

**SUMMARY STATEMENT**

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( Privileged Communication )

*Release Date:* 03/22/2019  
*Revised Date:*

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*Application Number:* 1 R21 TW011377-01

Principal Investigator

RAWAL, SHRISTI

Applicant Organization: RBHS-SCHOOL/ HEALTH RELATED PROFESSIONS

*Review Group:* ZRG1 HDM-A (55)  
Center for Scientific Review Special Emphasis Panel  
PAR-16-292 Mobile Health: Technology and Outcomes in Low and Middle Income Countries

*Meeting Date:* 03/01/2019  
*Council:* MAY 2019  
*Requested Start:* 07/01/2019

*RFA/PA:* PAR18-242  
*PCC:* MHEALTH

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*Project Title:* Development and Testing of a Mobile Health Application for Management of Gestational Diabetes

*SRG Action:* Impact Score:30 Percentile:15 #

*Next Steps:* Visit [https://grants.nih.gov/grants/next\\_steps.htm](https://grants.nih.gov/grants/next_steps.htm)

*Human Subjects:* 30-Human subjects involved - Certified, no SRG concerns

*Animal Subjects:* 10-No live vertebrate animals involved for competing appl.

*Gender:* 2A-Only women, scientifically acceptable

*Minority:* 5A-Only foreign subjects, scientifically acceptable

*Children:* 3A-No children included, scientifically acceptable

Project Year	Direct Costs Requested	Estimated Total Cost
1	125,000	192,012
2	100,000	153,610
<b>TOTAL</b>	<b>225,000</b>	<b>345,622</b>

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## **1R21TW011377-01 Rawal, Shristi**

**RESUME AND SUMMARY OF DISCUSSION:** This application proposes to develop and test the usability and preliminary efficacy of a smartphone application-based lifestyle intervention to support self-management of gestational diabetes mellitus (GDM) among patients in Nepal. During discussion, the Editors agreed that the proposal addresses a significant and emerging public health concern in low- and middle-income countries (LMICs) and the goals of the study are supported by a relatively well constructed set of scientific premises. If successful, findings may inform strategies to improve glycemic control and reduce adverse pregnancy outcomes in woman with GDM. The investigative team is outstanding though there is concern regarding unbalanced expertise at different study sites. Additional strengths of the proposal include a strong conceptual framework, rigorous study design and robust plans to build mHealth research capacity at the partnering LMIC institution. During discussion, however, the editors identified issues that detract somewhat from these strong points. The feasibility of bringing patients back for follow up is not adequately considered and it not clear that the proposed follow-up timeline is sufficient to establish glycemic control. These issues notwithstanding, overall, findings are expected to have a high to moderate impact on prenatal care for woman with gestational diabetes mellitus in resource limited settings.

**DESCRIPTION (provided by applicant):** The prevalence of gestational diabetes mellitus (GDM) is rapidly increasing worldwide, particularly in low- and middle-income countries (LMICs). Tight glycemic control via diet and lifestyle modification is critical to treating GDM and preventing its adverse health consequences, including increased risk of type 2 diabetes (T2D), in women and their children. However, in many resource-limited countries including Nepal, time for diet/lifestyle counseling often competes with other components of antenatal care. Mobile health (mHealth) technology can be leveraged to promote healthy behaviors, and support self-management and treatment of GDM, but this approach has not been tried previously in any LMICs. Taking a user-centered design approach, here we propose to develop a culturally- appropriate smartphone application (app) to support self-management of GDM (mGDM), and test its usability and preliminary efficacy, among patients in a tertiary level, university hospital of Kathmandu University, Nepal. Based on the Social Cognitive Theory framework for behavior change, this app will assist in self-management of GDM by increasing the patient's knowledge and self-efficacy to adhere to the recommended diet and physical activity regimens. The app will also help clinicians by generating easily digestible visual displays of patient data and behaviors, which can aid in their clinical decision-making and counseling. In the requirements gathering phase, 6 GDM patients will be recruited into a focus group to view paper prototypes and provide feedback on its features and functions. Additional questions will be asked about their perceived barriers, facilitators, and strategies for lifestyle modification. Key informant interviews will also be conducted with 5 clinicians (gynecologists, dietician, physical therapist) and 3 family members, asking them to provide feedback on the mGDM prototype, especially pertaining to the usefulness and format of the graphic summaries of patient data. After revising paper prototypes and developing the first digital prototype, six additional patients with GDM will be recruited for two rounds of usability testing including think-aloud protocol and focus group discussions. Final prototype will be developed following an iterative process of product design and user testing. After developing the app, we will recruit 60 women who are newly diagnosed with GDM, and randomly assign them to one of two treatment conditions: either (A) mGDM app + standard care, or (B) standard care alone, from 28 weeks of gestation to delivery. In this proof-of-concept trial, feasibility outcomes will be app usage, self-monitoring adherence, and app usability and acceptability. Exploratory treatment outcomes will be glycemic control measures at 6 weeks postpartum, neonatal birthweight, and rates of labor induction and caesarean delivery. Findings from the proposed study will empirically inform a future randomized control trial that will be fully powered to test the efficacy and cost-effectiveness of the mGDM app in improving treatment outcomes, using an R01 mechanism. We expect that the research activities and capacity building initiatives proposed in this application will build the institutional skills and create the organizational structure needed to enable future mHealth research initiatives at Kathmandu University, even beyond the scope of this proposed project.

**PUBLIC HEALTH RELEVANCE:** Adequate control and management of gestational diabetes mellitus (GDM) during pregnancy is critical to mitigate its short- and long-term health consequences in women and their children and may serve as a key strategy to curb the escalating type 2 diabetes epidemic in low- and middle-income countries (LMICs). Taking a user-centered design approach, here we propose to develop a culturally-appropriate smartphone application (app) to support self-management of GDM, and additionally, test its usability and preliminary efficacy, among patients in a sub-urban hospital setting in Nepal. App-based lifestyle interventions for GDM management are not common, especially in LMICs where its prevalence is rapidly increasing, and as such, our study findings will have important public health relevance for a broader population.

## CRITIQUE

### EDITORS' IMPACT STATEMENTS:

**Overall Impact 1:** The prevalence of gestational diabetes mellitus (GDM) is rapidly increasing worldwide, particularly in low- and middle-income countries (LMICs). Tight glycemic control via diet and lifestyle modification is critical to treating GDM and preventing its adverse health consequences, including increased risk of type 2 diabetes (T2D). However, in many resource-limited countries including Nepal, time for diet/lifestyle counseling often competes with other components of clinical care. Mobile health (mHealth) technology can be leveraged to promote healthy behaviors and support self-management and treatment of GDM. Taking a user-centered design approach, the investigators propose to develop a culturally- appropriate smartphone application (app) to support self-management of GDM (mGDM), and test its usability and preliminary efficacy, among patients in a tertiary level, university hospital of Kathmandu University, Nepal. There are two phases of this proposal. In the requirements gathering phase, 6 GDM patients will be recruited into a focus group to view paper prototypes and provide feedback on its features and functions. After revising paper prototypes and developing the first digital prototype, six additional patients with GDM will be recruited for two rounds of usability testing including think-aloud protocol and focus group discussions. Final prototype will be developed following an iterative process of product design and user testing. In the second phase, after developing the app, the investigators will recruit 60 women who are newly diagnosed with GDM, and randomly assign them to one of two treatment conditions: either (A) mGDM app + standard care, or (B) standard care alone, from 28 weeks of gestation to delivery. In this proof-of-concept trial, feasibility outcomes will be app usage, self-monitoring adherence, and app usability and acceptability. Exploratory treatment outcomes will be glycemic control measures at 6 weeks postpartum, neonatal birthweight, and rates of labor induction and caesarean delivery. Based on the Social Cognitive Theory framework for behavior change, this app will assist in self-management of GDM by increasing the patient's knowledge and self-efficacy to adhere to the recommended diet and physical activity regimens. The app will also help clinicians by generating easily digestible visual displays of patient data and behaviors, which can aid in their clinical decision-making and counseling. Therefore, the premise is solid and balanced, and the study is poised to resolve a long-standing issue of gestational diabetes mellitus (GDM) in Nepal. There are a few minor weaknesses, including unbalanced experiences in different facilities, and institutional support; and 6 weeks glycemic control may not be good enough. However, the overall impact and significance outweigh the minor weaknesses.

**Overall Impact 2:** This project seeks to develop and test the usability, acceptability, and preliminary effectiveness of a mobile app for the management of gestational diabetes in Nepal, where there is a growing prevalence of pregnancies complicated by GDM. The project is of high importance given the significant poor outcomes for both babies and their mothers who develop this condition. The advantage of a mobile app for providing a lifestyle intervention in Nepal, given the country's mobile service penetration is over 100%. The investigators, while mostly junior in the states, and more senior in Nepal, seem capable of successfully accomplishing all study aims. The project is innovative, as such mHealth innovations have not been introduced into Nepal, despite the mobile service penetration. Consistent

with the RFA guidelines, the investigators propose an entire aim of creating an organizational framework to strengthen mhealth research capacity at Katmandu University, where some of their project team worked together and successfully launched Nepal's first patient-centered health education app. The project is based on an appropriate theoretical framework, social cognitive theory, which suggests that increased self-efficacy and social support serve as mediators leading to improved self-management of GDM. The analytic plan is strong. Timeline is acceptable and there are no problems related to the clinical trial. Given these strengths, this proposal has a high likelihood of having a major impact, especially when combined with the strong preexisting relationship between investigators at the partnering institutions.

**Overall Impact 3:** The topic under study is woman with gestational diabetes and an mHealth strategy to help achieve glycemic control through diet and life style modifications to reduce adverse pregnancy outcomes. Gestational diabetes, which can adversely affect the mother and baby, is a growing concern in South Asia. The team has strong complementary expertise to support the PI (who is Nepalese). The behavior change intervention is guided by a strong theoretical framework (social cognitive theory) but not all relevant variables that influence diet appear to be included; feasibility metrics are robust. The collaboration seems to have strong potential for sustainability and capacity building (university and teaching hospital partners in Nepal). Minor concerns have to do with the inclusion of women with diabetes but are otherwise low risk. The sample size may not have sufficient power to detect actual behavior change (the baseline measurement is unclear as well) but will be able to describe feasibility. While there are other mobile health interventions in this context, this proposal has sufficient rigor and premise that findings have high potential for impact. Human subjects: protections adequately described; the exclusion of pregnant females under 18 is not a concern for this feasibility study.

## MAIL REVIEWERS' CRITIQUES:

### CRITIQUE 4

Significance: 1  
Investigator(s): 1  
Innovation: 1  
Approach: 2  
Environment: 1

**Overall Impact:** This well-conceived proposal that builds upon prior collaborative research with Rutgers University in chronic disease monitoring and management. The mHealth applications to be developed, field tested and utilized will focus on a patient centered approach to woman with gestational diabetes to help achieve tight glycemic control through diet and life style modifications in the hope of reducing adverse pregnancy outcomes.

### 1. Significance:

#### Strengths

- South Asia has become the diabetes hub of the world. Interventions that in low-resource settings like Nepal, where specialized antepartum care is limited, must rely heavily on consumer education, and on cost-effective ways of support patient practices to improve pregnancy outcomes.
- The far-reaching aims described in the proposal, if proven feasible and acceptable will provide a nidus for scale up.
- The potential for disrupting the intergenerational cycle of risk for type II diabetes and its longer-term sequelae is compelling.

## **Weaknesses**

- No weaknesses seen.

## **2. Investigator(s):**

### **Strengths**

- The PI is a Nepalese researcher on the faculty of Rutgers University, with a background in epidemiology. She has a history of collaboration on research directly linked to diabetes, cardiovascular disease, obesity and the knowledge of local dietary patterns.
- The team that has been assembled is stellar in its background with expertise in mHealth technology, high risk obstetrics, nutritional science, physical activity and risk reduction, obesity research and community health and provides a balance between US and Nepalese investigators.

### **Weaknesses**

- Given the vast and relevant experience of Dr. Pagoto, it is unlikely that 52 hours of consulting time will be sufficient.
- The team may benefit from additional biostatistical expertise.

## **3. Innovation:**

### **Strengths**

- The promotion of optimal health behaviors to gestational diabetic women via mHealth in low/middle income countries has not previously been described.
- The user-centered design approach consistent with Social Cognitive Theory is an innovative cost-effective initiative particularly appropriate for under-resourced settings. The monitoring of app usage, adherence and practical usability/ acceptability will provide critical feasibility findings necessary to a devise larger intervention trial.

### **Weaknesses**

- No weaknesses seen.

## **4. Approach:**

### **Strengths**

- While limited in scope, the “pilot” phase of the proposal seeks to assure appropriate input and adherence to local and cultural norms.
- There is sufficient expertise in app development among us research collaborators. However, partnering with a commercial firm within Nepal will strengthen mHealth capability and increase infrastructure to support future research.

### **Weaknesses**

- The clinical trial outcomes of glycemic control at 6 weeks post-partum, neonatal birthweight and rates of labor induction and caesarean deliveries may not be well correlated with tight glycemic control.
- The relative low number of women in the trial component may not allow for adequate trend data.

## **5. Environment:**

### **Strengths**

- The support of the Nepal Health Research Council of Nepal, Kathmandu University and the central role of its primary teaching hospital supports an appropriate environment to conduct a proof of consent study which will incorporate 60 women, newly diagnosed with gestational diabetes. It will employ a newly developed mHealth app and compare these with standard of care alone to determine clearly stated pre-specific outcomes.

**Weaknesses**

- It is not clear if the recruitment will occur at outpatient clinics linked to the hospital or among hospitalized patients.
- The percent of women/families that have access to smartphones is not mentioned.

**Study Timeline:**

**Strengths**

- The study timeline is appropriate.

**Weaknesses**

- None noted.

**Protections for Human Subjects:**

Acceptable Risks and/or Adequate Protections

Data and Safety Monitoring Plan (Applicable for Clinical Trials Only):

Acceptable

**Inclusion of Women, Minorities and Children:**

- Sex/Gender: Distribution justified scientifically
- Race/Ethnicity: Distribution justified scientifically
- For NIH-Defined Phase III trials, Plans for valid design and analysis: Not applicable
- Inclusion/Exclusion of Children under 18: Excluding ages <18; justified scientifically

**Vertebrate Animals:**

Not Applicable (No Vertebrate Animals)

**Biohazards:**

Not Applicable (No Biohazards)

**Applications from Foreign Organizations:**

Justified

**Select Agents:**

Acceptable

**Resource Sharing Plans:**

Acceptable

**Authentication of Key Biological and/or Chemical Resources:**

Not Applicable (No Relevant Resources)

**Budget and Period of Support:**

Recommend as Requested

**CRITIQUE 5**

Significance: 3

Investigator(s): 5

Innovation: 4

Approach: 4

Environment: 4

**Overall Impact:** This project proposes to develop a culturally appropriate smartphone application (app) to support self-management of gestational diabetes mellitus (GDM), and test its usability and preliminary efficacy, among patients in a tertiary level, university hospital of Kathmandu University, Nepal. Based on the Social Cognitive Theory framework for behavior change, this app will assist in self-management of GDM by increasing the patient's knowledge and self-efficacy to adhere to the recommended diet and physical activity regimens. The premise is solid and balanced and the study is poised to resolve a long-standing issue of gestational diabetes mellitus (GDM) in Nepal. The proposed studies of use of mobile app and theoretical framework do not offer a notable advantage over studies already done, and relevance to the success is questionable. Even if successful, it is unclear that these results would move the field of mobile app. At Nepali site, the facility has the experience of using mobile app. The facilities at Nepal site was not described well and it is unclear whether the university can fully support the high demands associated with this mHealth study.

**1. Significance:**

**Strengths**

- The premise is solid and balanced, and the study is poised to resolve a long-standing issue of gestational diabetes mellitus (GDM) in Nepal.
- Preliminary results support the value of using the mobile app to study GDM. These studies will provide specific insights into the role of mobile app in GDM.
- This application seeks to develop a mobile app and advance current knowledge of taking care of GDM. If successful, such understanding of GDM would further allow use of theoretical framework for GDM to be accomplished, which would have a high impact on the field of new born babies and taking care of pregnant woman.

**Weaknesses**

- The proposed studies of use of the mobile app and theoretical framework do not offer a notable advantage over studies already done, and relevance to the success is questionable. Even if successful, it is unclear that these results would move the field of mobile app.
- The application lacks justification that use of the app over text messaging as use of app always need to be on but text messaging is better controlled by the doctors.

**2. Investigator(s):**

### **Strengths**

- Over the past couple of years, the PI has published relevant papers in this area but the PI does not see patients like a medical doctor.
- The consultant in theoretical framework is highly accomplished in the field of behavior change.
- Co-investigator in Nepal has firsthand experience.

### **Weaknesses**

- The experience of the PI for conducting these complicated studies is not extensive. He does not appear to have significant expertise to provide guidance for critical aspects such as use of the theoretical framework and mobile app.
- The team appears to lack expertise in mobile app development, particularly important for completing Aims 1 and 2.
- The investigators have not worked together as a team.

## **3. Innovation:**

### **Strengths**

- The combination of mobile app and theoretical foundation is distinct from other approaches in mHealth to study GDM.

### **Weaknesses**

- Although the project uses new methods such as theoretical framework and mobile app, these methods are unlikely to generate different conceptual approaches related to theoretical framework than what currently drives mHealth.
- The concept of use of app is not new to the field.
- The research question is a modest extension of the investigator's existing work and does not move in new directions.
- Continued use of the well-established mobile app will yield only incremental additional knowledge.

## **4. Approach:**

### **Strengths**

- Specific Aim 2 was well-designed to test the main hypothesis. The investigators proposed well-controlled, appropriately powered set of rigorous experiments that addresses the impact of mobile app within this model system.
- The experimental design is comprehensive and cohesively covers all aspects of use of mobile app.

### **Weaknesses**

- The approach to develop the mobile app lacks any methodology like agile software development.
- Use of text messaging along with the mobile app would improve the outcome.

## **5. Environment:**

### **Strengths**



- The environment at Rutgers is outstanding because it has all of the necessary environment to build the app.
- At Nepal site, the facility has the experience of using mobile app.

**Weaknesses**

- The facilities at Nepal site were not described and it is unclear whether the university can fully support the high demands associated with this mHealth studies.

**Study Timeline:**

**Strengths**

- The time line is well justified along with the app development and getting feedback.

**Weaknesses**

- None.

**Protections for Human Subjects:**

Acceptable Risks and/or Adequate Protections

Data and Safety Monitoring Plan (Applicable for Clinical Trials Only):

Acceptable

**Inclusion of Women, Minorities and Children:**

- Sex/Gender: Distribution justified scientifically
- Race/Ethnicity: Distribution justified scientifically
- For NIH-Defined Phase III trials, Plans for valid design and analysis: Not applicable
- Inclusion/Exclusion of Children under 18: Excluding ages <18; justified scientifically

**Vertebrate Animals:**

Not Applicable (No Vertebrate Animals)

**Biohazards:**

Not Applicable (No Biohazards)

**Applications from Foreign Organizations:**

Justified

**Select Agents:**

Not Applicable (No Select Agents)

**Resource Sharing Plans:**

Acceptable

**Authentication of Key Biological and/or Chemical Resources:**

Not Applicable (No Relevant Resources)

## **Budget and Period of Support:**

Recommend as Requested

## **CRITIQUE 6**

Significance: 1

Investigator(s): 2

Innovation: 2

Approach: 1

Environment: 1

**Overall Impact:** The overall impact of this project is likely to be high based on several strengths and only a few weaknesses. There is a need for this type of MHealth app to overcome limitations in health resources for management of GDM in LMIC – a gap that also exists in HIC but for which there is active research. The team, although comprised of several relatively junior investigators with some key senior collaborators, appears to have the expertise and drive to see the project through to completion. The environment is strong on both sides, and the likelihood of building capacity for future mHealth is particularly strong given a) the senior expertise in Nepal and prior work; b) the specific inclusion of a plan within Aim 3. The scientific aims for development of the smart phone app and testing within a pilot study seems appropriate, although recruitment criteria should also include women with GDM but otherwise low risk pregnancy.

### **1. Significance:**

#### **Strengths**

- This study will address a significant and emerging problem in LMIC – GDM.
- The study appropriately identifies the key constraints in LMIC for counseling and care of women during pregnancy (and although they don't address the primary constraint which is universal screening/testing (!) they are working in a hospital with universal testing). One of the constraints to testing is what to do about it if you find it and this app may provide a feasible/acceptable management strategy.
- They create a cogent argument for this type of app and one can see the generalizability of such an app in other settings in other countries. Thus, if development, found feasible/acceptable and with future testing, this could be an important addition to prenatal care for women with GDM in LMIC.
- Although not mentioned, and absent glucose monitoring the app could be expanded as a primary resource on diet and physical activity during pregnancy for women as part of prenatal care who do not have GDM.
- The partnership and prior relationships between KU and Rutgers (and the investigators) and prior app development in Nepal to be expanded here enhance the significance of this project from the perspective of capacity building in mHealth.

#### **Weaknesses**

- There are no identified weaknesses.

### **2. Investigator(s):**

#### **Strengths**

- The team has the appropriate expertise to carry out the project, including expertise in GDM/obstetrics/antenatal care in Nepal, diet and lifestyle in Nepal, app based PA monitoring, app development including smartphone based development, SCT/behavior change within the context of mHealth and app; scientific coordination at high levels with Nepal, research grant administration, etc.

#### **Weaknesses**

- Several members of the research team are quite junior, the PI is in first year of faculty position at Rutgers. This is not necessarily a concern, as the career trajectories of the junior investigators is quite impressive, and it is balanced by senior collaborators, particularly at KU.

### **3. Innovation:**

#### **Strengths**

- The investigators appropriately argue that their planned development of an app which emphasizes dietary and physical activity monitoring as management of GDM in an environment with barriers to glucose monitoring and high clinical follow up.
- The app will provide an innovative approach to capture physical activity which has not been tested previously in LMIC.
- The extent to which they will develop content for an app for women, who may be vegetarian and whose carbohydrate intake may be close to 70%, is new, needed and of potential generalizability throughout South Asia.

#### **Weaknesses**

- It may be argued that the project is not innovative because it may be more about moving prenatal GDM monitoring from paper and pamphlets (SOC, which we don't know the content or quality of – although it might be good) to a mobile app.

### **4. Approach:**

#### **Strengths**

- The plan/set of activities for strengthening mHealth research in Nepal is strong, plausible and has high potential for continued growth beyond the project period.
- The approach for the app development are appropriate in sequence and accompanying research methodologies (Focus groups/key informant interviews, think out loud methodology and pilot testing compared to SOC).
- Their approach will build on prior results (which we do not much about them) regarding the diet and physical activity of women in Nepal. They will address guiding women in knowledge and self-efficacy regarding carbohydrate sources and assessment.
- They recognize the need to consider caste.
- These last 2 points add to the significance and likely overall impact of the project in that there is experience in the rather quick adaption of diet related materials/app in Nepal to the context of India.

#### **Weaknesses**

- The goals and sample size calculation for the pilot focusing on change in glucose challenge (prenatal to postpartum) is a stretch, as if the researchers are trying for a health outcome. Having said that the sample size and approach of the pilot to examine usability of the app and collection of data on biologic variables is appropriate, and the pilot results should inform the design of a larger trial to test the app.

## **5. Environment:**

### **Strengths**

- The environment appears appropriate for the project. They have identified the landscape for mHealth in Nepal, and although not everyone has one, they are likely to be on the rise.
- There is shared experience in the development of smartphone app for health through another project, and prior collaborations amongst the group.
- There is appropriate resources and structure in Nepal to carry out this project, in terms of scientific and medical resources, and technical expertise in app development.

### **Weaknesses**

- There are no recognized weaknesses

## **Study Timeline:**

### **Strengths**

- The timeline seems appropriate for app development, which is largely related to content development and user considerations, and the execution of the pilot trial is justified with data/evidence by the applicant.
- The PI has an ongoing study with some of the other investigators on diet and physical activity of women in Nepal and thus likely has local content which can be adapted for this project. They are not starting from scratch.
- The strength of the environment and the prior collaborations allow for this timeline.

### **Weaknesses**

- The timeline of app development (9 months at most) and recruitment for the pilot (6 months) may be optimistic.

## **Protections for Human Subjects:**

### Acceptable Risks and/or Adequate Protections

- This is a minimal risk study of a smartphone app as an alternate (better) support for women with GDM within the context of ongoing prenatal care.

### Data and Safety Monitoring Plan (Applicable for Clinical Trials Only):

#### Acceptable

- The description seems appropriate given the level of risk and the ongoing care of the participants in the pilot (Aim 2).

## **Inclusion of Women, Minorities and Children:**

- Sex/Gender: Distribution justified scientifically
- Race/Ethnicity: Distribution justified scientifically
- For NIH-Defined Phase III trials, Plans for valid design and analysis: Not applicable
- Inclusion/Exclusion of Children under 18: Excluding ages <18; not justified scientifically
- They will not recruit women with GDM during pregnancy who are less than 18, which I take to be age of majority in Nepal. There is no justification for this, although it could be argued that a pregnant woman < 18 with GDM would be so unusual as to detract from the scientific purpose of obtaining pilot data.

**Vertebrate Animals:**

Not Applicable (No Vertebrate Animals)

**Biohazards:**

Not Applicable (No Biohazards)

**Applications from Foreign Organizations:**

Not Applicable (No Foreign Organizations)

**Select Agents:**

Not Applicable (No Select Agents)

**Resource Sharing Plans:**

Not Applicable (No Relevant Resources)

**Authentication of Key Biological and/or Chemical Resources:**

Not Applicable (No Relevant Resources)

**Budget and Period of Support:**

Recommend as Requested

**THE FOLLOWING SECTIONS WERE PREPARED BY THE SCIENTIFIC REVIEW OFFICER TO SUMMARIZE THE OUTCOME OF DISCUSSIONS OF THE REVIEW COMMITTEE, OR REVIEWERS' WRITTEN CRITIQUES, ON THE FOLLOWING ISSUES:**

**PROTECTION OF HUMAN SUBJECTS:** ACCEPTABLE

**INCLUSION OF WOMEN PLAN:** ACCEPTABLE

**INCLUSION OF MINORITIES PLAN:** ACCEPTABLE

**INCLUSION OF CHILDREN PLAN:** ACCEPTABLE

**COMMITTEE BUDGET RECOMMENDATIONS:** The budget was recommended as requested.

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Footnotes for 1 R21 TW011377-01; PI Name: Rawal, Shristi

# Ad hoc or special section application percentiled against "Total CSR" base.

NIH has modified its policy regarding the receipt of resubmissions (amended applications). See Guide Notice NOT-OD-14-074 at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-074.html>. The impact/priority score is calculated after discussion of an application by averaging the overall scores (1-9) given by all voting reviewers on the committee and

multiplying by 10. The criterion scores are submitted prior to the meeting by the individual reviewers assigned to an application, and are not discussed specifically at the review meeting or calculated into the overall impact score. Some applications also receive a percentile ranking. For details on the review process, see [http://grants.nih.gov/grants/peer\\_review\\_process.htm#scoring](http://grants.nih.gov/grants/peer_review_process.htm#scoring).

## MEETING ROSTER

**Center for Scientific Review Special Emphasis Panel  
CENTER FOR SCIENTIFIC REVIEW  
PAR-16-292 Mobile Health: Technology and Outcomes in Low and Middle Income Countries  
ZRG1 HDM-A (55)  
03/01/2019**

**Notice of NIH Policy to All Applicants:** Meeting rosters are provided for information purposes only. Applicant investigators and institutional officials must not communicate directly with study section members about an application before or after the review. Failure to observe this policy will create a serious breach of integrity in the peer review process, and may lead to actions outlined in NOT-OD-14-073 at <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-073.html> and NOT-OD-15-106 at <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-106.html>, including removal of the application from immediate review.

### **CHAIRPERSON(S)**

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