RUTGERS
Robert Wood Johnson Medical School

Department of Orthopaedic Surgery

Title of Project:	The Impact of Two Different Physical Therapy Programs in the Rehabilitation of Patients Undergoing Anterior Approach Hip Replacement Surgery.
Principal Investigator:	Stephen Kayiaros, MD
Funding Source(s):	Self funded

1. Purpose/Specific Aims

The direct anterior approach (DAA) to total hip arthroplasty (THA) is gaining popularity with the orthopaedic community because of its muscle sparing approach and excellent postoperative results. With the DAA, patients no longer require post-operative hip precautions with their activities, as they did with other approaches (like posterior or lateral approaches). Many areas of orthopedic surgery, including joint reconstruction [Ref 2,4], have demonstrated improved early function due to improved surgical technique.

It is the purpose of this study to investigate different protocols for administering physical therapy (PT) after DAA THA, and to determine whether "Self-Directed Physical Therapy" (SDPT) generates results non-inferior to those of patients who have undergone Formal Physical Therapy (FPT) post-operatively.

This aim will be achieved by establishing a prospective randomized study where patients will be placed into the FPT or the SDPT arm. Recovery from surgery will be evaluated at 1, 3, 6, and 12 months. This study is based upon prior studies in the field of orthopedics that have evaluated the role of physical therapy in recovery, with particular attention to one study [ref 12] that compared a self-directed physical therapy (SDPT) protocol versus formal physical therapy (FPT) for total hip replacement patients..

1.1 Objectives

To show in patients undergoing DAA-THA that a formally guided postoperative physical therapy course produces results that are non-inferior to a self directed physical therapy regimen via accredited orthopedic functional hip scoring criteria.

1.2 Hypotheses

Self-Directed Physical Therapy for patients who have undergone a DAA THA demonstrates functional outcomes that are non-inferior to patients undergoing Standard Physical Therapy at 1, 3, 6, and 12 months post surgery.

RUTGERS | eIRB
APPROVED
IRB ID: Pro20140001090
Approval Date: 10/6/2017
Expiration Date: 10/5/2018

Endpoints to compare the SDPT group to the FPT group include: 1) number postop days requiring walking assist device; 2) Harris Hip Score (HHS), 3) Visual Analog Scale (VAS) for pain; 4) WOMAC pain score; 5) Timed up and Go Test; and 6) Short-Form 36. The VAS, HHS, WOMAC, and SF-36 are validated scores that are commonly used in peer-reviewed clinical studies to evaluate the results of total hip replacements. We expect the VAS, HHS, WOMAC, and SF-36 to consistently improve with each time point for both groups, without any significant difference in rate of change.

2. Background and Significance

Throughout the field of orthopedics, surgeons are developing less invasive techniques to address their patients' illness and injuries [Ref 1, 6-11]. By minimizing trauma to soft tissue during surgery, there is less postoperative pain and disability [Ref 1, 6-11]. While the vast majority of reconstructive orthopedic surgery, like the total hip replacement, still requires postoperative hospitalization, significant advances have been made to reduce soft tissue injury and thus improve the postoperative recovery [Ref 2-4]. The Direct Anterior Approach to the hip uses natural muscle planes to expose the hip joint, and studies have already shown these patients stop using canes/walkers sooner postoperatively when compared to older, muscle splitting approaches [Ref 11]. Our investigator, Dr. Kayiaros, uses both the posterior and anterior approach to the hip and believes patients undergoing the anterior approach are discharged home quicker, experience less postop pain, use walkers/canes for a shorter amount of time, are discharged from physical therapy sooner, and have a quicker return to activity and pre-surgical level of function when compared to posterior approach patients.

It follows that patients demonstrating improved recovery times will likely require less formal rehabilitation programs. A recent study just published in the ***Journal of Bone and Joint Surgery*** demonstrated that rigorous, formal postoperative physical therapy is not necessary following hip replacement surgery [Ref 12]. Another important study demonstrated that there was no difference between one-to-one, group, and self-directed therapy after total knee replacement [Ref 1-2]. These findings highlight the trend that better surgical technique, which is less invasive and tissue sparing, leads to better patient function after surgery and less rehabilitation burden.

The value of this study is to determine whether this minimally invasive approach precludes the need for a formally guided physical therapy program, or similar to total knee replacements, patients benefit equally from self-directed therapy after hip replacement.

3. Research Design and Methods

This study will be a prospective, randomized trial. Patients scheduled for total hip arthroplasty by the direct anterior approach with a single surgeon (Dr. Kayiaros), at a single institution (Robert Wood Johnson University Hospital) will be considered for enrollment. Because a total hip replacement is an elective procedure, in general, Dr. Kayiaros' surgical practice only attracts a specific cohort of patients, which includes only evaluating insured patients, and due to the long relationship between patient and surgeon after a hip replacement, he only performs surgery in English speaking patients that he can easily call and with whom he can communicate.

RUTGERS | eIRB
APPROVED
IRB ID: Pro20140001090
Approval Date: 10/6/2017
Expiration Date: 10/5/2018

Specific to this study, those patients that meet the inclusion and exclusion criteria will be given the option, via informed consent, to participate. There will not be any subject recruitment (such as flyers or ads), Dr. Kayiaros will offer enrollment to patients that come to his office for evaluation for hip replacement. Dr. Kayiaros will consent all subjects for this study.

Patients will be randomized (via randomized number generator program) to either receive formal PT (FPT) or self directed PT (SDPT). All patients will have a preoperative consultation with a physical therapist as part of Dr. Kayiaros' normal pre-op protocol. At that time, the SDPT patients will be given the SDPT protocol and will be taught the exercises to be performed at home.

Post-op, all hip replacement patients receive daily inpatient physical therapy and occupational therapy until the time of hospital discharge. This will be another chance for patients to ask questions and learn the home protocol (if applicable). All exercises in the protocol are part of standard post-operative therapy, and they are easy to learn and only require simple items, such as chairs and stairs. Furthermore, Dr. Kayiaros has online videos demonstrating the at-home exercises, which patients can access for further clarification, if needed.

If a patient decides at any time during the study to change his/her treatment group, then the patient will be switched from SDPT to FPT or from formal therapy to SDPT. These patients will be kept in the study and their data will be included in the statistical analysis using an Intention to Treat model (discussed in data analysis section).

3.1. Duration of Study

Each patient will be followed for a total of 12 months postop, however, the full duration of the study, including statistical analysis will take 2 years. No changes will be made to Dr. Kayiaros' standard post-operative protocol other than the aspect of physical therapy. Patients follow up in 1,3, 6, 12 months post operatively and yearly thereafter, which is the standard of care for patients after hip replacement. Data will be collected up until 12 months postoperatively.

3.2 Study Sites

Patients will see Dr. Kayiaros pre- and post-operatively in his office at University Orthopaedic Associates and will undergo surgery at Robert Wood Johnson University Hospital. He will see patients in his Somerset office:

- University Orthopaedic Associates: 2 Worlds Fair Drive, Somerset, NJ 08873

3.3 Sample Size Justification

We aim to enroll 200 patients in this study based on our power calculation, with the goal of randomizing 75 patients for each group with the total of 150 subjects. This is similar to a previous study [Ref 12] that analyzed 120 patients in each group. The primary outcome for this study is the Harris Hip Score, a validated and commonly used scoring system, which evaluates postoperative pain, ambulatory function, and use of walking aid to provide a global picture of patient function. Therefore this Harris Hip Score will be used as the main endpoint for calculation of sample size in this non-inferiority trial. A total number of 150 patients will be needed to test the non-inferiority in outcome between the two study groups. A total number of

RUTGERS | eIRB
APPROVED
IRB ID: Pro20140001090
Approval Date: 10/6/2017
Expiration Date: 10/5/2018

200 subjects will need to be assessed to identify the subjects eligible for participation in this randomized clinical trial.

Below is a breakdown of the statistical analysis performed by Professor Dr. Xavier Cabrera regarding power analysis using an alpha value of 0.05 to calculate the sample size based on the Harris Hip Score. Dr. Cabrera will not be used for data analysis after the data is fully collected because the study team is comfortable performing t-tests and chai-square tests, which is all that is required for analysis.

sd= 5 25 patients
test for a difference of 3 points power is 53%
test for a difference of 4 points power is 80%
test for a difference of 5 points power is 94%

sd= 5 45 patients
test for a difference of 3 points power is 80%

sd =3 25 patients
test for a difference of 3 points power is 80%

We will be highly sensitive in our ability to detect differences of only 3 points between groups. Therefore, 45 patients in each group provides acceptable power. We are increasing the number to 75 patients per group to account for any discrepancies.

3.4 Subject Selection and Enrollment Considerations

Dr. Kayiaros will inform patients of this study preoperatively, explaining the justification for this study and the hypothesis. All patients will have the option to enroll in this study if they meet the study criteria. If they choose not to enroll, no changes to Dr. Kayiaros standard THA protocols and there will be no impact to the subject. They will receive the standard of care for their hip surgery.

3.5.1 Inclusion Criteria

These inclusion/exclusion criteria are standard criteria implemented in investigation on primary THA studies.

Inclusion criteria for this study are as follows

- Patients aged between 18 and 80 years of age
- Patients undergoing primary DAA total hip arthroplasty for the diagnosis of osteoarthritis
- Patients with no previous invasive hip surgery (such as a previous hip replacement)

3.5.2 Exclusion Criteria

- Non-English speaking persons will be excluded in our study. Dr. Kayiaros does not have a formal translation service, as his patients are exclusively English speaking.
- Patients with a recent history (<1 year) of heart attack, stroke, and lung clots.

RUTGERS | eIRB
APPROVED
IRB ID: Pro20140001090
Approval Date: 10/6/2017
Expiration Date: 10/5/2018

- Previous invasive surgery on the hip undergoing replacement (this can alter surgery and require a more complex surgery)
- Patients with dementia, Parkinson's, or other memory problems will be excluded because they often have difficulty complying with physical therapy regimens and require special treatment/rehab.
- Non-ambulatory patients are excluded from this study because they require a significantly different postoperative therapy protocol from the standard hip replacement. These patients typically have significant muscle spasms and lack of muscle bulk that requires months of rehabilitation.
- Patients with impaired ability to consent, whether because of mental illness or otherwise, will be excluded do to their inability to adequately comply with the SDPT. They will need observed therapy.
- Patients being discharged to a rehabilitation center will also be excluded because there is no means to regulate their therapy.
- Patients that experience intraoperative complications (such as a fracture of the femur) are excluded from this study because such complications alter the postop weight bearing status and thus require significantly different therapy.

3.5.3 Subject Recruitment

Dr. Kayiaros will offer enrollment to patients he sees in his office that need a hip replacement. The patients are undergoing THA due to arthritis progression and this study will have no impact on whether they are offered a hip replacement. There will be no flyers or other forms of recruitment besides physician directed recruitment.

3.5.4 Consent Procedures

Consent will be obtained in the office by Dr. Kayiaros as a part of his pre-operative planning. Dr. Kayiaros will explain the study to the patient. He will answer any questions they have. He will stress that forgoing formal PT for SDPT is not a cost-based decision, but rather, to evaluate the post-op course of his patients undergoing DAA-THA. If the patient wishes to enroll, he will have the patient sign the informed consent. Enrollees will be given a copy of the informed consent for their records. Only English speaking patients will be enrolled, so a non-English consent is not needed. Only insured patients are evaluated in his office.

3.5.5 Subject Costs and Compensation

There will be no additional costs incurred by the patients for their participation in this study. All data collected is collected as a part of Dr. Kayiaros normal post-operative protocol. There will be no additional radiologic studies or lab tests beyond what is normally incorporated as part as Dr. Kayiaros' normal protocol. The 1,3, 6, and 12 month office follow up is the standard of care after hip replacement. Dr. Kayiaros, his physician assistant, or his staff physical therapist will see all patients, which is a standard after total hip replacement.

3.6 *Chart Review Selection*

RUTGERS | eIRB
APPROVED
IRB ID: Pro20140001090
Approval Date: 10/6/2017
Expiration Date: 10/5/2018

Charts will be reviewed by the study's staff, Jared Preston MD and Dexter Bateman MD. As part of their normal resident responsibilities, they have charting access at RWJUH and at University Orthopaedic Associates. Attached to this submission is the spreadsheet that will be used to collect data. Each patient will be identified by their study specific ID number. The spreadsheet will contain PHI.

Data to be collected include:

- Cohort (Standard Physical Therapy or Self-Directed Physical Therapy)
- Patient characteristics: name, gender, age, BMI, diagnosis for surgery, comorbidities, American Society of Anesthesiologists score (ASA), preoperative Harris Hip Score
- Surgical data: OR date/time, estimated blood loss, relevant intraoperative complications, postoperative DVT prophylaxis
- Postoperative data: number of transfusions, in-hospital complications, complications within 90 days of surgery, length of hospital stay
- Functional scores (collected at post-op office visits):
    - Harris Hip score (HHS),
    - Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC Score),
    - Visual analogue scale pain score (VAS),
    - Timed Up and Go Test (TUG Test),
    - Short Form-36 Health Survey (SF-36)
    - Date of cessation of walking aid.

4. Study Variables

4.1 Independent Variables or Interventions

The only variable being investigated is whether or not the type of physical therapy impacts patient's functional results in the early postoperative period. As described above, the DAA for THA minimizes soft tissue injury, lending itself well to quick return to function. To our knowledge, only one previous published study has investigated a similar hypothesis [Ref 12].

4.1.1 Drug or Device Interventions

Not applicable to this study. No drugs or devices are being studied under this protocol.

4.2 Dependent Variables or Outcome Measures

No additional data collection tools are being used beyond those which are normally used by Dr. Kayiaros.

The following questionnaires are being used in this study:

- Harris Hip Score:
    - Developed for the assessment of the results of hip surgery pre- and postoperatively, and is intended to evaluate various hip disabilities and methods of treatment in an adult population. Domains covered are pain, function, absence of deformity, and range of motion. The pain domain measures pain severity and its effect on activities and need for pain medication. The function

RUTGERS | eIRB APPROVED
IRB ID: Pro20140001090
Approval Date: 10/6/2017
Expiration Date: 10/5/2018

domain consists of daily activities (stair use, using public transportation, sitting, and managing shoes and socks) and gait (limp, support needed, and walking distance). Deformity takes into account hip flexion, adduction, internal rotation, and extremity length discrepancy. Range of motion measures hip flexion, abduction, external and internal rotation, and adduction.
    - The HHS is proven to be validated and reproducible for communication of information regarding hip surgery patients.
- WOMAC Score: The WOMAC consists of 24 items divided into 3 subscales:
    - **Pain (5 items):** during walking, using stairs, in bed, sitting or lying, and standing
    - **Stiffness (2 items):** after first waking and later in the day
    - **Physical Function (17 items):** stair use, rising from sitting, standing, bending, walking, getting in / out of a car, shopping, putting on / taking off socks, rising from bed, lying in bed, getting in / out of bath, sitting, getting on / off toilet, heavy household duties, light household duties
- SF-36:
    - Measure of general health, reported independently as mental and physical components.
    - Both component scales are normalized to the U.S. population along a 0-to-100 range (mean of 50 points), with a higher score indicating less disability.
- Visual Analogue Scale:
    - The VAS is the most common pain scale for quantification of pain in various specialties of medicine.
- Timed Up and Go Test
    - This is a commonly used method to determine the time it takes a patient to get up from a chair and walk a predetermined length.
- Patients will also undergo X-rays of their hips at 1 month post-op as part of his normal post-operative protocol.

4.3 Risk of Harm

To date, there is only one published paper investigating whether or not formal physical therapy is necessary after THA [Ref 12]. This randomized trial concluded that unsupervised home exercise is both safe and efficacious for a majority of patients undergoing total hip arthroplasty, and formal physical therapy may not be required.

A similar study has also looked at therapy after total knee replacements [ref 2], and found no advantage to therapist guided PT (“formal PT”). All patients in our study will receive a form of physical therapy – self directed or formal out-patient PT. This study will evaluate the method of delivering therapy. Additionally, the study that looked at methods of PT after total knee replacements found that none of the 163 patients were harmed by the various methods of therapy [Ref 2].

With that said, there is always some degree of risk. It’s possible that patients receiving SDPT will not progress in their postsurgical recovery at the same rate as those patients undergoing FPT, even though this was not observed in the recent study on THA [Ref 12]. To address this concern, Dr. Kayiaros or his physician assistant will evaluate patients at 2-weeks post-operatively, and those who are deemed to be behind in their recovery or who wish to

RUTGERS | eIRB
APPROVED
IRB ID: Pro20140001090
Approval Date: 10/6/2017
Expiration Date: 10/5/2018

attend formal outpatient therapy will be encouraged to do so. It will be stressed that switching to formal PT will not impact their care.. This is the same methodology used in the similar study [Ref 2]. The effects of this crossover on our analysis are explained in the data analysis section.

Even FPT is not a risk-free endeavor. Over exertion by the physical therapist can lead to muscle strains, tendonitis, or exacerbation of other existing injuries, such as ipsilateral/contralateral joint pain (arthritis), shoulder pain (rotator cuff deficiencies), or back pain (lumbar spinal stenosis). While there is no significant risk in undergoing formal physical therapy, additional discomfort is a reported side effect. It is therefore unclear whether all patients truly benefit from therapy, as only one study [Ref 12] to date has compared the outcomes for THA patients undergoing formal PT versus at home SDPT. Some patients may progress well without formal PT, and formal therapy may actually aggravate their course. If this is the case, the patients may chose to switch cohorts to the SDPT group. We will continue to include data if patients choose to crossover as part of our crossover analysis.

Additionally, patients that switch from SDPT group into the formal physical therapy group will remain in the "self-directed" group for statistical analysis based on the "Intention to Treat" model which is widely used in larger prospective randomized trials published in leading journals [Ref 11].

4.4 Potential for Benefit

Although the difference in benefit from Self-Directed Physical Therapy (SDPT) and Formal Physical Therapy is uncertain, participation in this study is potentially beneficial because the post-op rehabilitation will be followed and directed by Dr. Kayiaros irrespectively for randomization.

5. Data Handling and Statistical Analysis

All study data sheets will only be accessible on password-protected computers located at RWJUH. To ensure safety of the data, all data will be stored at RWJUH, not at the University Orthopaedic Associate's (UOA) office. Study data will always be kept separate from UOA's electronic medical records. The RWJUH network is a secured network/IST system. We created a password-protected folder on the RWJUH server that is only accessible by the study staff. This folder will house all data collected for the study (see attached spreadsheet). The subject's names will be collected, which will allow the study staff to coordinate data between the hospital's EMR, UOA's EMR, and the data spreadsheet. A spreadsheet matching study ID with name will be kept separate from the data collection sheet, and will only be accessed by the study staff. It will be kept in a separate, password-protected folder saved on the RWJUH network. Nowhere else will there be a link between PHI and our data collection sheet. All data will be held in secured fashion for 6 years following completion of the study by the study staff in the password-protected folder on the RWJ network. All hard copies (such as the office evaluations, which only contain study ID numbers and do not have personal identifying information) will be stored in a locked filing cabinet in the RWJUH Orthopedic Dept., which is only accessible by study staff. As per IRB protocol, the link to the identifiers will be destroyed after completion of the study, thus maintaining the confidentiality of the subjects in the study. We feel it is important to hold on to the data should we need to revisit the data for the safety of our patients or need to disclose any information to participating subjects.

RUTGERS | eIRB
APPROVED
IRB ID: Pro20140001090
Approval Date: 10/6/2017
Expiration Date: 10/5/2018

Statistical analysis will be performed by the study staff (Drs. Preston and Bateman). Data for the two groups will be analyzed using R software (R-project.org) for statistical analysis. Demographic and outcome measures are compared between the two groups using t-tests for continuous outcome measures and chai-square test for the binary outcome measures.

Equivalence in functional outcome scores at the 1, 3, 6, and 12-month time points between the two groups will highlight the efficacy of self-directed physical therapy.

There is the chance that patients will switch between randomized cohorts. To account for this switching, we will use an intent-to-treat analysis. As demonstrated in the ground breaking Spine Patient Outcomes Research Trial (SPORT), an intent-to-treat analysis is a valid way to analyze outcomes data based on pre-determined cohorts, and will account for any switching that may occur [11]. Per the SPORT trial, "adherence to assigned treatment was limited…intent-to-treat analyses demonstrated substantial improvements for all primary and secondary outcomes in both treatment groups."

6. Data and Safety Monitoring

This study has minimal risk for its enrollees. No DSMB is needed for this study. As part of his normal post-op protocol, Dr. Kayiaros will see patient in the office and evaluate their results, determining if intervention is needed.

7. Reporting Results

7.1 Individual Results

Subjects will be given immediate feedback regarding their progress at each follow up visit with Dr. Kayiaros. If a member of the SDPT therapy cohort demonstrates poor progress compared to their standard therapy counterparts at any follow up visit (as defined previously), Dr. Kayiaros will evaluate that patients' specific situation and determine any necessary interventions, whether that includes formal PT. We will continue to monitor their progress and will record their switch. If a patient switches cohorts during the study, they will not be removed from the protocol, as the analysis will use an intention-to-treat method.

7.2 Aggregate Results

The results of this study will be examined using statistical analysis. Although the patients type of physical therapy is not blinded to Dr. Kayiaros, and thus there is concern for recall bias. Yet the outcome measures are numerically based, completed by patients not Dr. Kayiaros, and the statistical analysis using t-tests and chai-squared will minimize bias. Patients follow up with Dr. Kayiaros for years after THA. Once the aggregate results are available, Dr. Kayiaros will provide them to the involved patients, and will also use the results to council his future patients and guide his decisions for postoperative care.

7.3 Professional Reporting

The goal for this study is publication in a peer reviewed orthopaedic journal, as well as for presentation at national and international arthroplasty society meetings.

RUTGERS | eIRB
APPROVED
IRB ID: Pro20140001090
Approval Date: 10/6/2017
Expiration Date: 10/5/2018

References

1. Rapid rehabilitation and recovery with minimally invasive total hip arthroplasty. Berger RA et al. Clin Orthop Relat Res. 2004 Dec;(429):239-47.

2. One-to-one therapy is not superior to group or home-based therapy after total knee arthroplasty: a randomized, superiority trial. Ko et al. J Bone Joint Surg Am. 2013 Nov 6;95(21):1942-9. doi: 10.2106/JBJS.L.00964.

3. An analysis of the relationship between the utilization of physical therapy services and outcomes of care for patients after total hip arthroplasty. Freburger JK. Phys Ther. 2000 May;80(5):448-58.

4. Functional problems and treatment solutions after total hip arthroplasty. Bhave A et al. J Arthroplasty. 2007 Sep;22(6 Suppl 2):116-24. Epub 2007 Jul 26.

5. Prospective randomized study of arthroscopic rotator cuff repair using an early versus delayed postoperative physical therapy protocol. Cuff DJ et al. J Shoulder Elbow Surg 2012 Nov; 21 (11): 1450-5.

6. Enhanced early outcomes with the anterior supine intermuscular approach in primary total hip arthroplasty. Berend KR, Lombardi AV Jr, Seng BE, Adams JB: J Bone Joint Surg Am 2009;91(suppl 6):107-120.

7. Soft-tissue changes in hip abductor muscles and tendons after total hip replacement: Comparison between the direct anterior and the transgluteal approaches. Bremer AK, Kalberer F, Pfirrmann CW, Dora C. J Bone Joint Surg Br 2011;93 (7):886-889.

8. Comparison of minimally invasive direct anterior versus posterior total hip arthroplasty based on inflammation and muscle damage markers. Bergin PF, Doppelt JD, Kephart CJ, et al. J Bone Joint Surg Am 2011;93(15):1392-1398.

9. Muscle damage during MIS total hip arthroplasty: Smith-Petersen versus posterior approach. Meneghini RM, Pagnano MW, Trousdale RT, Hozack WJ. Clin Orthop Relat Res 2006;(453):293-298.

10. Prospective randomized study of direct anterior vs postero-lateral approach for total hip arthroplasty. Barrett WP, Turner SE, Leopold JP. J Arthroplasty 2013; 28(9):1634-1638.

RUTGERS | eIRB
APPROVED
IRB ID: Pro20140001090
Approval Date: 10/6/2017
Expiration Date: 10/5/2018

11. Early outcome comparison between the direct anterior approach and the mini-incision posterior approach for primary total hip arthroplasty: 150 consecutive cases. Zawadsky MW et al. J Arthroplasty 2014; 29(6): 1256-60.

12. Formal Physical Therapy After Total Hip Arthroplasty Is Not Required: A Randomized Controlled Trial. Brian T. Urbani, MS, James J. Purtill, MD, William J. Hozack, MD, Richard H. Rothman, MD, PhD, Javad Parvizi, MD, FRCS, Matthew S. Austin, MD. JBJS Am. 19 April 2017 - Volume 99 - Issue 8 - p 648–655

RUTGERS | eIRB
APPROVED
IRB ID: Pro20140001090
Approval Date: 10/6/2017
Expiration Date: 10/5/2018