PROTOCOL

NCT03228719

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HUMAN SUBJECTS PROTOCOL
University of Delaware

Protocol Title: A novel physical therapy administered physical activity intervention after TKR

Principal Investigator
Name: Daniel K. White, PT, ScD, MSc
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Other Investigators: None

Investigator Assurance:

By submitting this protocol, I acknowledge that this project will be conducted in strict accordance with the procedures described. I will not make any modifications to this protocol without prior approval by the IRB. Should any unanticipated problems involving risk to subjects occur during this project, including breaches of guaranteed confidentiality or departures from any procedures specified in approved study documents, I will report such events to the Chair, Institutional Review Board immediately.

1. **Is this project externally funded?** X YES □ NO

If so, please list the funding source: NIH/NICHD K12-HD055931-09, NIH/NIAMS R21-AR071079-01A1.

2. Research Site(s)

X University of Delaware
□ Other (please list external study sites)

Is UD the study lead? X YES□ NO (If no, list the institution that is serving as the study lead)

3. **Project Staff**

Please list all personnel, including students, who will be working with human subjects on this protocol (insert additional rows as needed):

NAME	**ROLE**	**HS TRAINING COMPLETE?**
Daniel K. White	Principal investigator/physical therapist	Yes
Laura Schmitt	Physical Therapist	Yes
Hiral Master	Research Assistant	Yes
Dana Voinier	Research Assistant	Yes
Jason Jakiela	Research Assistant	Yes
Nazim Karaca	RedCap Administrator	Yes

Thomas Bye	Research Assistant	Yes
Jennifer Copson	Research Assistant	Yes
Jéssica Aily	Research Assistant	Yes

4. **Special Populations**
Does this project involve any of the following;

Research on Children? No

Research with Prisoners? No

If yes, complete the Prisoners in Research Form and upload to IRBNet as supporting documentation

Research with Pregnant Women? No

Research with any other vulnerable population (e.g. cognitively impaired, economically disadvantaged, etc.)? please describe. No, n/a

5. **RESEARCH ABSTRACT** Please provide a brief description in LAY language (understandable to an 8th grade student) of the aims of this project.

Total knee replacement (TKR) is a common surgery for people with knee osteoarthritis (OA). TKR often relieves pain. However, people remain generally inactive following TKR. Physical inactivity can lead to higher risk for heart disease, diabetes, and death. Little is known about how best to improve physical activity after TKR.

Physical activity monitors, such as the Fitbit®, are common. These monitors are worn on the body. They can accurately record the number of steps you take in a day. As the user, you can access these data on smart phones, computers and tablets. These monitors can help people increase physical activity. Physical therapists treat patients after TKR. Physical therapists create activity goals with their patients. The combination of an activity goal and a Fitbit® device could increase physical activity. We do not know if providing monitors combined with physical activity coaching by a licensed physical therapist can increase physical activity during and after outpatient rehabilitation.

Our plan is to research the effectiveness of this treatment. Our central hypothesis is that people who have an activity goal and Fitbit® will be more active.

6. **PROCEDURES** Describe all procedures involving human subjects for this protocol. Include copies of all surveys and research measures.

Participant recruitment: People receiving outpatient physical therapy rehabilitation at the University of Delaware Physical Therapy Clinic will be recruited to our study. Each of these patients who has a diagnosis of a unilateral TKR will be given a PT Recruitment Flyer by their treating physical therapist. The flyer includes a QR code, which the patient can use to access an online Consent to Contact Form. If the patient completes and electronically signs this form, a member of the physical activity research team will contact the patient. The researcher will contact the patient over the phone to explain the study, verbally confirm their identity, determine

if the patient is interested in participating in the study, and collect basic information related to study eligibility (after obtaining verbal consent for the documentation and storage of basic eligibility information using the attached verbal script). If the patient is eligible for the study and willing to participate, the researcher will remotely obtain consent from the patient and provide them will a copy of their signed informed consent.

Once consented, the patient will be formally enrolled in the study and baseline physical activity data will be collected. After physical activity data collection the participant will be randomized into a control group and an intervention group. The participants will be randomized using computer generated groups ("0" Control group and "1" Intervention group).

To promote recruitment rates, we will provide an Orthopedic Surgeon Recruitment Flyer for display and/or available for distribution to potential study participants at community clinics. The flyer provides basic information on study eligibility, a brief description of the physical activity intervention, and contact information for the study team.

Group Assignment:

All Participants: All participants in the study will receive the following:

Standardized Physical Therapy Rehabilitation: Participants will receive usual physical therapy rehabilitation provided by a licensed physical therapist using the University of Delaware's Rehabilitation Guidelines for Unilateral Total Knee Replacement. See attached documents for Rehab Practice Guidelines for: Unilateral Total Knee Replacement.

Home Exercise Program: Participants will be given a University of Delaware binder. Pictures and descriptions of the standardized home exercise program and exercise log are located in this binder. See attached documents for Home Exercise Program and Exercise Log.

Actigraph: Participants will be asked to wear an accelerometer called an ActigraphGT3X to objectively measure physical activity. The size of the Actigraph is 27g; 1.5" x 1.44" x 0.70". The Actigraph monitors physical activity in terms of steps per day and time spent in moderate to vigorous physical activity. Actigraph monitors will be disinfected prior to wear in accordance with EPA guidelines. The monitor will be worn around the participant's waist with the accelerometer located at the person's right anterior superior iliac spine (ASIS) and the participant will receive in-person instructions on how to properly wear this device. The Actigraph will be worn for approximately one week (7 days) after the patient enrolls in the study. Participants will also be asked to wear the monitor for approximately one week (7 days) after they discharge from formal physical therapy rehabilitation, at 6-months after discharge from formal physical therapy, and at 12-months after discharge from formal physical therapy. The patients will be instructed to put on the monitor when they get up in the morning and take off the monitor when they go to sleep in the evening. They will be asked to remove the monitor during situations that device could get wet, e.g., showering, swimming. See attached documents for Actigraph Instructions. If the device is lost or damaged the participant will notify their physical therapist or the physical activity research team for a replacement.

Exit Interview: After completing formal physical therapy rehabilitation, participants may be contacted via telephone by a researcher. The researcher will read several scripted exit interview questions to participants based on their group assignment. The information gathered from the exit interview will provide data on how to improve the feasibility of the study. See attached documents for exit interview questions.

Wawa or Amazon Gift Card: Participants will be given a $25 gift card (i.e. Wawa, Amazon) at discharge from physical therapy rehabilitation. We will ask participants if they have gift card preference, if not we will give them Amazon gift card. We will continue the same gift card preference as stated by participant at discharge for 6-month and 12-month follow-up. They will be given a $25 gift card for wearing the Actigraph at 6-months and a $50 gift card for wearing it at 12-months.

Control group: The control group will receive standardized physical therapy rehabilitation, home exercise program, an Actigraph and exit interview.

Intervention group: The intervention group will receive standardized physical therapy rehabilitation, home exercise program, an Actigraph and exit interview. They will also receive the following:

Fitbit® monitor : Participants in the intervention group will be given a Fitbit® monitor after baseline physical activity data collection, approximately one week after enrollment. If a participant already has a phsycial activity monitor they can choose to use it instead of the Fitbit® monitor. However, they will still be given a Fitbit® monitor regardless if they already have a physical activity tracking device or not. They will be asked to wear their Fitbit® monitor daily during waking hours to monitor their steps per day. Participants will be given written instructions on how to sync their Fitbit® monitor to their personal smartphone, tablet, or home computer. A physical activity researcher will also explain how to set up, sync, and use Fitbit® monitor in-person. Extra batteries will be provided as needed. If the device is lost or damaged the participant will notify their physical therapist or the physical activity research team for a replacement. At the end of the 12-month follow up participants will be asked to return their Fitbit® monitor with their Actigraph via the mail. See attached documents for Fitbit® monitor Instructions.

Steps per Day Goal Setting: Participants will be asked to self-track their steps per day using their Fitbit® monitor. The participant will be the only one with access to their Fitbit® log-in for their steps per day data. The participant's physical therapist will rely on the participant to self-report the steps per day goal. They will be asked to use their tablet, smartphone or home computer to either show the physical therapist in-person or have a written log of their weekly steps per day. Their steps per day goal will be recorded on their HEP Log. If the participant is less than 3-weeks status post-operative TKR they are not expected to increase their steps per day. Once the participant is more than 3-weeks status post-operative TKR they will be asked to increase their steps incrementally over the course of their rehabilitation with the end goal being 6,000 steps per day. Progression of weekly steps per day goal will be based on the participant's health status, their physical therapist and if the participant could achieve at least 4 of the 7 days per week at or above the prior week's steps per day goal.

Fitabase: Until the Fitabase service is terminated (11/3/19), participants will be given the option to connect their Fitbit account to Fitabase, a secure research platform that enables the research team to access, view, and download their Fitbit data. Each participant will be able to review the Fitabase Terms of Use and Security and Privacy Information as part of the Informed Consent process.

Fitbit Data Collected by Fitabase. Physical activity data will be collected by Fitabase for all participants who connect their Fitbit account to the Fitabase platform. Such data includes:

- Daily steps total

- Measured steps per minutes
- Estimated energy expenditure
- Distance moved
- Minutes of vigorous/moderate/light activity
- Minutes of sedentary time

Fitabase may also collect:

- Personal details that were voluntarily added to your Fitbit account, such as height, weight, gender, and age

A participant's Fitbit username and password will not be accessed, viewed, or stored by Fitabase.

Fitabase Authorization. If a participant agrees to authorize Fitabase to acess his/her Fitbit data, they will complete the authorization process either 1) in-person, at the time of their initial Fitbit® monitor set-up, or 2) online. If they choose to complete the Fitabase authorization process in-person, a research assistant will be present to assist them. The research assistant will create a profile for the participant that includes their assigned, unique study identifier. The research assistant will then use an internet-connected computer (laptop) to "manually connect a device" to the unique identifier. This will open a Fitbit authorization window in a web browser. The participant will be asked to enter their Fitbit login information (username and password) to connect their Fitbit® monitor device and authorize Fitabase to read and access their Fitbit data. This information will 1) be entered outside of the view of the research assistant and 2) is not passed to the Fitabase system as it uses the OAuth protocol established for API authentication. When the participant enters their information and connects their Fitbit account to Fitabase, the in-person authorization will be completed. This completion also signals an acceptance of the Fitabase Terms of Use and Privacy Policy.

If a participant chooses to complete the Fitabase authorization process online, they will be asked for a valid email address to send the authorization link. The research assistant will then create a profile for the participant that includes their assigned, unique study identifier. A link to Fitabase Authorization Page will be emailed to the participant. At the bottom of the online Fitabase Authorization Page, a "connect your device" button is present. The participant will be asked to read the Authorization Page and if they agree, to connect their Fitbit and authorize Fitabase to read and access their Fitbit data. This information will not be passed to the Fitabase system as it uses the OAuth protocol established for API authentication. When the participant enters their information and connects their Fitbit account to Fitabase, the online authorization will be completed. This completion also signals an acceptance of the Fitabase Terms of Use and Privacy Policy.

These participants will receive a set of Fitbit® monitor instructions that explain that they must sync their Fitbit® monitor with their smartphone, tablet, or computer **at least once every 7 days** in order for Fitabase to collect their data.

If a participant does not authorize Fitabase to access his/her Fitbit data, they are still able participate in the study and receive a Fitbit® monitor device. They will not complete the Fitabase authorization process.

Study Access to Fitbit Data. The research team has set up a study project within Fitabase for generating unique identifiers and connecting participants' Fitbit® monitor devices to the Fitabase system. When a member of the research team logs into the Fitabase system, they will be able to see all currently connected devices and the associated study identifiers. Each study

identifier has a profile that includes their Fitbit data (listed above). Authorization by the participant grants the research team access to all data generated by the participant's use of the Fitbit® monitor device up to the study completion date. This data will be downloaded and stored on the secure lab server for analysis. No other data will be downloaded. Once the study has been completed and the data has been downloaded and scanned for errors, the participant's profile will be deleted and the authorization will be removed.

Thank you notes and phone calls: All study participants will receive a thank you note at 3rd and 9th month from the discharge to remind them of their upcoming 6-month and 12-month follow-up, respectively. At the 5th month and 11th month, the research assistant will call all study participants to remind them of their upcoming 6-month and12-month follow-up, respectively. They will be told to expect in the mail: a pre-stamped envelope, an Actigraph, and a questionnaire. They will be asked to wear the Actigraph for one week and then mail it back to the research team along with completed questionnaire in the pre-stamped envelope. During these phone calls, participants will be asked about any changes in health status since their discharge from physical therapy. The research team may also call a participant at any time during the study if the participant has a change in health status. The research team will ask the participant for information needed to determine if an unanticipated problem, adverse event, or serious adverse event has occurred.

Concomitant Medication Log: When the research team contacts each participant during the follow up phase of the study (at 5 months and 11 months from PT discharge), they will ask each participant if they are currently taking any medications related to knee pain and recovery following surgery. The response and pertinent details (i.e. medication, frequency and dosage) will be documented in the Concomitant Medications Form.

3) Data Collection:

We will collect data from participant's medical chart. A research assistant will enter data into Redcap, operated by the Delaware Rehabilitation Insitute. Data includes includes the following:
1) Medical History
2) Insurance Information
3) Demographic Data
4) Geographic Data
5) Contact Information
6) Self-Reported Outcome Measures (Knee Outcome Score, Knee Injury and Osteoarthritis Outcome Score, Short Form -36, Tampa Scale of Kinesiophobia, Self-Efficacy for Exercise Scale, Apathy Scale, Patient Specific Functional Scale, Pain Catastrophizing Scale)
7) Standardized Examination/Evaluation Data, e.g. six-minute walk test, timed stair climb test, muscle strength, Pain, BMI, Range of motion, timed up and go

We will collect the following standardized outcomes at baseline, at discharge and 6-months after discharging from physical therapy rehabilitation. In the event a participant is unable to complete the data collection of the above paper forms (1-6), an electronic version will be sent to them via email through Redcap. This information is typically collected during the course of a physical therapy evaluation, re-evaluation, and/or discharge. These include the following:

- Age
- Height
- Weight
- Blood pressure
- BMI

- Affected Knee
- Type of TKR
- Falls since last evaluation?
- Previous joint replacement?
- Pain scores
- Range of motion
- Timed up and go
- Stair Climbing Test
- Six-minute walk test
- Knee extensor strength
- 30 second chair stand test
- Physical therapy and injection use prior to TKR
- Pain medication type
- Function and Disability questionnaire (PROMIS, SF-36, Apathy Scale, PSPS, KOS-ADL, Tampa Scale, Self-efficacy for Exercise Scale, KOOS, Pain Catastrophizing Scale)
- Demographics (race, marital status, living alone)
- Health History Questionnaire
- Self-Reported Activity level
- Socioeconomic information
- Level of Education
- Length of Stay
- Number of Physical Therapy Appointments
- Medical Script for Physical Therapy Services
- Billing Information
- Types and Dosage of Physical Therapy Treatment Interventions

See attached documents Physical Therapy Clinic Health History Form

7. STUDY POPULATION AND RECRUITMENT

Describe who and how many subjects will be invited to participate. Include age, gender and other pertinent information.

The enrollment capacity for this protocol is 173 participants. This includes two projects:

1. 43 participants enrolled in the pilot phase of this study (9/26/16 – 6/27/17)
2. 130 participants targeted enrollement for the current study (6/28/17 – ongoing)

Inclusion:

- Participants over the age of 45
- Seeking outpatient physical therapy rehabilitation for a unilateral TKR

Note: Participants are included irrespective of time since surgery as long as they are seeking PT for a unilateral TKR

Exclusion:

- No interest in increasing physical activity
- Having had another lower extremity surgery within 6-months that is unrelated to the TKR
- Planning on having another lower extremity surgery within 6-months that is unrelated to the TKR

- Any other medical condition that limits the participant's ability to participate in physical activity.

  Examples of medical conditions that limit physical activity include but are not limited to the following:

  1. Epilepsy
  2. Parkinson's disease
  3. Neuropathy
  4. Dementia
  5. Require the use of a wheelchair
  6. Rheumatoid arthritis
  7. Psychiatric disease
  8. Alcohol and/or drug abuse
  9. Current cancer treatment
  10. Uncontrolled diabetes (glycosylated hemoglobin level >7.0)
  11. Neurologic, vascular or cardiac problems that limit physical activity
  12. Orthopedic conditions that limit physical activity such as lumbar stenosis, severe hip or ankle OA
- Previous enrollment in a physical activity intervention study at the University of Delaware Physical Therapy clinic

Note: Participants are not excluded based on smart device usage and/or access to internet

Describe what (if any) conditions will result in PI termination of subject participation.

Discontinuation from the physical activity intervention does not mean discontinuation from the study, and remaining study procedures should be completed as indicated by the study protocol. If a clinically significant finding is identified (including, but not limited to changes from baseline) after enrollment, the principal investigator or qualified designee will determine if any change in participant management is needed. Any new clinically relevant finding will be reported as an adverse event (AE).

An investigator may discontinue or withdraw a participant from the intervention for the following reasons:
• Significant study intervention non-compliance
• If any clinical AE or situation occurs such that continued participation in the intervention would not be in the best interest of the participant
• If the participant meets an exclusion criterion (either newly developed or not previously recognized) that precludes further participation in the intervention

8. RISKS AND BENEFITS

List all potential physical, psychological, social, financial or legal risks to subjects (risks listed here should be included on the consent form).

- Risks associated with participation are those typically found during a physical therapy evaluation, e.g. risk of soreness from testing of muscle strength or length, fluctuating knee pain and/or swelling related to recovery from TKR, and fatigue during or following the evaluation.

- We will attempt to minimize risks during the evaluation. A physical therapist will appropriately guard the patient and will provide rest breaks as needed to minimize soreness and fatigue.
- There is minimal risk for starting a supervised physical activity program, including a mild temporary increase in knee pain.
- There is minimal risk for participating in the brief behavioral intervention, including being challenged to increase physical activity.
- There are no known risks wearing an Actigraph or Fitbit® monitor
- There is a possibility of a breach of confidentiality if data or identifying information should accidently be released.

In your opinion, are risks listed above minimal* or more than minimal? If more than minimal, please justify why risks are reasonable in relation to anticipated direct or future benefits.

Minimal risk.

*(*Minimal risk means the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests)*

What steps will be taken to minimize risks?

We minimize this risk of the intervention by having physical activity closely monitored by a licensed physical therapist.

Describe any potential direct benefits to participants.

Study participants who increase their physical activity may have benefits including increased lower body muscular strength, improved cardiovascular health, and improved quality of life.

Describe any potential future benefits to this class of participants, others, or society.

Our proposed study will provide important pilot data to show levels of physical activity after total knee replacement which will be important pilot data for future intervention trials.

If there is a Data Monitoring Committee (DMC) in place for this project, please describe when and how often it meets.

We will not establish an external Data Safety and Monitoring Board. We do have a Data Safety and Monitoring Plan. Danie White will meet with Laura Schmitt, our Clinic Liaison, on a weekly basis to discuss any potential adverse events and to ensure ongoing participant safety. Daniel White will be responsible for communication with other members of the research team regarding meeting discussions. The occurrence of adverse events or breaches in confidentiality will be monitored for each participant on an ongoing basis throughout the study. If an adverse event occurs, it will be reported immediately to the University of Delaware Human Subjects Review Board.

9. COMPENSATION

Will participants be compensated for participation?

Yes

If so, please include details.

Participants who wear the Actigraph monitor after their discharge from physical therapy will be given $25.00 as an honorarium.

Participants who wear the Actigraph monitor at 6-months will be given $25.00 as an honorarium, and $50.00 if they wear the Actigraph at 12-months.

10. DATA

Will subjects be anonymous to the researcher? No

If subjects are identifiable, will their identities be kept confidential? (If yes, please specify how)
Yes.
A copy of the consent form will be stored in a locked research cabinet or electronically on the lab server and REDCap within the University of Delaware Physical Therapy Department. Participant evaluations will be stored as part of their electronic medical record at the University of Delaware as required for insurance reimbursement.

Evaluations of individuals who agree to participate in the study will be coded (i.e. name at top of evaluation document will be replaced with participant ID number) and this coded evaluation will be stored electronically in a single Redcap project on the secure DRI server. Coded data will be stored indefinitely and will be accessible only to research personnel.

We will develop separate Redcap project on the secure DRI server that links participant ID numbers to participant names. This link will be destroyed three months after the conclusion of the study and will be accessible only to research personnel.

We will also develop a separate Redcap project on the secure DRI server that stores identifiable participant information. This information will be accessible only to research personnel.
Identifiable participant information includes:

- Name
- Date of Birth
- Phone number(s)
- Email address
- Home address

To summarize, we will use three separate Redcap projects (all located on the secure DRI server). The first project will contain coded evaluation data (with participant ID numbers). The second project will contain a file that links participant ID numbers to participant names. The third project will contain identifiable participant information (including participant name and contact information).

How will data be stored and kept secure (specify data storage plans for both paper and electronic files. For guidance see http://www.udel.edu/research/preparing/datastorage.html)

See response above. To reiterate, we will secure informed consents in a locked file cabinet within the University of Delaware Physical Therapy Department that is accessible only to research personnel. We will store coded data and identifiable participant information electronically (using Redcap) on a secure DRI server.

How long will data be stored? Indefinitely

Will data be destroyed? □ YES X NO (if yes, please specify how the data will be destroyed)

Will the data be shared with anyone outside of the research team? □ YES XNO (if yes, please list the person(s), organization(s) and/or institution(s) and specify plans for secure data transfer)

How will data be analyzed and reported?

Data will be coded and will be analyzed using appropriate statistical software packages. We will examine whether physical activity as measured by the Actigraph monitor is higher in those participants in the treatment versus Actigraph data from published studies. Results will be disseminated through written publications in reputable medical journals and professional presentations.

An interim analysis will be performed after half of the participant's 6 month follow-ups are completed. It is anticipated that this will be approximately 18 months after the start date. The interim analysis will be performed exactly the same as the final analysis. If the effect size of the physical activity intervention (which is standard care, a Fitbit™ monitor, individualized step goal, and face-to-face feedback with a physical therapist) group is greater than 3.0 (95% confidence interval 2.5-3.5), compared with the control group at this time point, then the intervention will have been deemed to work and the study will stop recruiting control group participants. Those in the control group currently will be asked if they want to switch arms and partake in the intervention.

At 18 months after the start of the study, we will conduct an interim analysis with four comparisons for adverse outcomes. The two arms of the study will be compared for number of AE, SAE, and UP, individually and jointly, if they are definitely or probably related to the intervention. If the intervention group is found to have more than 3.0 (95% confidence interval 2.5-3.5) times the odds of AE, SAE, UP, or their sum compared with the control, then we will stop the study.

11. CONFIDENTIALITY
Will participants be audiotaped, photographed or videotaped during this study? Yes

How will subject identity be protected?

The risk of breaching subject confidentiality will be minimized by identifying all participants by code numbers and by securing all data in locked files accessible only to research personnel. Neither the participant's name nor any identifying information will be used in any publication or presentation resulting from this study.

Is there a Certificate of Confidentiality in place for this project? (If so, please provide a copy).

No

12. CONFLICT OF INTEREST
(For information on disclosure reporting see:
http://www.udel.edu/research/preparing/conflict.html)

Do you have a current conflict of interest disclosure form on file through UD Web forms? Yes

Does this project involve a potential conflict of interest*? No

* As defined in the University of Delaware's Policies and Procedures ,a potential conflict of interest (COI) occurs when there is a divergence between an individual's private interests and his or her professional obligations, such that an independent observer might reasonably question whether the individual's professional judgment, commitment, actions, or decisions could be influenced by considerations of personal gain, financial or otherwise.

If yes, please describe the nature of the interest: Not applicable

13. CONSENT and ASSENT

_X___ Consent forms will be used and are attached for review (see Consent Template under Forms and Templates in IRBNet)

____ Additionally, child assent forms will be used and are attached.

__X__ Waiver of Documentation of Consent (attach a consent script/information sheet with the signature block removed).

We are requesting a Waiver of Documentation of Informed Consent in order to record and store eligibility information. The collection of the very basic eligibility criteria presents no more than minimal risk of harm to individuals and involves no procedures for which written informed consent is normally required. A verbal consent script is attached.

____ Waiver of Consent (Justify request for waiver)

14. Other IRB Approval
Has this protocol been submitted to any other IRBs? No

If so, please list along with protocol title, number, and expiration date. Not applicable

15. Supporting Documentation
Please list all additional documents uploaded to IRBNet in support of this application.

1) Cover Letter
2) Amendment Form
3) CITI Training Certificates (HSP and GCP) for Jéssica Aily