ Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

   (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
   (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

Category 3 ☐ Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:

   (i) the human subjects are elected or appointed public officials or candidates for public office; or
   (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

Category 4 ☐ Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

Category 5 ☐ Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:

   (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

Category 6 ☐ Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

The exemptions at 45 CFR 46.101(b) do not apply to research involving prisoners, subpart C. The exemption at 45 CFR 46.101(b)(2), for research involving survey or interview procedures does not apply to research with children, subpart D, except for use of educational tests (standardized) or research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

13. LOCATION OF THE RESEARCH

Research to be conducted at locations other than NYU: Submit a letter of support from the location. If personnel at the site are engaged in the research, IRB review/exempt clearance from the site is required. See OHRP Engagement Guidance or contact UCAIHS for more information.

a. List the specific site(s) at which the research will be conducted (include both domestic and international locations). If research is to be conducted in an international setting, please review the International Research guidance and submit Appendix B.

<table>
<thead>
<tr>
<th>Location Name (or description)</th>
<th>Address (street, city and state, or country)</th>
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Interviews with diabetic patients and doctors will be conducted in Hospital de Occidente, Quetzaltenango, Guatemala | Quetzaltenango, Guatemala

### 14. SUMMARY OF THE RESEARCH

**a.** Briefly summarize the purpose and procedures of the proposed research using non-technical language that can be readily understood by someone outside the discipline. *Use complete sentences (limit 300 words).*

Diabetes is a growing concern for the Maya populations of Guatemala. Changes in diet and lifestyle related to globalization and modernization and in the midst of poverty have created conditions for the rampant increase of this disease, now reaching 8.4% of the population of Guatemala and about 10% of the population of Quetzaltenango, the study site of the proposed research. The current research will investigate diabetes treatment adherence to doctor prescribed health protocols for women in the highlands of western Guatemala who have been diagnosed with type 2 diabetes. The population is indigenous Maya living in poor, rural areas of Guatemala. There has been virtually no adherence research protocol on this population and the results of the work will inform broader research perspectives on effective health outreach to poor, rural populations in Latin America. The study will conduct qualitative research on both female patients and their physicians in Quetzaltenango, Guatemala so as to gain a better understanding of the dynamics underlying patient adherence to treatment protocols. It sets the foundation for the design of an intervention aimed to improve treatment adherence by diabetes 2 patients.

**b.** Describe how the proposed research meets the criteria for exemption. Reference the exemption category or categories (see question #12 above) and the category’s corresponding requirements.

The study meets criterion 2. It consists of confidential interviews that will be tape recorded with patients and doctors. Doctors will be asked for their recommendations to patients diagnosed with diabetes 2 and their ideas to improve the dissemination of information, communication, motivation of patients to comply with recommendations and ways to facilitate the process. We consulted hospital doctors and obtained permission from the Hospital de Occidente through their own Research Committee, equivalent to our IRB. Patients will be asked questions about their knowledge base on the disease and their health beliefs (ideas about how they may have contracted the disease and ways to treat, cure, or control it) that may affect compliance with doctors' recommendations, and their current practice with respect to diet, weight, exercise and testing. We will also ask patients how communication with their doctors may be improved, how to better motivate them and how the practices may be facilitated. No harm will result from patients sharing the information with us so that we can develop a behavioral intervention to improve the well being of diabetes 2 patients in Guatemala and other developing countries.

### 15. RESEARCH METHODS & ACTIVITIES

Check all research activities that apply. *Attach a copy of materials to be used (e.g., interview/focus group questions, instruments, data collection forms, etc.)*

- [x] Audio, video, digital, or image recordings
- [ ] Existing data, not publicly available
- [x] Existing data, publicly available
- [x] Focus groups
- [ ] Internet or e-mail data collection
- [x] Record review (specify):
- [ ] Specimen research (must be existing at time of application)
- [x] Surveys, questionnaires, or interviews (one-on-one)
- [ ] Surveys, questionnaires, or interviews (group)
- [ ] Taste-testing

Form Date: 03/18/2013
Version 5.0
16. PARTICIPANT POPULATION

a. Specify the age(s) of the individuals who may participate in the research:

Age ranges: 40-50 years old

b. Specify the participant population(s) to be included (check all that apply):

☐ Adults
☐ Children (< 18 years)
☐ Student subject pools (e.g., psychology, etc.)
☐ Non-English speaking
☐ Unknown (e.g., research using secondary data/specimens, non-targeted surveys, program protocols)
☐ Other Population

Specify: Maya women

17. PARTICIPANT IDENTIFICATION, RECRUITMENT, & SELECTION

a. Describe how potential participants will be identified (e.g., advertising, individuals known to investigator (see policies on employees and students) record review, etc.). Explain how investigator(s) will gain access to this population, as applicable.

Hospital personnel will identify diabetic patients when they come for a doctor's visit and if they fit in the inclusion criteria we will ask them if they agree to participate in the study. We will offer patients a small payment plus diabetic blood testing kits and information on diet and exercise. We will identify each patient by number followed by town of origin, age, and time since diagnosis of Diabetes 2. The hospital research director has agreed to provide access to patients each day. Participation will be voluntary.

b. Describe the recruitment process, including the setting in which recruitment will take place. Explain how the process respects potential participants’ privacy. Provide copies of proposed recruitment materials (e.g., ads, flyers, website postings, recruitment letters, videos/digital recordings and oral/written scripts).

We will approach patients in the waiting room and ask them if they are willing to participate in a study to understand the experience of patients with diabetes. We will explain the goals of the study which are to improve adherence to treatment and control of the disease. We will explain that all information will be kept confidential, and that participation is voluntary.

18. INCENTIVES TO PARTICIPATE

Will participants receive compensation or other incentives (e.g., free services, cash payments, gift certificates, parking, classroom credit, travel reimbursement) to participate in the research study? Compensation plans should be pro-rated (not contingent upon study completion) and should consider participation withdrawals, as applicable.

If Yes → Describe the incentive, including the amount and timing of all payments.
At the end of the interview that will last about one hour, the patient will receive the equivalent to US$20 (about 150 Quetzales or two days of work), testing kits and information on diet and exercise for diabetes 2 patients.

19. INFORMED CONSENT PROCESS

a. Indicate the consent process(es) and document(s) to be used in the study. Check all that apply. Provide copies of documents, as applicable. See Forms and Guidance for sample language for consent and/or use the consent form generator which can be modified to fit your research study. You may also contact UCAIHS for more information.

☑ Informed Consent – Form
☐ Parental Permission – Form

☑ Informed Consent – Verbal Script/Online/Unsigned (Provide in writing for approval)
☐ Translated Consent – Form(s), Script(s), etc. (provide only English version until approved; once approved provide translated versions and certification of translation)

☐ Other (Specify):
☐ Not Applicable (existing data or specimens) Provide data use agreement or letter from owner of the data granting access.

b. Describe the consent process. Explain who will obtain consent and when and where consent will be obtained and how subjects and/or their legally authorized representatives will be provided sufficient opportunity (e.g., waiting period, if any) to consider participation.

Oral Consent for patients
This is part of a study on treatments for diabetes type 2. If you agree to participate we will ask you general questions about your life, the times you felt sick and the symptoms you had. We will also ask you about the things doctors have told you to do, what you feel you are able to do and what you feel is difficult to do. Your answers will be confidential and we will not tell your doctors or anyone else what you have said. The information you give us will be recorded under a given number. There are no correct or incorrect answers, we want to know what you understand about the disease and the treatment, the causes, and things you understand you can do to control your diabetes. We want to know how the communication with your doctor and receipt of information about diabetes and treatment may be improved. We will be paying you for your time 150 Quetzals and you will receive testing kits and information on diet and exercise.

Oral Consent for Physicians
We are conducting a pilot study to develop behavioral interventions for treatment adherence to prescribed directions to control Diabetes Type 2. We are interested in the types of communications that take place between you and your patients and the expected outcomes. We would like to know what is your understanding of the difficulties in communication, motivation of patients to comply, expected compliance for diverse patients, and any recommendation you may have to improve and facilitate any aspect of the process with the goal of achieving better adherence to treatment and overall outcomes. If you agree to talk to us, you will receive an honorarium of $800 Quetzals. Your responses will be tape recorded and kept confidential. The aggregate material will be used to design an intervention to improve treatment adherence.

20. PRIVACY OF PARTICIPANTS

a. Describe the provisions to protect the privacy interests of the participants. Consider the circumstances and nature of information to be obtained, taking into account factors (e.g., age, gender, ethnicity, education level, etc.) that may influence participants’ expectations of privacy.

Participants will be told that the information will be used in combination with that of others without identifying them individually and that they don't need to give us their name or address, just their age and town of origin. Participants know that diabetes is now common and that so many suffer similar symptoms.
and problems and that we will not ask any information that may cause them any personal harm.

b. Does the research require access to personally identifiable private information?  
   - Yes  
   - No  
   **If Yes** Describe the personally identifiable private information involved in the research. List the information source(s) (e.g., educational records, surveys, medical records, etc.).

21. CONFIDENTIALITY OF DATA

   a. Explain how information is handled, including storage, security measures (as necessary), and who will have access to the information. Include storage security procedures for both electronic and hard copy records.
   
   We don't need to follow the patients in the future. We will only record a number for each followed by their age and town of origin. We will ask general demographic information of their household to understand socioeconomic situation, sources of support and education levels. No individual personal information that may identify them in the future will be recorded.

   b. Indicate what will happen to the identifiable data at the end of the study.  
      
      **Research-related records should be retained for a period of at least three years after the research has been discontinued (i.e., no further data collection, long term follow-up, re-contact, or analysis of identifiable/coded data).** For federally-sponsored projects, research records must be retained for a period of at least 3 years after the final expenditures report has been filed. Other sponsors may have different requirements; review your award agreement for relevant terms and conditions.
      
      - Identifiers permanently removed from the data and destroyed (de-identified)
      - Identifiable/coded (linked) data are retained
      - Identifiable data not collected (data collected anonymously)

22. HIPAA RESEARCH AUTHORIZATION

   Will individually identifiable Protected Health Information (PHI) subject to the HIPAA Privacy Rule requirements be accessed, used, or disclosed in the research study? **Note that if the PHI belongs to NYU SoM, this study cannot be reviewed by the UCAIHS. You must apply via NYU SoM.**
   
   - No  
   - If Yes, **Provide a copy of the Written Authorization Form**

23. APPLICATION CONTENTS

   Indicate the documents being submitted for this research project. Check all appropriate boxes.

   - Application for Exemption (This Form)
   - Appendix A: Additional NYU Co-Investigators & Key Personnel (questions 4 & 5)
   - IRB Review Certification for NYU Research Involving Non-NYU Affiliated Sites (question 6)
   - Appendix B: Research in International Settings (question 13)
   - Consent form(s), Assent Form(s), Permission Form(s), and Verbal Script(s) (question 19)
   - Data Collection Form(s) involving protected health information (question 15)
   - Recruitment Materials (e.g., ads, flyers, telephone or other oral script, radio/TV scripts, internet solicitations) (question 17b)
   - Script(s), Instructions, or Information Sheet(s) (question 15)
   - Instruments (e.g., questionnaires or surveys to be completed by participants) (question 15)
   - Other Committee Approvals (IRBs, REBs, Dissertation Committee, Steinhardt Student Clearance, etc.)
Letters of Support from cooperating institutions (questions 13)

Research Protocol/Approved Dissertation proposal

Complete Grant Application or Funding Proposal (question 10)

Other supporting documentation and/or materials:

Applications and attachments to be mailed electronically to: exempt.humansubjects@nyu.edu

Please follow the electronic submission instructions on the UCAIHS web site.

23. ASSURANCE: PRINCIPAL INVESTIGATOR (or Advisor)

I agree to follow all applicable policies and procedures of New York University and federal, state, and local laws and guidance regarding the protection of human subjects in research, as well as professional practice standards and generally accepted good research practice guidelines for investigators, including, but not limited to, the following:

- Perform the research as approved under the direction of the Principal Investigator (or Advisor) by appropriately trained and qualified personnel with adequate resources;
- Initiate the research only after written determination of exemption has been received;
- Obtain and document (unless waived) informed consent and HIPAA research authorization from human subjects (or their legally authorized representatives) prior to their involvement in the research using the final version of the consent form(s) and process submitted for determination;
- Promptly report to UCAIHS events that may represent unanticipated problems involving risks to subjects or others;
- Provide significant new findings that may relate to the subjects willingness to continue to participate;
- Inform UCAIHS of any proposed changes in the research or informed consent process (via a new Exempt Application) before changes are implemented, and agree that no changes will be made until an exempt determination is made by UCAIHS (except where necessary to eliminate apparent immediate hazards to participants);
- Maintain research-related records (and source documents) in a manner that documents the validity of the research and integrity of the data collected, while protecting the confidentiality of the data and privacy of participants;
- Retain research-related records for audit for a period of at least three years after the research has ended (or longer, according to sponsor or publication requirements) even if I leave the University;
- Contact UCAIHS for assistance in amending (to request a change in Principal Investigator) or terminating the research if I leave the University or am unavailable to conduct or supervise the research personally (e.g., sabbatical or extended leave); and
- Inform all Co-Investigators, research staff, employees, and students assisting in the conduct of the research of their obligations in meeting the above commitments.

I verify that the information provided in this application is accurate and complete.

Signature of Principal Investigator (or Advisor)  Date

Liliana R. Goldin

Typed name of Principal Investigator (or Advisor)

Signature of Co-Investigator (or Student Investigator)  Date

Typed name of Co-Investigator (or Student Investigator)

Departmental/School approval (if required)

Signature of Departmental/School Approver  Date

Form Date: 03/18/2013 Version 5.0