Certificate of Action

Investigator Name: Richard D. Komistek, PhD Michael Paul Bolognesi, MD	**Board Action Date:** 09/04/2018
Investigator Address: 1506 Middle Drive, 310 Perkins Hall Knoxville, TN 37996, United States	**Approval Expires:** 09/04/2019 **Continuing Review Frequency:** Annually
Sponsor: University of Tennessee **Institution Tracking Number:**	**Sponsor Protocol Number:** None **Amended Sponsor Protocol Number:**
Study Number: 1189113	**IRB Tracking Number:** 20182087
Work Order Number: 1-1104527-1	**Panel:** 1
Protocol Title: In vivo kinematics for subjects implanted with Klassic TKA	

THE FOLLOWING ITEMS ARE APPROVED:
Investigator
Investigator
Confidentiality Pledge #18232267.0 - As Submitted
Protocol (08-10-2018) Version 1.2
Consent Form [S0]
Data and Safety Monitoring plan (DSMP) #18232266.0 - As Submitted
Klassic TKA Revocation of Consent #18232268.0 - As Submitted
Subject Inclusion Criteria Checklist #18232265.0 - As Submitted

Please note the following information:
The Board requires that all subjects must be able to consent for themselves to be enrolled in this study. This means that you cannot enroll incapable subjects who require enrollment by consent of a legally authorized representative.

Federal Regulations do not recognize Co-Principal Investigators. Therefore, the Board has approved the two investigators for this study as if each is THE Investigator and holds each individually responsible for the conduct of the entire study.

Financial Disclosure (08-23-2018) Michael Bolognesi

THE IRB HAS APPROVED THE FOLLOWING LOCATIONS TO BE USED IN THE RESEARCH:
Hofmann Arthritis Institute's Center for Precision Joint Replacement, 24 South 1100 East, Suite 101, Salt Lake City, Utah 84102

ALL IRB APPROVED INVESTIGATORS MUST COMPLY WITH THE FOLLOWING:
As a requirement of IRB approval, the investigators conducting this research will:

- Comply with all requirements and determinations of the IRB.
- Protect the rights, safety, and welfare of subjects involved in the research.
- Personally conduct or supervise the research.
- Conduct the research in accordance with the relevant current protocol approved by the IRB.
- Ensure that there are adequate resources to carry out the research safely.
- Ensure that research staff are qualified to perform procedures and duties assigned to them during the research.
- Submit proposed modifications to the IRB prior to their implementation.
    - Not make modifications to the research without prior IRB review and approval unless necessary to eliminate apparent immediate hazards to subjects.

This is to certify that the information contained herein is true and correct as reflected in the records of this IRB. WE CERTIFY THAT THIS IRB IS IN FULL COMPLIANCE WITH GOOD CLINICAL PRACTICES AS DEFINED UNDER THE U.S. FOOD AND DRUG ADMINISTRATION (FDA) REGULATIONS, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) REGULATIONS, AND THE INTERNATIONAL CONFERENCE ON HARMONISATION (ICH) GUIDELINES.

- Submit continuing review reports when requested by the IRB.
- Submit a closure form to close research (end the IRB's oversight) when:
    - The protocol is permanently closed to enrollment
    - All subjects have completed all protocol related interventions and interactions
    - For research subject to federal oversight other than FDA:
        - No additional identifiable private information about the subjects is being obtained
        - Analysis of private identifiable information is completed
- If research approval expires, stop all research activities and immediately contact the IRB.
- Promptly report to the IRB the information items listed in the IRB's "Prompt Reporting Requirements" available on the IRB's Web site.
- Not accept or provide payments to professionals in exchange for referrals of potential subjects ("finder's fees.")
- Not accept payments designed to accelerate recruitment that are tied to the rate or timing of enrollment ("bonus payments") without prior IRB approval.
- When required by the IRB ensure that consent, permission, and assent are obtained and documented in accordance with the relevant current protocol as approved by the IRB.
- Promptly notify the IRB of any change to information provided on your initial submission form.

Consistent with AAHRPP's requirements in connection with its accreditation of IRBs, the individual and/or organization shall promptly communicate or provide, the following information relevant to the protection of human subjects to the IRB in a timely manner:

- Upon request of the IRB, a copy of the written plan between sponsor or CRO and site that addresses whether expenses for medical care incurred by human subject research subjects who experience research related injury will be reimbursed, and if so, who is responsible in order to determine consistency with the language in the consent document.
- Any site monitoring report that directly and materially affects subject safety or their willingness to continue participation. Such reports will be provided to the IRB within 5 days.
- Reports from any data monitoring committee, data and safety monitoring board, or data and safety monitoring committee in accordance with the time frame specified in the research protocol.
- Any findings from a closed research when those findings materially affect the safety and medical care of past subjects. Findings will be reported for 2 years after the closure of the research.

If your research site is a HIPAA covered entity, the HIPAA Privacy Rule requires you to obtain written authorization from each research subject for any use or disclosure of protected health information for research. If your IRB-approved consent form does not include such HIPAA authorization language, the HIPAA Privacy Rule requires you to have each research subject sign a separate authorization agreement. "

Federal regulations require that the IRB conduct continuing review of approved research. You will receive Continuing Review Report forms from this IRB when the expiration date is approaching.

Thank you for using this WCG IRB to provide oversight for your research project.

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In vivo kinematics for subjects implanted with Klassic TKA

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In vivo knee kinematics will be assessed for 20 subjects that have been implanted with a Total Joint Orthopedics Klassic knee system by Dr. Aaron Hofmann of the Hofmann Arthritis Institute's Center for Precision Joint Replacement (24 South 1100 East, Suite 101, Salt Lake City, UT 84102). This is the location from which all participants will be recruited and where fluoroscopy data collection will occur. Enrollment will be increased to 24 subjects to ensure that researchers acquire the necessary 20 usable datasets for analysis and also to account for any subjects that may drop out of the study. There will be 12 subjects with the Klassic TKA in the right knee and 12 with the Klassic TKA in the left knee. At present, all TKA available for surgeons to use are asymmetric where there is a distinct femoral and tibial component for the left knee and a distinct femoral and tibial component for the right knee. The Klassic knee system is a symmetrical knee implant, where the same femoral and same tibial component can be used for either the right or left knee. The kinematics for the 10 left knees vs the 10 right knees will be compared. The results from this study will also be compared with previously published results for fluoroscopic studies assessing the in vivo kinematics during a deep knee bend that is available in the literature to determine if there is a difference. The designers of the Klassic knee implant believe this knee implant will function similar to asymmetric knee implants. All TKAs should be judged clinically successful (KSS ≥80). Each subject should have a well-functioning prosthesis and be at least six months post-operative.

Deciding which subjects received which type of implant was up to the discretion of Dr. Hofmann, according to his professional opinion. The determination as to which type of implant subjects received is outside the scope of this particular study. Subjects will already have the knee implants and must be at least six months post-operative.

We will use the following inclusion criteria to recruit participants for this study:

1. Subjects will have a Klassic knee system.
2. Subjects must be at least six months post-operative.
3. Participants must be judged clinically successful with their most recent (new) Knee Society "Knee Score" (Attachment 7) equal to or greater than 80.
4. Participants must be able to perform a deep knee bend.
5. Subjects must be willing to sign the Informed Consent (IC) / HIPAA form to participate in the study.
6. Must speak English.

Exclusion criteria:

1. Pregnant, potentially pregnant or lactating females. To satisfy radiation protocol, each female subject will be asked if she is pregnant, or possibly could be pregnant. A pregnant person will not be allowed to participate in the study.
2. Subjects without the required type of knee implant.
3. Bilateral subjects (i.e., patients with both knees implanted)
4. Subjects who are unable to perform a deep knee bend.
5. Subjects who are unwilling to sign Informed Consent/ HIPAA documents.
6. Subjects who do not speak English.

Study locations

Subject recruitment and fluoroscopic exams will take place at of the Hofmann Arthritis Institute's Center for Precision Joint Replacement
24 South 1100 East, Suite 101
Salt Lake City, UT 84102
(801) 355-6468

Analysis will take place at the University of Tennessee's Center for Musculoskeletal Research laboratories, Science and Engineering Research Facility
1414 Circle Dr.
Knoxville, TN 37996
(865) 974-0198

CMR administrative offices
310 Perkins Hall
1506 Middle Dr.
Knoxville, TN 37996
(865) 974-2093

Recruitment

Dr. Hofmann will recommend eligible subjects for recruitment from his practice that have been implanted with the TJO Klassic knee system whose post-operative conditions permit them to capably perform the study activities. A partial waiver of HIPAA authorization will be completed so patient medical files may be reviewed to ensure complete eligibility. Dr. Daniel Mangiapani, (Sub-Investigator), from the Hofmann Arthritis Institute will review those patients' medical records to determine if they meet the remaining eligibility required for the study according to the study-specific criteria. A study-specific Subject Inclusion Recruitment/Enrollment sheet (Attachment 4) with eligibility requirements will be used when reviewing the patient medical files. The forms will not contain any identifying patient information – only boxes to be checked to indicate whether or not a potential subject is completely eligible. The form will be sent to UT researchers (e.g., research coordinator, PI, Sub-Investigator), and they will advise Dr. Mangiapani as to whether or not the patient may be contacted about participating in the study. Dr. Mangiapani will then contact the subjects to explain the study and inquire as to whether or not they are interested in participating by one of the following methods: primarily telephone calls utilizing a script (Attachment 5), in-office discussion and possibly mail correspondence, if necessary, using a recruitment letter (Attachment 6). If a subject is agreeable to participate, s/he will be scheduled for a time to visit the Hofmann Arthritis Institute on the day of data collection.

On this scheduled day, University of Tennessee (UT) researchers will travel to the Hofmann Arthritis Institute to collect the kinematic data of participant implanted knees at least six months post-operatively under fluoroscopic surveillance using a C-arm fluoroscopic unit while subjects perform a deep knee bend activity. The fluoroscopy unit to be used is owned by the Hofmann Arthritis Institute and will be run by a radiation technician employed by the Hofmann Arthritis Institute. The fluoroscopic images will be stored on password protected laptop for subsequent analysis.

Data Collection

University of Tennessee researchers (Milad Khasian, Manh Ta, Jarrod Nachtrab, or Garett Dessinger) will travel to Salt Lake City, UT to conduct the fluoroscopic data collection. Any of these graduate research assistants, as well as either a PI (R. Komistek, Ph.D.), Co-PI (M. Bolognesi, M.D.), or Sub-Investigators (A. Hofmann, M.D., A. Sharma, Ph.D., Daniel Mangiapani, M.D.) for the study, will be present during the fluoroscopy procedure to walk subjects through the activity. A radiation technician (RT) employed by the Hofmann Arthritis Institute will collect fluoroscopic video while subjects perform the deep knee bend.

Dr. Mangiapani and/or UT researchers will consent the participants. They will meet with each potential participant individually to make sure s/he has been properly informed of the procedures and to help with any of the IC/HIPAA form. CMR researchers will inform all subjects that they do not have to participate and are free to leave if they wish and will answer any questions subjects may have about the study. Participation is entirely voluntary.

In addition to fluoroscopy video, subjects will be videotaped from the shoulders down (to maintain subject anonymity) while performing the activity (live feed perspective). The speed level of each trial will be based on the comfort level of the subject. One of the researchers will be ready and in close proximity to assist each subject in case the participant requires help. This precaution will be practiced for all participants, regardless of physical wellbeing, age or prior results; no assumptions will be made as to any participant's capabilities.
When both the subject and study team are ready, the following activity will be performed:

1. Deep knee bend
   a) The subject will begin standing in a starting position in which the knee is fully extended. When ready the subject will flex the knee through its full weight bearing range of motion.
   b) Once maximum weight bearing flexion is achieved the activity is complete, and the subject can rise to a comfortable resting position.

Participants will be asked to practice the activity to ensure they can comfortably complete them and experience no pain with the fluoroscopy machine off (no radiation). The practice portion of the data collection without radiation will not be video-recorded. During the fluoroscopy procedure, the RT will follow the motion of the implanted knee with the fluoroscopy machine; only the knee joint (from the fluoroscopy machine) will be recorded on the fluoroscopy footage. The participant will be allowed to rest as necessary and be instructed to stop the activity at the first sign of pain.

Researchers will be at the Hofmann Arthritis Institute during the fluoroscopic exams, serving as consultants to the RT on site. They will not operate the fluoroscopy unit, but will be available to the RT and the Institute staff if questions arise. Researchers will be on hand to assist the participant at any time during the procedure. The participant has the right to stop the procedure at any time; researchers or the RT can end the procedures at any time if they feel the participant is at risk, but the participant can choose to remain in the study if s/he feels that there is no risk to her/his surgical procedure or recuperation. If researchers and the M.D. present during data collection concur that a subject is at risk and the subject persists in participating, the researchers will ask the subject to discontinue the activities and not to participate in the study.

Multiple trials of the activity may be conducted to ensure researchers have successfully collected the raw data required to complete the study. Radiation time will be kept as low as reasonably achievable (ALARA) and will not exceed two minutes. The RT will start the fluoroscope just prior to the subject beginning each activity trial and will stop the fluoroscope immediately after the subject completes each activity trial to ensure that the subject is not exposed during idol periods. Fluoroscopy on-time will be recorded on subject IC/HIPAA forms.

The fluoroscopic footage for the activity will be stored on digital video files on a secure computer workstation, and participant information will be removed and replaced with identifiers by researchers selected by Dr. Komistek to lead the study, which may include any researchers that attend data collection. All researchers with access to identifiable subject data will sign statements of confidentiality. This study data will then be uploaded onto a secure server that University of Tennessee researchers will use to conduct the kinematic analysis.

Private Health Information/Medical Record Data

The surgeon and his staff will provide subjects' clinical information from their medical records – PHI – to Dr. Komistek and his researchers to aid in the interpretation of the results and correlate clinical outcomes versus kinematic results, although only researchers present during data collection or those appointed by Dr. Komistek to lead the study will have access to PHI; they will sign confidentiality statements. This information can be used to rule out any unique kinematic patterns. This information will only be used by the UT researchers and will not be provided to any other source.

The clinical/demographic information acquired from the medical records with participant authorization obtained as required by HIPAA will include:

- Post-operative New Knee Society "Knee Score" (that was used to ensure subject met inclusion criteria). Researchers need the post-operative NKSS that was acquired prior to enrollment that qualified candidates as potential participants.
- Implant information
- Date of surgery

On the day of data collection, the list of subject names will be given to UT researchers and the researchers will use this to generate subject-specific identifiers. A table will be generated for this study, indicating the participant's name and generated ID number; this table with subject names and corresponding ID numbers will be provided to Dr. Mangiapani, so he will be aware of which identifier is linked with each subject. Then, Dr. Mangiapani will upload the PHI from medical

files into an excel spreadsheet created by the UT researchers present during data collection or those appointed by Dr. Komistek that will only have the generated ID numbers. This spreadsheet will be securely transferred to UT researchers via UT's secure email known as the Vault.

The subject data – fluoroscopy frames, video footage and data from medical files– will be uploaded and stored on CMR's secure server at UT, Knoxville for use in this and future studies (if participant permission is obtained via IC) by the researcher(s) who attend data collection or appointed by Dr. Komistek. Once data has been uploaded, the database automatically removes subject identifiers and assigns an ID for each subject. This ID will coincide with the one assigned to each individual on the day of data collection. Only these files of de-identified data (no dates of surgery) are now available for researchers to review and analyze. Only Dr. Adrija Sharma (Sub-Investigator and CMR database administrator) has access to the identifiable data that was originally uploaded by the GRA, as it remains in a password-protected portion of the secure server. Only Dr. Sharma can grant access to this identifiable password-protected portion of the database by changing a user's level of authentication with different privilege levels. Researchers would like to retain this study data in our secure database so as to continue to add relevant, current data to our digital collection to help us work with manufacturers in the future to create better implants that last longer and will not require revision surgery. Participants will be asked if their study data may remain a part of the CMR data collection for use in future studies in the IC. Likewise, should a subject choose to withdraw from the study, s/he will have the option as to whether or not data collected from them at the point of withdrawal may be used for data analysis or if their information should be destroyed from CMR records; subjects choosing to withdraw will be asked to complete a Revocation of Consent wherein they may indicate their preference regarding the data collected from them.

These files will be accessible by only the personnel indicated under Section 5. Depending on the subjects' response to the Archiving Data section of the IC (page 8), these video files may be kept indefinitely for the possibility of future use.

SPECIFIC RISKS AND PROTECTION MEASURES

1. Fluoroscopic Procedures

As with every clinical study, there may be some risks. However, doses of radiation exposure received will be much lower than those known to produce detectable health effects. Previously reported literature shows that fluoroscopy-based procedure (angiography) on the lower limb result in a typical effective dose of 0.83 mSv per min (0.083 rem per min) (Verdun[1]). Mettler, et al. have reported that the typical effective dose for a conventional knee procedure is 0.005 mSv (0.0005 rem)[2]. According to either estimate, the additional risk of a fluoroscopic procedure involving the knee ranges between "Negligible" to "Low" for a 2 minute exam (Verdun). A previous fluoroscopy TKA study conducted at another hospital with a 2 minute on-time limit

[1] Verdun FR, Bochud F, Gundinchet F, Aroua A, Schnyder P, Meuli R. Quality Initiatives Radiation Risk: What You Should Know to Tell Your Patient 1. *Radiographics* 2008 Nov 28(7):1807-16.
[2] Mettler, et al. "Effective Doses in Radiology and Diagnostic Nuclear Medicine." *Radiology* 248.1 (2008): 254-263. http://radiology.rsna.org/content/248/1/254.full.pdf+html

shows that the average effective dose was 0.14 mSv (0.0014 rem) with a maximum dose of 0.27 mSv (0.027 rem). The additional risk for all subjects in this previous study would be considered "Negligible." To account for subject variability and differences in imagining techniques, all subjects enrolled in this study will receive fewer than 2 rem. 2 rem is considered "Low" risk. It is unlikely that anyone in this study will approach the 2 rem limit. Since the fluoroscopy data will be collected in one session, there will only be one day in which the participants will be exposed to this amount of radiation.

In conclusion, a participant who will be fluoroscoped for less than two minutes will be exposed to a *maximum* amount of only 2.0 rems of radiation. This means that the maximum total exposure rate will be less than 2 rems per subject for the entire experiment (Attachments 3 and 4). The participant's knee joint will be fluoroscoped using negligible to low risk levels of radiation according to published literature (Attachments 2 and 3).

We are estimating a total maximum time of 45 minutes to permit the subject time to complete the IC/HIPAA form, ask any questions s/he may have, practice the activity or repeat the activity that could not be completed, and collect all necessary fluoroscopy data from each subject.

2. **Participant Confidentiality**

The investigators will ensure subject confidentiality to the extent that is permissible by law is maintained throughout the study and after. Researchers not notated as Investigators of this study that have access to PHI will sign pledges of confidentiality. Complete confidentiality cannot be guaranteed.

Computer Database

As noted, on the day of data collection, the list of subject names will be given to UT researchers and researchers will use this to generate subject-specific identifiers; Dr. Mangiapani will be provided with this list of subject names and corresponding generated identifiers. These assigned identifiers will be uploaded into an excel spreadsheet created by UT researchers. Dr. Mangiapani will be aware of each subject's respective identifier from the table provided to them on the day of data collection after UT researchers generate the subject-specific identifiers. They will upload the PHI from subject medical files into the excel spreadsheet and transmit the document back to UT researchers via UT's secure email transmission known as the Vault (https://vault.utk.edu/).

After the study data has been entered into the spreadsheet by the surgeon's office, researchers present during data collection or appointed by Dr. Komistek will upload the subject data, including PHI, fluoroscopy, and video footage, into the CMR digital data collection. Consequently, student researchers in CMR who assist in data analysis cannot access subject-specific information. All participant queries (lookups) generate the participant identification number (the ID generated by UT researchers) and no subject identifiers. No identifiable images exist in the database. This study data will be kept indefinitely on the secure CMR database for possible future research (with the permission of each participant – requested in the IC). In the case of participant withdrawal from the study, the Revocation of Consent that the participant will be asked to complete requests that the participant indicate whether or not data collected prior to

withdrawal may be used for data analysis purposes, or if it should be removed from the CMR data collection completely and destroyed.

Hard Copy
In compliance with HIPAA regulations, all participants will have their identities withheld from all public files. Individuals not indicated as Investigators below will have access to participant information and they will sign pledges of confidentiality. The personnel in the following list will have access to participant PHI:

List of Persons Involved in Research:

- Dr. Richard Komistek, PI, University of Tennessee Professor, Biomedical Engineering, Knoxville, TN
- Dr. Michael Bolognesi, Co-PI, Duke Orthopaedics, Orthopaedic Surgeon, Durham, NC
- Dr. Aaron Hofmann, Sub-Investigator, study surgeon, Hofmann Arthritis Institute, Orthopaedic Surgeon, Salt Lake City, Utah
- Dr. Daniel Mangiapani, Sub-Investigator, Hofmann Arthritis Institute, Adult Joint Reconstruction Fellow, Salt Lake City, Utah
- Dr. Adrija Sharma, Sub-Investigator, UT Research Assistant Professor, Biomedical Engineering, Knoxville, TN
- Clinical research staff from Hofmann Arthritis Institute appointed by Drs. Hofmann or Mangiapani, Salt Lake City, Utah
- Radiation technician(s) from Hofmann Arthritis Institute will operate the fluoroscopy machine.
- Rebecca Robertson, Research Coordinator, UT staff.
- Researchers present during data collection and/or the lead student researchers appointed by Dr. Komistek.
    - Graduate students:
        - Garett Dessinger
        - Jarrod Nachtrab
        - Milad Khasian
        - Manh Ta
    - * Undergraduate student researchers employed by CMR will be involved in analyzing the data after it has been collected and transferred to CMR's digital data collection. Since subject information will be removed and replaced with the assigned identifiers before the data is transferred to the database, it will not be possible for these undergraduate students to be able to identify subjects. They will only have access to the study data that has been uploaded onto the secure CMR digital collection. These undergraduate student researchers will not have contact with subjects.
- Institutional Review Boards
    - The University of Tennessee's IRB has waived oversight to WIRB for this study's review and approval. The required Reliance Agreement is included with this submission.
    - Western Institutional Review Board on behalf of the Hofmann Arthritis Institute.

Clinical Observations:
There are no clinical observations made during this data collection or from the images obtained through data collection. There will be no radiology report generated for this procedure conducted as a result of this study. Therefore, no RT will review such a report for the procedures, which would be the only way such a "significant problem" would be determined. No data will be returned to the surgeon's office for evaluation or surgeon review. However, if researchers see anything in the imaging that is extremely out of the ordinary (*e.g.,* floating body, severe dislocation, potential tumors [spots of incredibly dense tissue on bones and skin]), they will bring this to the attention of Dr. Hofmann or his staff. It is not anticipated that the imaging collected during this study would potentially provide benefit to specific subjects by influencing the physician's treatment plan.

BENEFITS
The potential benefits from this study include, but are not limited to:

- Better understanding of the joints analyzed with the same technique in the past.
- Future implant design improvements based on the kinematic findings.
- New and advanced surgical techniques for TKA based on the results.
- There is no intention of any direct benefit to participants of the study. Information related to the data gathered may be provided to the surgeon by the researchers if something out of the ordinary is seen during the imaging. However, researchers are not radiologists and cannot interpret anything they may see. If there is something within the imaging that is obviously wrong as mentioned above, then this could result in potential modification of a subject's treatment plan if images collected as a result of this study reveal any kind of "significant problem."

METHODS TO OBTAIN "INFORMED CONSENT" FROM PARTICIPANTS
Informed consent will be obtained prior to any procedures being conducted. Subjects who are agreeable to participate will be scheduled to visit the Hofmann Arthritis Institute on the day that UT researchers will travel there for data collection. Dr. Mangiapani and/or UT researchers will be responsible for consenting the participants, giving them ample time to review and complete the forms and assist the participants with review of the documentation, if the participants are unable to read the form on their own. Only upon signed consent will the subject be allowed to participate in the study. If the subject chooses to be removed from the study after participating, his/her video footage and any other demographical data that was collected will be managed according to the subject's response on the Revocation of Consent form. A copy of his/her Revocation of Consent will be attached to his/her IC and placed in a separate, secure file for IRB review. These consent forms will be stored at UT, Knoxville and will be accessible by only the aforementioned personnel.

Dr. Hofmann will not be present during the consenting process to avoid possible subject coercion to participate. Subjects may contact Dr. Hofmann's office with any questions they may have.

From previous studies, we have determined that it takes approximately 15 minutes to consent a subject and answer any questions that s/he may have. We have also estimated approximately 30 minutes for researchers to guide the subject through the steps of the procedure, allow the subject

to practice the activity and then to actually perform the activity under fluoroscopic surveillance; actual radiation exposure will be up to, but not more than two minutes. We have estimated a total time of approximately 45 minutes for each subject to be consented, complete the KSS survey and complete the fluoroscopy procedure.

STATISTICAL ANALYSIS PLAN

Basic descriptive statistics (mean, standard deviation and range) will be analyzed for the condylar movement, axial rotation, and range-of-motion.