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Protocol

Mobile Intervention - Physical Activity in Cancer Treatment

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TABLE OF CONTENTS

1.0 BACKGROUND

Recent analyses have indicated that physical activity reduces mortality risk among patients with renal cell carcinoma (RCC), and gastrointestinal cancer, particularly colon cancer [1]. Physical activity also provides additional benefits for patients undergoing treatment for cancer such as improved quality of life and sleep, and reduced treatment-related fatigue . However, individuals receiving treatment for RCC and gastrointestinal cancer often fail to engage in sufficient physical activity. Many cancer survivors experience a decrease in their physical activity after diagnosis [2] and the majority of RCC and gastrointestinal cancer survivors do not meet the recommended guidelines for physical activity [3]. Traditional physical activity interventions require significant resources and present substantial barriers for participants (travel, time commitments, etc.). In contrast, mobile technologies enable delivery of interventions with significantly fewer resources. These technologies also facilitate the delivery of just-in-time adaptive interventions (JITAIs) in which intervention support is provided at only at times when an opportunity for positive changes exists.[4] The purpose of this support the development of a JITAI in RCC and gastrointestinal cancer patients. Evaluation of the acceptability and efficacy of three intervention strategies (affective framing, intention planning, goal-setting, and savoring) will determine their inclusion in the JITAI.

2.0 STUDY OBJECTIVES

Aim 1. Determine the feasibility and acceptability of the proposed mobile technology intervention to increase physical activity patients receiving treatment for renal cell carcinoma and gastrointestinal cancer.

Aim 2. Evaluate the effect of the proposed intervention components (affective framing, intention planning, and goal-setting) on changes in physical activity.

3.0 STUDY DESIGN

3.1 Overview of Study Design

For this project, we will enroll 50 participants diagnosed with renal cell carcinoma or gastrointestinal cancer in an eight-week study. Using a micro-randomized design, participants will receive affective framing messages and intention planning prompts on a randomized schedule, such that participants will receive each message type on 50% of days.

4.0 STUDY POPULATION

4.1 Inclusion Criteria

1) Males and females 18 years to 89 years of age
2) Diagnosed with renal cell carcinoma or gastrointestinal cancer
3) < 150 minutes of weekly moderate-to-vigorous physical activity, as per PAVS survey
4) Own a smartphone (required for syncing the Fitbit device).

4.2 Exclusion Criteria

1) Medical condition contraindicating exercise participation
2) Cognitively unable to give informed consent.
3) Unable to read and communicate in English

4.3 Participant Recruitment and Retention

We will recruit participants from the clinics in the UT Southwestern Harold C. Simmons Comprehensive Cancer Center (SCCC).

5.0 STUDY PROCEDURES

5.1 Informed Consent

Individuals will go through the informed consent process prior to completing any study activities. Study personnel will explain the details of the study to the potential participant and then give him or her time to read through the informed consent document. Study personnel will then go through the document with the potential participant and answer any questions he or she may have

5.2 Screening

Potential participants will be screened for eligibility based on all inclusion and exclusion criteria, detailed in sections 5.1 and 5.2. All participants who are screened will complete the Demographics Form.

5.3 Baseline

Study assessments (described in section 6.0) will be collected at initial visit.

5.4 Treatment and Study Intervention

Participants will receive a Fitbit Versa and instructions on its use. Participants will be asked to wear the device for eight weeks, removing it only for charging and when engaging in activities in which the device could be submerged in water beyond its recommended depths (water resistant up to 50 meters).

Manual Connection and Pre-Authorization: At baseline, a research staff member will create a unique email and password combination in order to create an account on Fitbit.com.
During the account creation process the following information will be entered:

- First Name: A de-identified placeholder name will be entered
- Last Name: A de-identified placeholder name will be entered
- Date of Birth: The first day of the month of birth will be entered OR The first day of the year of birth will be entered.
- Gender/Sex: The participant's gender will be entered.
- Height: The participant's height will be entered.
- Weight: The participant's weight will be entered.

It is important to note that the personal demographic details - date of birth, gender, height, and weight - are required for accurate estimation of data captured by the Fitbit Device.

The Fitbit account will be connected to a research device. Once the device is connected to the study-generated and study-controlled Fitbit account it will be manually connected to the Fitabase platform and assigned a unique study ID so that data will be synced and available for viewing and downloading by research staff. All data associated with the Fitbit device will be linked to the chosen unique study ID in the Fitabase platform.

Participants will be given the connected Fitbit device and be provided with the associated email/password so that they may login into the Fitbit.com user account, use the online dashboard, and associated mobile applications. They will be informed that research staff will be able to access, view, and download their data through the Fitabase platform. The participant will be given a copy of the Fitabase Terms of Use and the Privacy Policy for review during the consent process. By consenting to use the Fitbit device as part of this study the participants also signals an acceptance of the Fitabase Terms of Use and Privacy Policy.

At enrollment, participants will indicate a preferred time to receive affective framing messages and EMA prompts (morning), and intention planning prompts (evenings).

Ecological momentary assessment.
Each morning during the eight-week intervention, participants will receive questions about their current affect, intent to engage in physical activity, and self-efficacy for engaging in physical activity. At each request, participants will be given the option to "snooze" the request for up to one hour. The assessment questions will be viewed and responded to on the Fitbit Versa device. We will utilize the Fitabase Engage platform (see Figure 3), which utilizes the Fitbit SDK to deliver assessments and message prompts via the Fitbit Versa. Assessment questions have been validated for their use in EMA.[5-7] Daily questions will include:

Figure 3. Representations of messages delivered via the Fitabase Engage platform.

*Actual messages will be customized as described below.

Physical Activity Intention (One item; *1 strongly disagree to 5 strongly agree*)
"I intend to meet my goal of XXX steps today"

Physical Activity Self-Efficacy (One item; *1 not confident at all to 5 completely confident*)
"I believe I can complete my goal of XXX steps today."

Affect (Nine items assessing positive and negative affect; *1 not at all to 5 extremely*)
"How (happy, cheerful, relaxed, stressed, anxious, angry, depressed, energetic, fatigued/tired) do you feel right now?"

Affective Framing Messages. After completing the daily EMAs, participants may receive an affective framing message. Message delivery will occur on a 1:1 randomization schedule, such that participants will receive messages on 28 of the 56 intervention days. The study biostatistician will generate randomization schedules for each participant using block randomization with variable block sizes. Messages will be randomly selected from a pool of 14 messages, meaning each message will be received twice during the eight-week study. Messages will emphasize potential improvements in mood, energy, and calmness.[8,9] Examples of these messages:
"Research has shown that physical activity often results in improved mood."
"Most people report feeling happier and more relaxed after exercise."

Weekly Goal Setting. Each Sunday evening, participants will receive a prompt to select a step goal for the upcoming week. Along with this prompt, participants will receive feedback on their activity during the previous week. Participants will receive either: 1) the average daily number of steps taken during the previous week, or 2) the highest daily number of steps taken during the previous week.

Intention Planning Prompts. Delivery of these messages will occur on a 1:1 randomization schedule, such that participants will receive messages on 28 of the 56 intervention days. Planning prompts will be delivered in the evening at a time preferred by the participant. At each request, participants will be given the option to "snooze" the request for up to one hour. Using a drop-down

menu, participants will be able to indicate the time, duration, and location to complete the following prompt:
"Tomorrow, at (time), I will walk for (duration) minutes at (location)."

Activity recognition. We will utilize Fitbit SmartTrack feature to automatically detect physical activity bouts. The SmartTrack settings will be customized to identify all physical activity bouts of ≥ 10 minutes. Approximately one hour after completion of a physical activity bout, participants will be asked to report on their current affect and reflect upon their experience during the physical activity bout. Delivery of these assessments will occur after each activity bout; however, in the event of multiple activity bouts occurring in one day, assessments will be limited to the first activity bout of that day. Participants will be given the option to "snooze" for up to one hour if they are unavailable.

Affect (Nine items assessing positive and negative affect; *1 not at all to 5 extremely*)
"How (happy, cheerful, relaxed, stressed, anxious, angry, depressed, energetic, fatigued/tired) do you feel right now?"

Remembered Experience (One item; *1 very good to 5 very bad*).
"Think back to how you felt during your physical activity today - How do you remember feeling?"

Savoring – After completing the EMAs, participants will receive the savoring messages after 50% of their detected activity bouts (1:1 randomization schedule). Participants will receive imagery-based prompts, as those have been shown to elicit more positive affect responses compared to descriptive prompts (Nelis et al 2015). Delivery of the savoring prompts will occur over approximately 1-minute, with pauses interspersed between prompts to allow for the participant to imagine their experience (see below).
"Thinking back to that physical activity bout, try to create an image of that in your mind. Spend a moment re-living the activity."
(10 seconds)
"Replay that memory as if you were watching a movie in mind."
(10 seconds)
"What could you see around you?"
(10 seconds)
"What could you hear?"
(10 seconds)
"How did you feel in that moment?"
(10 seconds)
"What was happening around you?"
(10 seconds)
"What did you do immediately after your activity?"

5.5 Participant Discontinuation

In order to ensure safety, female participants who become pregnant during the study will be required to discontinue participation in the intervention. Participants may be asked to stop study intervention if any situation arises that, in the investigator's judgment, poses a safety risk.

Participants who must stop the study intervention will still be asked to complete assessment visits as scheduled.

5.6 Participant Remuneration

Participants will be paid up to a total of $40 for their participation in the trial to compensate for their time, travel arrangements, and the burden of participation. Participants will be paid $20 for attending the each of the assessment visits (baseline and Week 8). Participants will be paid for each eligible visit using the UT Southwestern Greenphire ClinCard system. Participants will also receive instructions on how use the card.

6.0 STUDY ASSESSMENTS

6.1 Schedule of Assessments

Study assessments may have a window of +/- 2 weeks to allow visits to occur concurrent with standard of care visits. Week 8 and 10 can occur at the same visit if needed. Remote phone/video visits are allowed

Assessment	Baseline	Week 8	Week10
Informed Consent	X		
Demographics (age, gender, race, diagnosis, stage)	X		
Weight, height, ECOG performance status	X		
Physical Activity Vital Sign	X		
Physical Activity Readiness Questionnaire	X		
Eligibility Criteria	X		
Completion of Fitbit Versa Registration	X		
Physical Activity Stages of Change Questionnaire	X	X	
Physical Activity Self-Efficacy Questionnaire	X	X	
Multidimensional Outcome Expectation for Exercise Scale	X	X	
Affective Associations	X	X	
Affective Attitudes	X	X	
Anticipated Affect	X	X	
Functional Assessment of Cancer Therapy - Kidney Symptom Index*	X	X	
Functional Assessment of Cancer Therapy - Gastric Cancer~	X	X	
Quick Inventory of Depressive Symptomatology	X	X	
Brief Fatigue Inventory	X	X	
Generalized Anxiety Disorder	X	X	
Pittsburgh Sleep Quality Index	X	X	
Pain - Frequency, Intensity, and Burden Scale	X	X	
Dimensional Anhedonia Rating Scale	X	X	
Exercise Vital Sign	X	X	
Intervention Acceptability			X

* Only applicable for renal cell carcinoma patients

~ Only applicable for any GI cancer patient

6.1.1 Study Assessments

At baseline and at the end of the eight-week intervention, participants will complete assessments of: 1) potential moderators of physical activity behavior change, and 2) psychosocial outcomes.

Primary outcome measurement:

Fitbit Versa. The primary outcome measure will be daily step counts measured by the Fitbit Versa. Wrist-worn Fitbit devices demonstrate acceptable reliability and validity for measuring step counts.[13] We will utilize Fitabase, a comprehensive data management platform that utilizes the Fitbit partner-level API, to capture near real-time participant activity data.

Theoretical moderators of physical activity behavior change:

Physical Activity Stages of Change Questionnaire: 4-item scale that assesses current stage of activity.

Physical Activity Self-Efficacy Questionnaire: 3-item scale that assesses self-efficacy for physical activity.

Multidimensional Outcome Expectations for Exercise Scale: 15-item scale that assesses a multitude expectations for physical activity.

Affective associations: 6-item scale that assesses feelings about exercise.

Affective attitudes: 3-item scale that assesses feelings during exercise.

Anticipated affect: 2-item scale that assesses the anticipated affect of regular physical activity.

Psychosocial Outcomes:

Functional Assessment of Cancer Therapy: 19-item scale that assesses quality of life in cancer patients.

Quick Inventory of Depressive Symptomatology – Self-Rated (QIDS-SR): 16-item scale that assesses severity of depression-specific symptoms.

Brief Fatigue Inventory (BFI): 9-item scale that assesses fatigue in cancer patients

Generalized Anxiety Disorder 7 item Scale (GAD-7): 7-item scale that assesses anxiety symptoms.

Pittsburgh Sleep Quality Index (PSQI): 19-item scale that assesses sleep quality and disturbances.

Pain – Frequency, Intensity, and Burden Scale (P-FIBS): 4-item scale that assesses the frequency, intensity, and burden of pain.

Dimensional Anhedonia Rating Scale (DARS): 21-item scale that assesses anhedonia.

Exercise Vital Sign (EVS): 2-item scale that assesses an estimate of an individual's physical activity.

Intervention Acceptability:

After completion of the study, at Week 10, participants will complete an intervention acceptability questionnaire. Using a series of 5-point Likert scale questions, we will evaluate overall intervention satisfaction and also satisfaction with specific components of the intervention (i.e., message content, message frequency, Fitbit ease of use, etc.)

7.0 STATISTICAL ANALYSES

Aim 1. Aim 1 of the proposed pilot study will evaluate the feasibility and acceptability of the proposed intervention. The feasibility of the study will be assessed by the following criteria displayed in Table 1.

Table 1. Feasibility and acceptability measures and benchmarks.

FEASIBILITY		
	Measure	**Benchmark**
Recruitment	Enrollment rate	7 participants/month
Intervention Adherence	Response rate to intervention messages Response rate to EMA prompts Fitbit use (% of days with > 8 hours wear time)	75% 75% 70%
Retention	Completion of follow-up assessments	90%
ACCEPTABILITY		
	Measure	**Benchmark**
Intervention satisfaction	Satisfaction questionnaire	75% of participants rate ≥ 4 on 5-point Likert scale

Aim 2.

Hypothesis 2a: *Participants will have greater daily step counts on days receiving an affective framing message compared to non-message days.*

A repeated-measures mixed effects model will be used as described in Klasnja et al. (2015) with participant and time as random effects and other effects as fixed. Daily step count will be the dependent variable while main effects of affective framing intervention (message/no message) and linear time effects will be within-subjects factors, and an intervention by time interaction term will be included. We also will consider more complex effects of time (e.g., quadratic effects). We will include scores of the Physical Activity Intention, Physical Activity Self-Efficacy, and Affect as time-varying covariates. As described in Klasnja, et al. (2015) we will include the scores for the day prior to the intervention so the covariates will not be affected by the intervention. We will also classify each day as a cancer treatment day (i.e. day on which chemotherapy or radiation therapy is received) or not and presence/absence of cancer treatment will also be a time-varying covariate. A time lag is not needed for this covariate as the timing of cancer treatment will not be influenced by the intervention. Presence/absence of an implementation planning message on each day will also be included as a time-varying covariate and an affective framing by planning message interaction will be included to assess synergistic effects of the two messages. The baseline measurement of theoretical moderators of physical activity behavior change (Physical Activity Stage of Change, Physical Activity Self-Efficacy, Multidimensional Outcome Expectations for Exercise Scale) and psychosocial characteristics Functional Assessment of Cancer Therapy – General, Quick Inventory of Depressive Symptomatology – Self-Rated, Brief Fatigue Inventory) will be considered as covariates as will other baseline demographic and clinical variables determined to improve the fit of the final model.

Hypothesis 2b: *Participants will have greater daily step counts on days receiving the implementation planning message compared to non-message days.*

The same repeated-measures mixed effects model described for Hypothesis 2a will be used for this hypothesis. Only the interpretation of the results will be different as the presence/absence of the implementation message will be the main effect and the affective framing intervention will be considered the covariate.

Hypothesis 2c: *Participants randomized to receive feedback prompts reporting their highest daily step count will achieve greater step counts compared to participants that receive feedback prompts reporting their average daily step counts.*

Participants will be randomized at baseline for the duration of the study because we expect that the intervention will have a cumulative effect over the course of the study. The hypothesis will be tested using a repeated-measures mixed effects model with participant and time as random effects and other effects as fixed. Daily step count will be the dependent variable. The intervention (highest vs average steps feedback) will be a between-subjects factor and time the within-subjects factor and an intervention by time interaction term will be included. We also will consider more complex effects of time (e.g., quadratic effects). The baseline characteristics described in Hypothesis 2a will be considered to improve the fit of the final model. We will also consider the inclusion of time-varying covariates if a clinically meaningful imbalance between groups is found.

Exploratory analyses

For Aim 2a and 2b we will also evaluate the moderating effects of time-varying factors measured through daily EMA (Physical Activity Intention, Physical Activity Self-Efficacy, and Affect). Our ultimate goal is to be able to evaluate these factors to inform decision rules in the ultimate adaptable intervention. The proposed sample size limits the power to detect time-varying moderators of intervention effects and formal analysis of moderating effects will only be conducted in the subsequent clinical trial. These analyses will use a repeated-measures mixed effects model as described above for Hypotheses 2a and 2b, and the moderating effect will be represented by a 3-way interaction of intervention, covariate, and time.

Power calculations

The study design for Aims 2a and 2b will require subjects to be randomized each day to receive the intervention or not. Each day there will be a 50% probability of receiving the intervention (1:1 randomization schedule) so that the average subject will receive the intervention on 28 of the 56 study days. The sample size for Hypotheses 2a and 2b of 50 is based on the sample sizes in the table below which assume 80% power with an alpha=0.05. We also assume that the effect size (standardized difference between treatment groups, similar to Cohen's *d*) is constant during the 56-day study period. Note that for Cohen's *d* an effect size of 0.2 or less is considered 'small' (Cohen, 1998) (small effect=0.2, medium effect=0.5, large effect=0.8), therefore, the proposed sample size of 50 will be able to detect effect sizes that are about half of a 'small' effect.

The power analysis for Hypothesis 2c is based on a repeated measures analysis of variance comparison of two groups with 56 repeated observations assuming a correlation between repeated measurements of 0.5, 80% power, and alpha=0.05. Given these assumptions, an effect size of 0.29 can be detected with the proposed sample size of 50. Based on Cohen's guidelines for an ANOVA f-test an effect size of 0.29 is slightly larger than a 'medium' effect (small effect=0.1, medium effect=0.25, large effect=0.4).

Table 1. Sample size calculations.

Hypotheses 2a and 2b		Hypothesis 2c	
Effect Size	Sample Size to Obtain 80% Power	Effect Size	Sample Size to Obtain 80% Power
0.200	17	0.290	50
0.109	50	0.265	60
0.099	60	0.245	70
0.091	70	0.203	100
0.076	100	0.100	402

8.0 REPORTING AND MONITORING

8.1 Statement of Compliance

This trial will be conducted in compliance with the appropriate protocol, appropriate ICH guidelines (including current Good Clinical Practice [GCP]), the principles of the Declaration of Helsinki, and all other applicable regulatory requirements. The study team must obtain written approval of the study protocol, consent form, other supporting documents, and any advertising for participant recruitment from the UT Southwestern institutional review board (IRB) in order to participate in the study. Prior to study initiation, the protocol and the informed consent documents will be reviewed and approved by an appropriate UT Southwestern IRB. Any amendments to the protocol or consent materials must be approved before they are implemented. Annual progress reports and Serious Adverse Event (SAE) reports will be submitted to each IRB, according to its usual procedures.

8.2 Regulatory Files

The regulatory files should contain all required regulatory documents, study-specific documents, and all important communications. Regulatory files will be reviewed at each participating site for regulatory document compliance prior to study initiation, throughout the study, as well as at the study closure.

8.3 Informed Consent

Every study participant is required to sign a valid, IRB-approved current version of the study informed consent form prior to the initiation of any study related procedures.

Prior to signing the informed consent form, research staff who are knowledgeable about the study will explain the study to the potential participant and provide the participant with a copy of the consent to read. If the participant is interested in participating in the study, a researcher who is authorized to obtain informed consent will review each section of the informed consent form in detail, answer any of the participant's questions. The participant will consent by signing and dating the consent document. The person obtaining consent will also sign and date the consent document. Every study participant must be offered a copy of the signed consent form. The consent must be properly executed and complete to be valid. All persons obtaining consent must have completed appropriate training.

The informed consent form must be updated or revised whenever important new safety information is available, or whenever the protocol is amended in a way that may affect a participants' participation in the trial.

Study participation is voluntary and there are no benefits lost if an individual declines participation. Individuals who refuse to participate or who withdraw from the study will be treated without prejudice. Study sites will be responsible for maintaining signed consent forms as source documents for quality assurance review and regulatory compliance.

8.4 Study Documentation

Study documentation includes all case report forms, source documents, monitoring logs, Institutional Review Board correspondence and approved consent form and signed participant consent forms.

Source documents include all recordings of observations or notations of clinical activities and all reports and records necessary for the evaluation and reconstruction of the clinical research study. Whenever possible, the original recording of an observation should be retained as the source document; however, a photocopy is acceptable provided that it is a clear, legible, and exact duplication of the original document.

8.5 Records Retention and Requirements

All research records for all subjects will be stored by the investigator in a secure location to be accessed only by authorized research personnel. Study records will be stored in accordance with local IRB, State, and Federal Regulations but, in any case, will be kept for a minimum of 2 years following study completion.

8.6 Reporting to Sponsor

The principal investigator will submit any and all required reports accurately to the sponsor in a timely manner. Reports may include any significant changes possibly affecting the safe and accurate conduct of the trial or its outcomes. The principal investigator will also submit to the sponsor a detailed final report on the study at its conclusion.

8.7 Safety Monitoring

8.7.1 Data and Safety Monitoring

On a monthly basis, Dr. Beg will examine accumulating data to assure protection of participants' safety while the study's scientific goals are being met. These meetings will determine whether there is support for continuation of the trial, or evidence that study procedures should be changed, or if the trial should be halted, for reasons relating to the safety of the study participants, or inadequate trial performance (e.g., poor recruitment).

8.7.2 Protocol Violations Reporting and Management

A protocol departure is any departure from procedures and requirements outlined in the protocol. Protocol departures may occur on two levels, deviation versus violation. The difference between a protocol deviation and violation has to do with the seriousness of the event and the corrective action required. A protocol deviation is considered an action (or inaction) that by itself is not likely to affect the scientific soundness of the investigation or seriously affect the safety, rights, or welfare of a study participant. Protocol violations are departures that may compromise the participant safety, participant rights, inclusion/exclusion criteria or study data and could be cause for corrective actions if not rectified or prevented from re-occurrence. Protocol violations will be monitored for (1) significance, (2) frequency, and (3) impact on the study objectives, to ensure the integrity of the trial. The PI or designee will make the decision about whether a departure from the protocol will be designated as a protocol deviation or a protocol violation. All protocol violations and deviations will be reported to the IRB as required.

8.7.3 Subject Confidentiality/Privacy

Participant records will be held confidential by the use of study codes for identifying participants on CRFs, secure and separate storage of any documents that have participant identifiers, and secure computing procedures for entering and transferring electronic data.

All research information obtained on participants is confidential, and disclosure to any third parties without specific authorization is strictly prohibited. To maintain subject privacy, all study forms and reports will be identified by a coded study identification number only. No subject identifying information will be included in any presentations or publications resulting from the study.

Study records may be inspected by the sponsor and its authorized representatives, other government agencies such as the U.S. Department of Health and Human Services (DHHS) Office for Human Research Protections (OHRP), authorized Node Staff, or the local IRB for quality assurance purposes.

8.7.4 Adverse Events (AEs) and Serious Adverse Events (SAEs)

The Primary Investigator (PI) will review or seek consultation for each Serious Adverse Event (SAE) as needed. These reviews will include an assessment of the possible relatedness of the event to the study intervention or other study procedures. The PI will also provide advice for decisions to exclude, refer, or withdraw participants as required. The study staff will be trained to monitor for and report Adverse Events and Serious Adverse Events.

8.7.5 Reporting Adverse Events and Serious Adverse Events

Adverse Events

Adverse events severe in nature (grade 3) will be documented from the time consent is signed through the end of study participation.

For the purpose of this study, the following AEs will not require reporting in the participant's record and will not be captured:

- Grade 1 (mild) unrelated event.
- Grade 2 (moderate) unrelated event.

Serious Adverse Events

For the purpose of this study, all SAEs will be documented in the participant's record with the exception of the following:

- Admission to a hospital/surgery center for preplanned/elective surgeries (captured in the Visit Summary/Progress Note).
- Admission to a hospital for scheduled labor and delivery (captured in the Visit Checklist/Progress Note).

Local documentation and reporting guidelines should also be followed based on local IRB requirements.

9.0 DATA MANAGEMENT AND PROCEDURES

9.1 Data Collection Forms

The data collection process consists of data entry into the CRFs according to the instructions provided and project specific training. The investigator is responsible for maintaining accurate, complete and up-to-date records, and for ensuring the completion of the CRFs for each research participant. CRFs will be monitored for completeness, accuracy, and attention to detail throughout the study.

9.2 Data Acquisition and Entry

Data entry into an electronic database shall be performed by authorized individuals.

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