MARS
(MULTICENTER ACL REVISION STUDY)

Sponsored by AOSSM for members
Developed by over 100 AOSSM surgeons

“Mini MOP”
Manual of Operations and Procedures

PIs: Kurt P. Spindler and Rick W. Wright
Study Coordinator: Laura J. Huston
Chair, AOSSM Research: David R. McAllister
Director of Research: Bart Mann
Funding Sources: AOSSM and through AOSSM a grant from MTF
# TABLE OF CONTENTS*

D. Recruitment, Screening, and Eligibility Criteria
   1. Screening and Recruiting of Patients
   2. Eligibility Criteria

E. Informed Consent

I. Participant Evaluations and Follow-up

L. Adverse Events

O. Data Collection and Study Forms

Q. Good Clinical Practice

R. Reports

* Only the sections important to enrollment of patients into MARS study are included in this “Mini MOP”. All sections will be forthcoming in a complete MOP soon. Therefore, this “Mini MOP” correctly begins with Section D.
D. MARS Recruitment, Screening, and Eligibility Criteria

1. Screening and Recruiting of Patients

   a. Screening
      
      i. The PI will perform the initial screening during the office visit.
      
      ii. Once the PI deems the patient qualifies for the study, a Study Coordinator (SC) / Research Assistant (RA) / Research Nurse (RN) will be notified.
      
      iii. The PI/SC/RA/RN will use the Screening and Enrollment Log (Study Form #3) to be placed in the MARS regulatory binder and a copy should be mailed monthly with other items to the data coordinating center (Vanderbilt University, Nashville, TN).

   b. Recruiting
      
      i. Ask PI to check with the patient to see if he/she is interested in participating in the study.
      
      ii. If the patient expresses interest, the PI or Study Coordinator or his/her designate will approach the patient and explain the study in detail. If the patient gives verbal agreement to participate, continue with the consenting process.

2. Eligibility Criteria

   Inclusion criteria:
   
   • All ACL-deficient candidates presenting to the clinic, between the ages of 12† and 65, scheduled to have a revision ACL reconstruction by a participating (MARS Study) surgeon.
   
   • All participants must have undergone a primary ACL reconstruction in the past and are currently identified as having experienced failure of their primary ACL reconstruction, as defined by either MRI, knee laxity (KT > 5mm), a positive pivot shift or Lachman’s, functional instability, and/or by arthroscopic confirmation.
   
   • All ACL-deficient patients seeking a revision ACL reconstruction that have either partial (Grade I or II) and/or complete (Grade III) simultaneous ligamentous injuries to the collateral ligaments (MCL or LCL) and/or the posterior cruciate ligament (PCL) will also be included.
   
   • Non-operative treatment of patients with ACL reconstruction failure are also eligible to participate.
   
   • The following graft types will be the only ones accepted for inclusion:
      
      o Any autograft
      
      o Fresh-frozen allografts from a single donor source (Musculoskeletal Transplant Foundation). These grafts should consist of either:
- bone-patellar tendon-bone
- tibialis anterior
- achilles tendon

(see MTF specification sheet)

† Only skeletally mature individuals, those with closed distal femoral and proximal tibial physes. This approach reflects clinical practice in this country, as over 84% of orthopaedic surgeons in the AAOS believe open growth plates are a contraindication to revision ACLR (Marx, 2001).

Exclusion criteria:
- Patients presenting with prior infection, arthrofibrosis, or regional pain syndrome.
- Subjects will be excluded if their allograft source does not come from MTF.
- Patients unwilling or unable to complete their repeat questionnaire two years after their initial visit.
E. Informed Consent Process

1. Process

   a. **Adult (≥18 years old):** Patient signature is obtained on IRB approved consent form. Consent document’s wording is specific to each performance site’s IRB requirements.

   b. **Minor (12-17 years old):** Since adolescents are the highest risk group for an ACL tear, they must be included in the study for scientific validity. The signature of an adult parent or guardian must also be obtained in addition to the patient’s signature.

   c. A copy of the signed consent form is given to each patient and/or parent or guardian. The original signed consent form at each performance site is placed in the site’s regulatory binder and a copy is sent to Vanderbilt. Similarly, the Consent Process Source document (Study Form #4) should be completed at this time, with the original kept in the site’s regulatory binder and a copy sent to Vanderbilt.

   d. Patients will be introduced to the study by a participating surgeon during a preoperative office visit. Informed consent will be obtained by either the surgeon or his/her designee (nurse, physician assistant, study coordinator, research assistant, etc.) prior to the day of surgery. In addition to the informed consent document, a one-page information flyer will be handed to the patient while in the office to aid in their understanding of risks and benefits of participation in the study (Study Form #5).

      After reading thru the informed consent, the designated research person will verify that the patient and parent/guardian (if the patient is less than 18 years of age) has appropriately signed the consent document. Once the informed consent process is complete and the patient has been given a copy of the consent for their records, they will be given a self-administered outcome questionnaire to complete within one week of their scheduled revision ACLR (see Study Form #6 –Patient Questionnaire). This questionnaire can be completed in the office if within one week of ACLR, at home (either mailed in a self-addressed, stamped envelope or brought to the operating room on the day of surgery), or completed preoperatively on the day of the revision ACLR. The questionnaire includes questions regarding demographics, sports history, mechanism of injury, co-morbidities, along with a series of patient-oriented outcome measures (KOOS, WOMAC, Marx Activity Scale, SF-36, IKDC). The estimated average time to complete this questionnaire is 20-25 minutes.

2. Informed Consent Document Templates

   a. **Adult (≥18 years old)** – see pages E2-E5
   b. **Minor (12-17 years old)** – see pages E6-E8
Vanderbilt University Institutional Review Board
Informed Consent Document for Research

Principal Investigator: Kurt P. Spindler, M.D.
Study Title: Multicenter ACL Revision Study (MARS)
Institution/Hospital: Vanderbilt University Medical Center

This informed consent applies to adults (18 years of age or older).

Name of participant: _____________________________________________  Age: ___________

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.

You do not have to be in this research study. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether you still would like to be in this study.

1. What is the purpose of this study?

You are being asked to take part in this research study because you are having revision ACL surgery. The purpose of this study is to follow up patients who have had this surgery, in order to understand why some people do well and can return to their pre-injury level, while others don't. Many sports medicine clinics across the U.S. are interested in this, so a large study is underway. We plan is to enroll 1,200 athletes in this study -- 60 of which from Vanderbilt.

You will be asked to fill out a questionnaire that allows us to track your functional level. The doctor will also complete a form of what they found during surgery and how they repaired the knee. Our goal is to use these two forms (the patient and the doctor's forms) to find out if there are any links between the type of injury patients have and how they do after surgery.

The results will help us improve the quality of care for patients who have been treated for repeated ACL injuries, and to find out which treatments are most cost effective with regards to both short and long-term outcomes.

2. What will happen and how long will you be in the study?

You will be asked to complete a questionnaire to let us know how and when the knee was injured, and how you are doing. This should take around 25 minutes to complete. We will ask you to fill this same questionnaire out 4 times. The first time will be before the ACL surgery. The 2nd time will be 2 years after surgery, the 3rd time will be 6 years after surgery, and the 4th time will be 10 years after surgery. We plan to enroll 1,200 athletes in this study -- 60 of which from Vanderbilt.

The 2, 6, and 10-year follow-up questionnaires will be sent through the mail. Upon completion, we would like you to mail the questionnaire back to the Vanderbilt Sports Medicine Clinic using the self-addressed stamped envelope that will be enclosed.
At 1, 5, and 9 years after surgery, a staff researcher from Vanderbilt's Sports Medicine Center will try to contact you (either by phone or by email), or the emergency contact person that you list on the questionnaire. The purpose is to get the most up-to-date contact information (so that the questionnaire can be mailed to you the next year).

Along with the questionnaire at the time of surgery, the doctor will complete an in-depth form detailing what's wrong with the knee and how they fixed it. The two forms will be analyzed to see if there are any links between injury and outcomes.

3. Costs to you if you take part in this study:

There are no costs to participate.

4. Side effects and risks that you can expect if you take part in this study:

It will take roughly 25 minutes to complete the questionnaire. Other than 25 minutes of your time, there are no other inconveniences or expected risks as a result of participating in this study.

5. Risks that are not known:

We believe that there are no unknown risks as a result of completing this questionnaire.

6. Payment in case you are injured while in this study:

Immediate and necessary care for injury will be done at Vanderbilt without charge if you are hurt from being in this study. There are no plans for Vanderbilt to pay for further treatment beyond this care or provide money for such injury.

7. Good effects that might result from this study:

a) The benefits to science and humankind that might result from this study are:
To look at factors that are important to the patient -- things such as level of pain, function, return to activity level, and overall patient satisfaction after undergoing an ACL revision surgery. This study will also help us predict which injuries and treatments lead to better short and long-term patient-oriented outcomes.

b) The benefits you might get from being in this study are:
There is no benefit to you for being in this study.

8. Other treatments you could get if you decide not to be in this study:

All subjects will have the same standard treatment, regardless of whether you are enrolled in this study.

9. Payments for you time spent taking part in this study or expenses:

You will receive $20 for completing the initial survey, and $20 each time you complete the 2, 6, and 10-year follow-up surveys.

10. Reasons why the study doctor may take you out of this study:

You may be withdrawn from the study due to no fault of your own because of data collection concerns.

11. What will happen if you decide to stop being in this study?
If you want to withdraw from the study, you should contact Dr. Kurt Spindler in writing and let him know that you wish to withdraw study consent. His mailing address is Medical Center East, South Tower, Suite 4200; Nashville, TN 37232-8774. At that time, we will stop getting any more data about you.

Deciding not to be part of the study will not change your regular medical care in any way.

12. Who to call for any questions or in case you are injured:

If you have any questions about this research study or if you feel you have been hurt by being a part of this study, please feel free to contact the study coordinator, LAURA HUSTON at (615) 343-8695. If you cannot reach the research staff, please page the study doctor (Dr. Kurt Spindler) at (615) 835-5301.

For additional information about giving consent or your rights as a person in this study, please feel free to call the Vanderbilt University Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

13. Confidentiality:

All efforts, within reason, will be made to keep your personal information in your research record confidential but total confidentiality cannot be guaranteed.

Completed patient and surgeon forms will be collected by the study coordinator at each research site and mailed to the central study site (Vanderbilt University). Once at the central site, all forms will be scanned into a password-protected database. Once entered into the database, the information will be de-identified. The researchers at Vanderbilt will have access to all of the identifiable information, so that they are able to mail the follow-up questionnaires to you. Other research personnel will only have access to the de-identified information contained in the database. All original forms will be kept in locked file cabinets within the research room of the Sports Medicine Center. This information will be kept indefinitely in the event that data clarification is needed.

14. Privacy:

Privacy of Protected Health Information for:

**Adult (18 years and older):**

All efforts, within reason, will be made to keep your protected health information (PHI) private. PHI is your health information that is, or has been gathered or kept by Vanderbilt as a result of your healthcare. This includes data gathered for research studies that can be traced back to you. Using or sharing (“disclosure”) such data must follow federal privacy rules. By signing the consent for this study, you are agreeing (“authorization”) to the uses and likely sharing of your PHI. If you decide to be in this research study, you are also agreeing to let the study team use and share your PHI as described below.

As part of the study, Dr. Spindler and his study team may share the results of your study and/or non-study linked results of the questionnaire and the surgeon form, as well as parts of your medical record, to the groups named below. These groups may include people from the Vanderbilt University Institutional Review Board, the Federal Government Office for Human Research Protections, the National Institutes of Health, or representatives from our external funding source, the American Orthopaedic Society for Sports Medicine. Federal privacy rules may not apply to these groups; they have their own rules and codes to assure that all efforts, within reason, will be made to keep your PHI private.
The study results will be kept in your research record for at least six years after the study is finished. At that time, the research data that has not been put in your medical record will be archived at a secure Vanderbilt location. Any research data that has been put into your medical record will be kept for an unknown length of time.

Unless told otherwise, your consent to use or share your PHI does not expire. If you change your mind, we ask that you contact Dr. Spindler in writing and let him know that you withdraw consent. Dr. Spindler’s mailing address is Medical Center East, South Tower, Suite 4200; Nashville, TN 37232-8774. At that time, we will stop getting any more data about you. But, the health data we stored before you withdrew consent may still be used for reporting and research quality.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.

Date    Signature of patient/volunteer
Vanderbilt University Institutional Review Board  
Informed Consent Document for Research

Principal Investigator: Kurt P. Spindler, M.D.  
Study Title: Multicenter ACL Revision Study (MARS)  
Institution/Hospital: Vanderbilt University Medical Center

This informed consent applies to teenagers, 12-17 years of age.  

Name of participant: ____________________________________________   Age: ___________

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.

You do not have to be in this research study. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether you still would like to be in this study.

1. What is the purpose of this study?
   You are being asked to take part in this research study because you are having revision ACL surgery. We are doing this study because we want to find out how you do after your surgery. We want to know if you can return to playing sports and doing the things you did before your injury. Many sports medicine clinics across the U.S. are interested in this, so a large study is underway. We plan to enroll 1,200 athletes in this study -- 60 of which from Vanderbilt.

2. What will happen and how long will you be in the study?
   We will ask you to fill out a questionnaire that asks how you got injured, what activities you could do before you got hurt, and what activities you can do now. It will take you around 25 minutes to complete.

   We will ask you to fill this same questionnaire out 4 times. The first time will be just before your ACL surgery. The second time will be 2 years after surgery, the 3rd time will be 6 years after surgery, and the 4th time will be 10 years after surgery. The 2, 6, and 10-year follow-up questionnaires will be sent to you through the mail. After you are done filling out the questionnaire, we will ask you to mail it back to Vanderbilt Sports Medicine Clinic using the self-addressed stamped envelope that will be enclosed.

   At 1, 5, and 9 years after your surgery, a research employee from Vanderbilt will try to call or email you, your parents, or the emergency contact person that you wrote on the questionnaire, in order to get your most up-to-date contact information (so that the questionnaire can be mailed to you the next year).

3. Costs to you if you take part in this study:
   There are no costs to participate.

4. Side effects and risks that you can expect if you take part in this study:
It will take roughly 25 minutes to complete the questionnaire. Other than 25 minutes of your time, there are no other inconveniences or expected risks as a result of participating in this study.

5. Risks that are not known:

We believe that there are no unknown risks as a result of completing this questionnaire.

6. Payment in case you are injured while in this study:

Immediate and necessary care for injury will be done at Vanderbilt without charge if you are hurt from being in this study. There are no plans for Vanderbilt to pay for further treatment beyond this care or provide money for such injury.

7. Good effects that might result from this study:

a) The benefits to science and humankind that might result from this study are:
   The results of this study will help us to treat people who have ACL injuries better, in order to get them back to where they were before their injury in terms of function and activity level.

b) The benefits you might get from being in this study are:
   There is no benefit to you for being in this study.

8. Other treatments you could get if you decide not to be in this study:

You will receive the same treatment regardless of whether you enroll in the study.

9. Payments for you time spent taking part in this study or expenses:

You will receive $20 for completing the 1st survey, and $20 each time you complete the 2, 6, and 10-year follow-up surveys.

10. Reasons why the study doctor may take you out of this study:

You may be withdrawn from the study due to no fault of your own because of data collection concerns.

11. What will happen if you decide to stop being in this study?

You do not have to be in the study if you don't want to. You will get the same treatment, no matter if you’re in the study or not. If you want to stop being in the study, we would like you (or your parents) to write to Dr. Spindler, letting him know that you don't want to be in the study any longer. His address is:
   Kurt Spindler, MD
   Medical Center East, South Tower, Suite 4200
   Nashville, TN 37232-8774

At that time, we will stop sending you the questionnaires.

12. Who to call for any questions or in case you are injured:

If you have any questions about this research study or if you feel you have been hurt by being a part of this study, please feel free to contact the study coordinator, LAURA HUSTON
at (615) 343-8695. If you cannot reach the research staff, please page the study doctor (Dr. Kurt Spindler) at (615) 835-5301.

For additional information about giving consent or your rights as a person in this study, please feel free to call the Vanderbilt University Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

15. Confidentiality:
All efforts, within reason, will be made to keep your personal information in your research record confidential but total confidentiality cannot be guaranteed.

Only a couple of people who work in the Sports Medicine Department will know that you are in this research study. What you tell us in the questionnaire will not be shared with (your school/your parents) unless you or someone else is in danger.

16. Privacy:

Privacy of Protected Health Information for:

Older Child (12-17 years old): All efforts, within reason, will be made to keep the data in your research record private but we cannot promise total privacy. The data we collect on you may be shared with others (for example, Vanderbilt University Institutional Review Board, the National Institutes of Health, the Federal Government Office for Human Research Protections, or representatives from our external funding source, the American Orthopaedic Society for Sports Medicine) if you or someone else is in danger or if we have to do so by law.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY
I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.

_____________________________ ___________________________
Date Signature of patient/volunteer

_____________________________ ___________________________
Date Signature of parent/legal guardian
I. PARTICIPANT EVALUATION AND FOLLOW-UP

Time Zero (Baseline):
Patient will be introduced to the study by a participating surgeon during a preoperative office visit. Informed consent will be obtained by either the surgeon or his/her designee (nurse, physician assistant, study coordinator, research assistant, etc.) prior to the day of surgery. In addition to the informed consent document, a one-page informational flyer (see Study Form #5 – “What is MARS?” handout) will be handed to the patient while in the office to aid in their understanding of risks and benefits of participation in the study.

After reading thru the informed consent, the designated research person will verify that the patient and parent/guardian (if the patient is less than 18 years of age) has appropriately signed the consent document. Once the informed consent process is complete and the patient has been given a copy of the consent for their records, they will be given a self-administered outcome questionnaire to complete within one week of their scheduled revision ACLR (see Study Form #6 – Patient Questionnaire). This questionnaire can be completed in the office if within one week of ACLR, at home (either mailed in a self-addressed, stamped envelope or brought to the operating room on the day of surgery), or completed preoperatively on the day of the revision ACLR. The questionnaire includes questions regarding demographics, sports history, mechanism of injury, co-morbidities, along with a series of patient-oriented outcome measures (KOOS, WOMAC, Marx Activity Scale, SF-36, IKDC). The estimated average time to complete this questionnaire is 20-25 minutes.

After the revision ACLR surgery, the surgeon will complete a detailed form that includes information on previous knee surgery, examination under anesthesia, operative findings (ligaments, articular cartilage, and meniscus) and their treatment (see Study Form #7 – Surgeon Form). The surgeon form also includes sections on specific surgical technique used and projected rehabilitation milestones.

Time One (One year after surgery)
Patients are sent a letter to verify their correct address for future contact at their first follow-up time point (two years following surgery) (see Study Form #9 – Patient Follow-up letter). The coordinating center (Vanderbilt University) will take responsibility for tracking all follow-up.

Time Two (Two years after surgery)
Patients will receive a phone call from the coordinating site (Vanderbilt) to confirm their current contact information so that a questionnaire may be sent to them. They will be asked whether or not they have had any additional knee surgery in the year since their revision ACL surgery. If so, they will be asked to provide the following information:

- Which knee?
- What type of surgery?
- Date(s) of the additional surgery
- Name of physician

If the physician who performed the subsequent surgery is not the original treating physician, the patient will be asked to obtain a copy of the operative report to send to Vanderbilt Sports Medicine.

In addition, each participating site must also verify at their institution whether their patients have had additional surgical procedures in either knee since enrollment in the study. To do so, the
Research Assistant (or designated personnel) at each site must search their respective surgeon’s operative logs and their institution’s medical records for any potential operative procedures performed by one of his/her partners.

All patients will be asked to complete a self-administered questionnaire, which is identical to the one they completed preoperatively. Patients receive $20 for their time and effort after they have completed the follow-up questionnaire and it has been received at Vanderbilt.

**Time Three (Six years after surgery)**

Patients will receive a phone call from the coordinating site (Vanderbilt) to confirm their current contact information so that a questionnaire may be sent to them. They will be asked whether or not they have had any additional knee surgery in the year since their revision ACL surgery. If so, they will be asked to provide the following information:

- Which knee?
- What type of surgery?
- Date(s) of the additional surgery
- Name of physician

If the physician who performed the subsequent surgery is not the original treating physician, the patient will be asked to obtain a copy of the operative report to send to Vanderbilt Sports Medicine.

In addition, each participating site must also verify at their institution whether their patients have had additional surgical procedures in either knee since enrollment in the study. To do so, the Research Assistant (or designated personnel) at each site must search their respective surgeon’s operative logs and their institution’s medical records for any potential operative procedures performed by one of his/her partners.

All patients will be asked to complete a self-administered questionnaire, which is identical to the one they completed preoperatively. Patients receive $20 for their time and effort after they have completed the follow-up questionnaire and it has been received at Vanderbilt.

**Time Four (Ten years after surgery)**

Patients will receive a phone call from the coordinating site (Vanderbilt) to confirm their current contact information so that a questionnaire may be sent to them. They will be asked whether or not they have had any additional knee surgery in the year since their revision ACL surgery. If so, they will be asked to provide the following information:

- Which knee?
- What type of surgery?
- Date(s) of the additional surgery
- Name of physician

If the physician who performed the subsequent surgery is not the original treating physician, the patient will be asked to obtain a copy of the operative report to send to Vanderbilt Sports Medicine.

In addition, each participating site must also verify at their institution whether their patients have had additional surgical procedures in either knee since enrollment in the study. To do so, the Research Assistant (or designated personnel) at each site must search their respective surgeon’s
operative logs and their institution’s medical records for any potential operative procedures performed by one of his/her partners.

All patients will be asked to complete a self-administered questionnaire, which is identical to the one they completed preoperatively. Patients receive $20 for their time and effort after they have completed the follow-up questionnaire and it has been received at Vanderbilt.
L. Adverse Events

1. **Overview:**
   Since this is a clinical cohort study, NO INTERVENTION for treatment of patients is a result of this study. Thus, adverse events defined below cannot be the direct result of this research study. They are captured nonetheless since they could potentially influence the outcome.

2. **Adverse Event Report**
   (Study Form #10 – Adverse Events—Each Subject; Study Form #11—Each Site) will be completed if any of the following outcomes occur:
   - ACLR knee infection
   - Graft failure within the first six months of surgery
   - Deep venous thrombosis or pulmonary embolus

3. **Serious Adverse Events**
   (Study Form #12—Serious Adverse Event Report Form)
   As defined by the FDA, any event is considered a “serious adverse event” if it results in any of the following outcomes:
   - Death/fatality
   - Life-threatening
   - Persistent or significantly disabling or incapacitating
   - an inpatient hospitalization or prolongation of hospitalization
   - a congenital anomaly or defect
   - a significant medical incident that, based on appropriate medical judgment, may jeopardize the subject and require medical or surgical intervention to prevent one of the outcomes listed above.
   - A breach of subject’s privacy rights
   - Emotional distress, risk of criminal or civil liability, or damage to the subjects’ financial standing, employability, or reputation.

4. **Adverse Event Reporting Policy**
   As such, if such an event occurs, the site will be required to fill out the Adverse Event Report form (or Serious Adverse Event Report form) and submits it to their IRB, as well as sending a copy to the coordinating site as soon as possible but no later than 10 working days of the investigator’s knowledge of the problem.
O. MARS Data Collection and Study Forms

1. Overview

a. All forms will be distributed from the coordinating site (Vanderbilt). Each patient/surgeon form packet should have unique (but matching) ID number on the top right side.

b. The original, signed informed consent is kept at each site, while a copy is sent to the coordinating site.

c. Similarly, copies of the questionnaires are kept in the patient’s file at each site, while the **ORIGINALS** are sent to the coordinating site.

d. Completed informed consent document, patient questionnaire, and surgeon form is sent by performance site research personnel directly to Vanderbilt (coordinating center) via overnight mail at the end of every month.

e. All forms are maintained at Vanderbilt in locked files located within a locked research center.

f. Access to study forms is by designated research personnel at Vanderbilt only.

g. No marks or corrections are made on the forms by research personnel without written explanation on the form and reviewed by the research coordinator.

h. A log of all forms is maintained at Vanderbilt.

2. Every Study Form Referenced by Number (included at end of this section)

#1 Delegation of Duties
#2 IRB Certification Verification
#3 Screening and Enrollment Log
#4 Consent Process Source Document
#5 “What is MARS?” handout
#6 MOON/MARS Patient Questionnaire
#7 Surgeon Form
#8 Case Report Form
#9 Patient Follow-up Letter
#10 Adverse Events—Each Subject
#11 Adverse Events—Each Site
#12 Serious Adverse Event Report Form
#13 Protocol Violation Log

For informational use only (not actively used in this study):
#14 ACLR Educational pamphlet (Vanderbilt only)
#15 MOON ACLR Rehabilitation Guidelines
#16 Patient Follow-up Telephone Log (Vanderbilt only)
3. **General Instructions for Completing Forms**

All data recorded on forms must be verifiable in the source documents maintained by the clinical site(s) according to FDA Guidelines and good clinical practice. Examples of specific instructions for completing paper forms follow.

When completing the study forms, **PRINT IN CAPITAL LETTERS** using black ink. Note, participants should **not** be identified by name on any study document submitted with the forms (e.g., ECG tracing, lab reports). Replace the participant name with the participant initials and I.D. number.

**Participant's I.D. Barcode Number:** The participant’s unique 5-digit I.D. barcode number must be recorded on **EVERY** document, including pages for which no study data are recorded. This number will be used to de-identify the dataset.

**Participant Initials:** Record participant's first, middle and last initials. If a participant has no middle name, place a dash (-) in the designated space. If the participant has a hyphenated last name, record the first letter of the first part of the name.

**Dates:** All dates must be verifiable by source documents. Estimates are **not** acceptable unless specifically indicated in instructions.

**Abbreviations:** Use of abbreviations not specifically noted in the instructions for completing the forms can be problematic and should be held to a minimum.

**Extraneous Writing:** Comments written extraneously on forms cannot be captured in the database; thus, write only in the spaces indicated.

**Correcting errors:** If an error has been made on the study forms, place a **single** line through the erroneous entry and record the date and your initials. Indicate the correct response.

**Skipping items:** **DO NOT SKIP ANY ITEMS.** Some items may carry "Unknown" or "Not Applicable" response choices which should be checked when necessary.

**Incomplete data:** Data may not be available to complete the form for various reasons. Circle the item for which data is not available and indicate the reason near the appropriate field:

- If an evaluation was **not done**, write **ND** and provide a reason.
- If the information is **not available**, but the evaluation was done, write **NAV**.
Note: Only in rare circumstances, as in the case of lost documentation, should NAV be recorded on the form. Every effort should be made to obtain the information requested.

- If an evaluation is not applicable, write NA.

Incomplete or Illegible forms: Incomplete forms that do not have adequate explanation (as described above) compromise the integrity of the entire study. Errors, such as incomplete or illegible forms, are problems that require time and energy to resolve. If an entire page of the forms cannot be completed (i.e., no parts have any responses), and it is unlikely that it will be completed, draw a diagonal line through the form and write NOT DONE, NOT AVAILABLE or NOT APPLICABLE, as appropriate. The header information must be completed even though no data are recorded on the form. If a form can only be partially completed at the time of monitoring, but will be completed when the information becomes available, follow the direction of the clinical monitor.

☆ DO NOT LEAVE FORMS INCOMPLETE OR UNUSED WITHOUT EXPLANATION.
4. GUIDELINES TO COMPLETE PATIENT AND SURGEON FORMS

Subsection 1: MOON/MARS PATIENT QUESTIONNAIRE

Do I need a research coordinator?
If the surgeon, as principal investigator, can:

- obtain site IRB approval,
- answer any questions the patient may have related to the study,
- maintain the patient screening and enrollment log,
- obtain proper patient informed consent,
- hand out the Patient Questionnaire preoperatively within one week of surgery,
- complete the Surgeon Form, and
- mail this back to Vanderbilt in accordance with the established timeline,

the study can be accomplished without a Research Coordinator. However, one must also be able to log in the number of patients participating in the study and any adverse events. If there is no Research Coordinator, the surgeon must verify that the unique ID number (top right-hand corner) matches the Patient Questionnaire with the Surgeon Form and that the knee side, date of surgery, and date of birth are accurately filled in on both the Patient Questionnaire and the Surgeon Form.

Questions about the patient-oriented outcome questionnaire. Patients frequently ask, “Why is the questionnaire so long?” and “How much time does it take to fill it out?”
First, the questionnaire is long because it contains a series of validated patient outcome questionnaires in their original form to maintain the validity. The questionnaire begins with a KOOS which is a WOMAC plus two additional subscales or domains, followed by a Marx Activity Level, followed by an SF-36, and then finally followed by the IKDC Subjective Questionnaire. There is additional information on demographics and social history in addition to sporting activity and associated medical conditions and treatment. We advise the patients that the form will take about 25 minutes to complete and that they answer EACH QUESTION TO THE BEST OF THEIR UNDERSTANDING.

Another question frequently asked by patients: “What do I do if a question does not apply to me?”
Neither the surgeon, research coordinator, nor study personnel should assist the patient in interpreting the questions since these forms are made to be self-interpreted by the patient and to be answered as the patient interprets the question. With that in mind, one can easily review the form themselves and realize that the series of questions SP-1 through SP-5, which is part of the KOOS, really does not apply to the patient since the surgeon and patient have self-limited their activities in the last week as a consequence of the impending surgery. This is well recognized by the data analysis staff and therefore will be accounted for in the analysis. In stark contrast, the next subscale, Q-1 through Q-4, or quality of life on the KOOS, is highly relevant to the patient as you can see by reviewing these items. Finally, there is a time-sensitive nature in answering these questions that are highlighted; the WOMAC and KOOS ask for the last week; the Marx Scale asks for the last year; the SF-36 asks for the last four weeks; and the IKDC in symptoms asks for the last four weeks, but IKDC in activities has no timeline, and IKDC in function the timeline is from the point of injury.
Subsection 2: SURGEON DOCUMENTATION FORM

The Surgeon Form can be broken down into several components.

A. EVALUATION OF THE PATIENT AND KNEE AND PREVIOUS SURGERY (BEFORE THE EXAMINATION UNDER ANESTHESIA).

STEP ONE IS TO IDENTIFY RECONSTRUCTION TYPE AND THE OPERATED SIDE.

STEP TWO IS TO VERIFY THAT THE UNIQUE ID NUMBER, DATE OF SURGERY, SURGEON’S INITIALS, AND PATIENT’S INITIALS MATCH 100% WITH THE COMPLETED PATIENT QUESTIONNAIRE, THEREFORE ASSURING THE SURGEON FORM.matches WITH THE APPROPRIATE PATIENT QUESTIONNAIRE FORM.

QUESTION 1a -- The surgeon or the research coordinator interviewing the patient should ask from the patient’s perspective if the contralateral knee is normal, nearly normal, abnormal, or severely abnormal?

QUESTION 1b -- This should be followed by asking the mechanism of injury from the patient’s perspective (with regards to nontraumatic versus traumatic, contact versus noncontact, and gradual versus sudden in the case of nontraumatic scenarios).

QUESTION 2 -- One should check whether there is any inflammatory arthritis such as rheumatoid arthritis.

QUESTION 3a -- Ask whether there is an MRI, and carefully check the box whether there has been previous knee surgery.

QUESTION 3b – Answer if a bone bruise exists on MRI.

QUESTION 3c – Identify the location of bone bruise.

QUESTION 4 -- If there is no previous knee surgery, one can then skip to Question 12 under the “Examination Under Anesthesia” section.

If there is previous surgery on either knee, check “Yes” for Question 4 and then you can determine which side or if it applies to both sides. Note -- on a revision ACL reconstruction there will always be prior surgery indicated as “Yes” on the same side as the surgery currently being performed. When filling out the type of previous surgery it is optimal to have the prior operative reports but this may not always be obtainable. Therefore, the surgeon can figure out based upon the surgical scars and the witnessed pathology in the knee to provide the best estimate of previous surgery.

QUESTION 5 -- One wishes to capture any meniscal surgery here, both for the medial and lateral side.

QUESTION 6 – Intended to capture any ligament surgery for the right and left side, and the type of grafts (auto- or allograft), and in addition any PCL or collateral.

QUESTION 7 – If extensor mechanism surgery was performed, should be denoted as well.
QUESTION 8 -- Next, if there was any osteoarthritis surgery record it here.

QUESTION 9 a and b -- Articular cartilage surgery can then be determined by location between right and left along with one’s treatment like shaving, abrasion, drilling, microfracture, cell therapy, and mosaicplasty.

QUESTION 10 -- Record if any arthroscopic or open debridements for intraarticular knee infection have been performed, including which side (R or L) and if “yes”, the number of debridements.

QUESTION 11 -- Finally, the type of plica or synovial surgery should be recorded. Finally, if any extensor mechanism surgery has been performed this should have been recorded in Question 7.

Summary: Every effort should be made to obtain the op note from prior surgery and to send this along with the form to Vanderbilt. However, on inspection of the knee at the time of surgery, the surgeon can usually tell what prior procedures have been performed and/or what injuries there have been to the articular surface.

B. EXAMINATION UNDER ANESTHESIA

GENERAL INFORMATION: THE EXAMINATION UNDER ANESTHESIA IS PATTERNED AFTER THE RECOMMENDATIONS OF THE IKDC COMMITTEE AND THEREFORE-follows its format. THE OPERATING SURGEON MUST FILL OUT EACH QUESTION IN THIS FORM BEGINNING WITH QUESTION 12, RECORDING WHETHER THIS IS THE EXAM UNDER ANESTHESIA SINCE IN A POTENTIAL FOLLOW-UP EXAMINATION (for example, at 2, 6, or 10 years where there is no operative procedure) this would be a “NO”.

QUESTIONS 14, a, b, c, and d -- Generalized Laxity and Alignment subcomponent: When filling out this section the surgeon should choose a single score within each. For alignment assessment a caveat is it should be either “normal” or what it states is “obvious varus” or obvious valgus”. Thus, all obvious, not subtle varus or valgus should be recorded. Likewise for patella -- unless obviously baja vs alta or patella subluxation.

QUESTIONS 15 a and b -- How do I measure range of motion? To measure range of motion one should assess whether an instrumented goniometer is used. The range of motion is patterned after the IKDC recommendation where all values are positive. For example, the degrees of hyperextension are recorded as a positive value. The extension is recorded as a positive value and can only be zero or if there is no deficit from extension. For example, if the patient is 10 degrees short of extension to the neutral position, this should be recorded as “10” in the middle box. Likewise, the amount in degrees of flexion is recorded as a positive value. Thus, a person with a 10 degree hyperextension would be recorded as “10-0-150”. However, a person with a 10 degree loss of extension would be recorded as “0-10-150”. It should be noted that the critical value is the comparison of side-to-side and not the absolute value, thus the side-to-side differences will be the critical measure being evaluated in our data analysis.

QUESTION 16 -- Effusion: Self-explanatory.
QUESTIONS 17; 18 a, b, c; 19 a, b; and 20 -- How do I measure the AP stability of the ACL?
The Lachman examination can either be instrumented or measured as judged by the IKDC. For example, the IKDC measures the side-to-side difference in degrees of laxity. You would estimate whether this is “normal” or “tight”, the degree of laxity being 3-5 mm vs 6-10 mm vs >10 mm or being “too tight” as -1 to -3 mm or <-3 mm. When assessing if you are doing this instrumented you must check off “yes”, decide which technique, and give the absolute values of excursion which is the side-to-side difference. Finally, record the force, whether it is 15, 20, 30, max manual, or a different amount of force (measured in pounds). It is recommended that the 30-pound value be utilized at least for one of these measurements. Finally, the endpoint of the Lachman should be assessed as well as the total translation.

QUESTIONS 21 a, b; 22; and 23a, b -- How do I measure the status of the Posterior Cruciate Ligament?
The questions regarding posterior sag, posterior drawer, and posterior endpoint measure the posterior cruciate ligament. We are trying to determine whether the tibial plateau is anterior, flush, or just behind the medial femoral condyle versus significantly behind, and this should be scored appropriately. The posterior drawer is then compared at 70 degrees, side-to-side difference, and categorized then at zero to 2 mm, 3-5 mm, 6-10 mm, or >10 mm. In simple terms, one would expect, in general, that someone who has a tibial plateau flush with the medial femoral condyle could have 3-5 mm of posterior displacement. One would generally find that in people with the tibial plateau behind the medial femoral condyle would find 6-10 mm of displacement. In a patient with the tibial plateau significantly sagged behind the medial femoral condyle one would probably expect >10 mm of displacement. Finally the posterior drawer is assessed, whether it is firm or soft.

QUESTIONS 24, 25, 26, and 27 -- How do I assess collateral ligament instability?
Collateral ligament instability is assessed in Questions 24 and 25 for Medial Joint Opening and in Questions 26 and 27 for Lateral Joint Opening. It is a side-to-side comparison, normal side versus contralateral side or in other words, the involved versus the uninvolved side. For the medial collateral ligament, medial joint opening is assessed at zero and 20 degrees with a valgus force and filled out accordingly. For the lateral side, a varus force is applied at zero and 20 degrees and the measurements are documented accordingly.

QUESTIONS 28a and 28b -- How do I define the pivot shift and reverse pivot shift?
The pivot shift documents the functional status of the ACL and has been shown to correlate with patient outcome after ACL reconstruction. One has to test the pivot shift on the uninvolved or “normal” side as well as the involved side. “Negative” means there is no shift, “glide” means there is a slight slipping or rotation that occurs, “clunk” means that the femur and tibia sublux out of place, and “gross” means there is gross subluxation where the femur just drops right out behind the tibia. Note it is not uncommon for individuals with significant laxity bilaterally with 10-15 degrees of hyperextension on their normal (uninvolved) side to have a Grade 1 or slide. The reverse pivot shift also compares the uninvolved knee with the involved knee and assesses the functional status of the posterior cruciate ligament.

QUESTIONS 29 a,b; 30 a,b -- How do I assess posterolateral and posteromedial structures?
These assessments can be performed in the prone or supine position. The position used must be recorded. The key is each test is a side-to-side comparison to be made at 30 and 90 degrees for both internal and external rotation. The first step (Question 29) is for the examiner to check off the appropriate box indicating whether the examination is performed supine or prone. It is felt that most people would do this test in the supine position as this is the way the patient is lying on
the table prior to the ACL reconstructive procedure. External rotation to test the posterolateral structures will be tested at 30 and 90 degrees to try to determine if the side-to-side difference is <5 degrees, 6-10 degrees, 11-19 degrees, or >20 degrees off. Likewise to assess the posteromedial structures (Question 30) an internal rotation test is done at 30 and 90 degrees and a side-to-side comparison is made to be <5, 6-10, 11-19, or >20 degrees.

QUESTIONS 31, 32, 33 -- How do I define crepitus in the knee?
We define crepitus in tests for patellofemoral, medial compartment, and lateral compartment. We define it as “none”, “moderate”, or “severe” with severe meaning you can palpate it and it is audible (based on the IKDC classification system). Patellofemoral crepitus is defined for both the involved and the normal knee and when going to full extension from 90 degrees of flexion. The medial compartment is defined with passive motion and a varus force. The lateral compartment is assessed with passive motion and a valgus force. Thus, though most of these tests will be negative early on, at long-term follow-up these may be positive and therefore this test should be carefully conducted under anesthesia and accurately documented to see if it changes over time. The grading system is based on International Knee Documentation Committee. It should be noted that sometimes in performing a pivot shift, when there is a valgus force applied, when compressing the lateral compartment one can sometimes hear some crepitus that is occurring if they have significant meniscal or articular cartilage damage.

C. VENDOR IMPLANT/ALLOGRAFT LABELS

Why do I need to save and attach all the labels from these allografts?
This section is very important because when an implant or an allograft is placed into a patient’s knee there is a self-adhesive barcode label which includes the key information that can track that implant and label back to the supplier and the manufacturing process. There are multiple labels for each allograft or device that the nurses are required to place in the patient’s operative record. We request that all additional labels be placed on Page 8 of the Surgeon Form. By placing the implant and allograft labels here any potential effect on patient-oriented or structural outcomes can be tracked to the individual, type of implant, as well as the allograft. For example, if there was concern over a certain type of failure or infection as related to a type of allograft this could be traced directly back, not only to the allograft but also back to the gender, age, and type of donor of the allograft. This information on the types of allografts, gender, and age as related to clinical outcome failure is unknown. Likewise, specific graft fixation or meniscus implants can be evaluated. By placing the labels here in the future when programs are developed these can be scanned in and potentially analyzed. In summary, labels from all implants placed into the knee and any allografts should be placed on this page. One needs to remind the circulating nurse to save a copy of these labels for you or place them directly on this page. Perhaps by bringing the form into the OR and opening to this page your operative staff will place them directly on this page.
D. INTRAOPERATIVE Categorization of Intraarticular Injuries and Ligament Status

In pages 9 and 10 of your Surgeon Evaluation form there is a scale diagram of the Left Knee and the Right Knee. They are labeled “LEFT KNEE ARTHROSCOPY DIAGRAM” and “RIGHT KNEE ARTHROSCOPY DIAGRAM”. We request you draw all pathology and treatment on the appropriate diagram. The diagram has lateral and coronal views of the knee. The following anatomic structures are shown, including the medial collateral ligament, lateral collateral ligament, medial femoral condyle, medial tibial plateau, lateral femoral condyle, lateral tibial plateau, patella, and trochlea. In addition, they document the ACL, PCL, medial meniscus, and lateral meniscus. It is recommended that the pathology and the location of the pathology that the operating surgeon sees in the knee be documented on these forms. In particular, we request that as best as possible you scale the type of pathology onto the articular surface, meniscus, and ligaments. For example, if the MCL is torn and you know the location, then put a mark either at the femoral site, midsubstance, or tibial site. Likewise for the lateral collateral ligament. For the ACL, try to draw the tear across the ACL, whether it’s midsubstance or femoral; if the notch is tight, then try to draw the notch shape in and then try to actually estimate how you reshape the notch with the notchplasty. For articular cartilage pathology we would like you to put the location and grade of chondromalacia on the individual surface, patella, trochlea, medial femoral condyle, medial tibial plateau, lateral femoral condyle, lateral tibial plateau. Document the location in two planes for the patella and trochlea (in the central figure), for the medial femoral condyle, in the coronal figure central on the page, and then corresponding lateral location on the sagittal view. For the medial tibial plateau and lateral tibial plateau we would like you to draw this on the view of tibial plateau in the central figure with the meniscus removed on the bottom.

Now, for meniscal pathology we would like you to draw what you see as the shape of the meniscus tear and how you treated it. We would like you to consider the meniscus’ posterior half and anterior half. We would like you to consider its three zones, starting from central to peripheral. For example, the first zone would be the central zone which is avascular, the next zone being the middle zone which will approach at its most lateral extent with the peripheral third approaching some vascularity, and the third zone is peripheral. Complete meniscus tears are a solid line whereas partial tears are dashed or dotted line. Define a complete tear as extending to both the femoral and tibial surfaces of the meniscus. Thus, all radial and oblique tears are complete. But longitudinal can be incomplete (exit only femur or tibia) or complete which would extend all the way through. After a meniscus tear is drawn then one estimates the amount of resection. If resections have taken more than one-half of a compartment, for example, the central third of the posterior horn, this compartment is considered excised. If they take one-half of the central third and one-half of the middle third, then two-thirds of the posterior horn has been excised. This will help you and make it easy to fill out and understand how we quantitate meniscal pathology and treatment. For repair draw the location and number of “implants or sutures” used.
INTRAOPERATIVE DATA

General Information: There are several pieces of information we would like you to fill out.

(1) **QUESTION 1** -- What is the tourniquet time?

(2) **QUESTION 2** -- What type of documentation did you use? Video, pictures, video AND pictures?

(3) **QUESTION 3** -- Are there any loose bodies?

(4) **QUESTIONS 4 AND 5** -- Finally, we want you to assess whether there is any inflammatory arthritis and this can be categorized, or any synovitis treatment.

**QUESTIONS 6, 7, 8, and 9 -- LIGAMENTS**

**How do we define an ACL reconstruction?**
An ACL reconstruction is the act of drilling tunnels for placement of a graft for the femur or the tibia and obviously in the majority of cases, both.

**How do we define a primary ACL reconstruction?**
The primary ACL reconstruction is the first time one places tunnels into the femur and the tibia. (It is okay for the sutures to be repaired through small diameter drill tunnels as long as there is no graft inserted in these tunnels.)

**How do we define a revision ACL reconstruction?**
A revision ACL reconstruction occurs when there has been a tunnel placed with a graft in at least the tibia or the femur, and obviously in most cases it is both. If there has been a prior bone-patella-bone, hamstring, or allograft used to replace an ACL tear and you have a complete tear or stretched out graft (functional failure), this would be considered a revision ACL reconstruction.

**QUESTION 6 -- How do we define an ACL tear?**
An ACL tear would be when there are normal ligament ACL fibers that have undergone partial or complete tearing. We ask if there is a partial tear what percent of the intact fibers are functioning in their normal anatomical attachment to the femur and tibia and providing anterior restraint. Thus, if someone has had complete elastic failure of this graft with 50% of it pulled off and the other 50% stretched out like a rubber band, one would consider this a complete ACL tear. Conversely, if someone has 50% of their ACL torn such as the posterolateral section or anteromedial section with 50% of the ligament in its anatomical attachment on the femur and the tibia, one would consider this 50% intact. Note in previous situation with 50% stretched out graft the functional failure would be determined by a positive pivot shift and increased excursion on Lachman exam.

**QUESTION 7 -- What is an ACL graft tear?**
An ACL graft tear is when an autograft or allograft tissue has been placed to span the intraarticular region between the femoral and the tibial side and has at least one, usually both tunnels. The amount of relatively normal fibers that are left in their anatomic configuration are estimated. Thus, it can be complete or partial. One can have the obvious where the ACL graft being inspected is completely absent, which would be considered a complete tear. In another situation where there has been an acute traumatic event and the ACL graft has been well healed and then tears, obviously this is a complete tear. Conversely, one could have a situation where part of the graft is torn and part is stretched out, and an assessment of what part is functioning should be made analogous to % of ACL ligament intact as above.

**QUESTIONS 8 and 9 -- Why document PCL and PCL graft tear status?**
There are two reasons: (1) we want to make sure that we are not dealing with a complete PCL or PCL graft tear as this would be in a multi-ligament knee and clearly has a different outcome than a revision unilateral cruciate tear. (2) These questions have been addressed in the MOON database and are preserved for this modification of the form.

**QUESTION 10 -- How do I define and why do I define MCL tear identified arthroscopically?**

**AT THE TIME OF THE EXAM UNDER ANESTHESIA** we want the surgeon to categorize the amount of medial collateral ligament laxity. **WE DEFINE GRADE II AS LAXITY ONLY AT 20 DEGREES AND GRADE III WITH LAXITY AT ZERO DEGREES.** This is clearly defined and must be followed in the grading system outlined. Finally, we believe location of a tear might be important (at the femur, meniscal tibia, meniscal femoral, or tibia) and, therefore, we ask the surgeon to categorize this. This may be seen arthroscopically as increased separation between the meniscal tibial distance, which is clearly a sign that the meniscal tibial part of the MCL is torn; one can also find gapping between the meniscal femur. We request that the individuals fill out the best single answer OR if there is more than one site they should check off the combination listed. We recognize that in Grade II MCL tears no location may be visualized arthroscopically and since no open procedure is usually performed, please check “not localized”.

**QUESTION 11 -- How do I define LCL laxity?**

We define Grade I as no laxity under anesthesia, Grade II as laxity only at 20 degrees, and Grade III as laxity at zero degrees. We understand that when you have laxity at zero degrees that probably some other posterior corner elements have been injured as well. In the lateral complex we again want you to identify where you believe the site of failure has occurred. There are several choices given. We would like you to fill out the best possible choice. For example, we look at partial LCL, complete LCL, popliteus, posterolateral corner, complete LCL and posterolateral corner, or complete in everything—LCL and posterolateral and popliteus. Thus the choices for the lateral complex go from very mild to more severe and if none of these categories are compatible with your findings you can check off the box “other”.

**QUESTIONS 12, 13, and 14 -- ACL SURGERY**

There are three types of ACL surgery that we ask the surgeon to fill out: (1) **Question 12-- ACL Reconstruction**, (2) **Question 13—ACL Repair**, and (3) **Question 14--Revision ACL Reconstruction**. Because this form has been adopted and used by the MOON members and will continue to be used by the MOON members we ask three separate questions: (1) ACL reconstruction, “yes” or “no”. If the answer is “no” and you are a MARS member, you should not be filling out this form. If the answer is “no” and you are a MOON member, you can use this form for your own use but it should not be sent in or captured in the MOON database. We expect that, in general, meeting the inclusion criteria, this answer should be “yes”. Thus, you can ask, “Why even include this question?” This question is important because it is one of our key questions in looking at the database to make sure that every patient that we analyze has an ACL reconstruction. We also believe that these forms are available for individual sites to use in different ways; for example, someone may want to capture information on PCLs or capture information on meniscal repairs and we are happy to have these forms help individuals capture their own data to promote and advance the science and outcomes for our patients.

**QUESTION 13 -- Did you perform an ACL repair?**
We expect this answer to be “no”. However, if you did perform a repair, please indicate where it is: midsubstance, avulsion of the tibia, avulsion of femur, repair and augmentation. This question may be important in the future as other biotechnology becomes available to identify certain individuals that may warrant a repair rather than a reconstruction. Remember, this form was designed to try to be appropriate for 5 and 10 years out.

**QUESTION 14 -- What type of ACL reconstruction did you perform?**  (Please keep in mind this same form is being used for two different groups – MARS and MOON – and your next steps depend on which group you are in and how you answer this question.)

The **MOON members** that are doing primary ACL reconstructions will check “Primary” and will proceed to the next page and complete the Primary ACL Reconstruction section.

The **MARS members** should check off “Revision”. **More about QUESTION 14** – If this surgery is a revision you must answer questions about high tibial osteotomy and meniscus transplant. First, if an HTO was performed prior to today’s revision or at today’s revision surgery, check the appropriate box. Next, if a meniscus transplant was performed prior to today’s surgery or at today’s revision surgery, check the appropriate box for medial, lateral, or both. Finally, once you answer questions about HTO or meniscus transplant, then MARS participants only go to Section D. (Note: if no boxes are checked the assumption is no HTO or transplant was performed.)

**QUESTIONS 15-31 -- MOON MEMBERS ONLY who are performing PRIMARY ACL RECONSTRUCTION:** How do I define graft type and graft source?

**QUESTION 15** –
Graft type refers to the major categories, whether this is autologous tissue and therefore autograft, allogenic tissue or therefore allograft, or prosthetic. We ask you to check a single box for the most appropriate choice being used. We recognize that in the year 2007, 99% should be either autograft or allograft.

**QUESTION 16** –
Graft source is defined as the actual type of tissue being used. For example, check off bone-patellar tendon-bone if that is what you use, regardless of whether it is autograft or allograft; check off “hamstring-semitendinosis” if that is what you use; etc. Clearly, achilles tendon, tibialis anterior, and tibialis posterior can only be allografts.

**QUESTION 17 -- Why capture the number of strands of hamstring or the previous graft harvest?**
The number of strands of hamstrings, whether these hamstrings are two, three, or four construct, may be important in the outcome evaluation. For example, in a systematic review the two-stranded hamstring construct had greater laxity than bone-patellar tendon-bone but the three- and four-stranded hamstring construct did not. This would have to be evaluated in future outcomes. This is why this is important. The surgeon should fill out the number of strands that was actually used in doing that ACL reconstruction.

**QUESTION 18 --**
Previous graft harvest needs to be defined for both knees. For example, you could have an individual whose right knee you are reconstructing for the first time but they previously had a left knee ACL reconstruction where they harvested the contralateral patellar tendon. One would
therefore check that on their right knee they had a prior autologous patellar tendon so any graft that has been harvested before needs to be marked off in this checkbox.

**QUESTIONS 19-26 -- How do we define the technique of primary ACL reconstruction?**

We do this by defining exposure (Question 19) as either one-incision, two-incision, traditional arthrotomy where we violate the patella retinaculum, or a mini-arthrotomy where we operate through the patella defect or medial to the patella tendon and keep the patella retinaculum intact. Second, we define how much notchplasty (Question 20) we performed at this procedure. Third, we define the femoral position (Question 21) as being a bone tunnel, completely over-the-top situation, or a modified over-the-top situation. We next define the method to select where the femoral position is (Question 22). This is defined as freehand or by a reference guide, by an isometer x-ray, or reference probe and x-ray. Finally, we define the type of fixation (Question 23) being used to the best single answer. If this cannot be identified by the choices listed, then check “other”. We clearly want to define whether we used a bioabsorbable or non-bioabsorbable implant. For the tibial position (Questions 24-26) we go through a similar scenario. We define whether this is in the bone tunnel or we’ve modified it. We define how we achieve the tibial position and we define the type of fixation being used. Again, with the tibial fixation we want to try to check the most appropriate box but if nothing fits, you can check “other”.

**QUESTIONS 27-31 -- How do we define the postoperative rehab milestones?**

All patients undergoing primary ACL reconstruction (excluding those with meniscal repairs) should follow the MOON rehabilitation program. In addition, we would like you to categorize several things that we think are important.

**QUESTION 27**

We want you to estimate the millimeters of excursion of your graft in range of motion from zero to 90 degrees.

**QUESTION 28**

We want you to define whether an extraarticular procedure was performed. This is more of historic significance since by “extraarticular” we mean a non-anatomic tethering-type procedure on the lateral side. We expect almost no one performs this at this point. Next we ask a series of questions related to guidelines in the postoperative rehabilitation.

**QUESTION 29**

We want to know when you allow full active and passive range of motion of the knee. According to the MOON protocol this is allowed immediately in a primary ACL reconstruction without meniscal repair.

**QUESTION 30**

When is full weight-bearing allowed? In the MOON protocol this is usually established within the first week; therefore, most people would put down approximately 7 days.

**QUESTION 31 -- How long do you use a functional ACL stabilizing brace in the postoperative period?**

This means if you use a custom de-rotation brace or an off-the-shelf de-rotation brace or to protect the medial and lateral support we want to know if you use this for 30 days, 60 days, or 90 days. For example, if someone had a significant MCL injury in a primary ACL reconstruction, one may put them in a protective stabilizing brace maybe up to 8 weeks. The MOON rehabilitation protocol does not define the use of functional ACL stabilizing braces in this
category. Because meniscal repair techniques vary between inside-out (which uses suture material where early weight-bearing probably does not have an abrasive or erosive effect on the articular surface) versus other all-inside meniscal techniques have varying degrees of implants on the meniscus with some of them being rigid like an arrow (documented case reports where this can abrade on the articular surface), we could not come up with a defined weight-bearing strategy for meniscal repair. Therefore, the primary ACL reconstruction with a meniscal repair, the weight-bearing without support, range of motion, and use of a functional brace need to be clearly defined by the individual surgeon and linked carefully to the type of implant and technique being used. We feel this is in the best care of the patient. We respectively submit that if there is an implant on the surface of the meniscus in an all-inside technique one should proceed with caution about early weight-bearing. Especially in light of the reason for using meniscal repair is to preserve the articular cartilage in the long term, one should not sacrifice a few weeks of early weight-bearing to destroy the potential value of the meniscal repair to begin with.

D. MARS – REVISION ACL RECONSTRUCTION

INTRODUCTION

The intent of this section is to explain question-by-question how to interpret the question itself as well as how to appropriately check the boxes.

QUESTION 32 – What is the Revision Number and date of the last ACL Reconstruction?

We define the first time a primary ACL reconstruction fails as “one ACL revision”. Thus, if a patient had a primary ACL reconstruction fail and then had a revision ACL reconstruction fail, the number would be “two”. Thus, the revision number equates to the number of times the individual has had an ACL reconstruction REVISION. We capped this number at “five” believing that after 5 attempts, if this exists, this person probably is unique and different from the major group of patients that we would be capturing.

QUESTION 32a –

We believe time from last ACLR to revision may be important and, therefore, we want to capture the month and year even if the exact date is not known.

QUESTION 33 – What is the cause of failure?

We want to know what, in the surgeon’s opinion, was the cause of failure that brought this patient to a revision ACL reconstruction. We are trying to define this as clearly as possible. For example, we would like the surgeon to pick the most appropriate box from the choices given: Traumatic, Technical error, Biologic failure, or Infection. However, if the surgeon feels that none of these single boxes describes the cause and feels a combination is more appropriate, then check “Combination of the above” or, in some special or unique case, you might check “Other”.

“Traumatic” should be defined as a well functioning ACL reconstruction graft that has had an acute mechanism that is consistent with tearing a primary ACL reconstruction. By “technical error” we mean that the technique from the prior surgery has in some way resulted in failure. This could be fixation, tunnel placement, or inappropriate harvest of a graft. By “biologic failure” we are trying to determine the individuals where there seems to be poor healing of the graft where there is adequate tunnel placement, adequate fixation, and adequate rehab and compliance but the tissues just did not seem to heal and stretch out. Finally, if “infection” occurred after the primary or revision ACL reconstruction and is the cause of failure, in the surgeon’s opinion, this should be noted and IF THIS IS NOTED, you are finished filling out the
QUESTION 34 -- Why ask the surgeon if this is his own failure?
One hypothesis could be that fellowship-trained surgeons and members of the AOSSM that have extensive experience will probably have less technical errors and infections than the average individual. Further, by reconstructing one’s own failure, if it is truly from a traumatic cause, one could anticipate a better outcome. This question will be used to determine outcome measures, whether a surgeon revising his own failure has a better outcome than a surgeon revising someone else’s failure. If there is a difference, then we can investigate whether the etiologies of this difference such as the patient population may account for this difference.

QUESTION 35 -- How do we define Technical Failure?
The surgeon should check all the boxes that apply that, in his opinion, accounted for the failure of this ACL reconstruction. There could be one, two, or several that could apply. For example, we want to consider “tunnel malposition”, “knee malalignment” (such as an extremely varus knee), fixation failures, a problem with a poor harvest of an autograft source, a problem with a prior allograft source, or some associated soft tissue laxity. Finally, if there is some other reason that is not listed, as a last resort one should check off “other”.

QUESTION 36 -- Why document patient’s PRIOR incisions?
We want the surgeon to check all that apply, whether the incisions in the past have been used to harvest a BTB ipsilateral, contralateral, hamstrings, or whether there is an allograft tibial incision. For example, an autograft tissue on a BTB can be harvested vertically or horizontally and this should be noted appropriately. One would consider an allograft reconstruction as having a small tunnel just for the tibia. The rationale behind knowing the prior incisions is that it tells us what graft was harvested and it also gives us an idea whether there is cutaneous numbness or whether there are changes in the tibial tubercle from harvest of a BTB. For example, as documented in a previous systematic review, if you are assessing patient outcome for kneeling, if there has been a prior harvest of the BTB, there will be significantly more kneeling pain in this group than not. Thus, in evaluating kneeling pain in patients after revision ACL reconstruction, we cannot conclude they have more kneeling pain from the revision technique unless we understand whether they had a prior patellar tendon harvest from that site.

QUESTION 37 -- How do we define PRIOR Surgical Technique?
We define surgical technique as any of four different procedures: arthroscopic rear-entry two-incision, arthroscopic one-incision, traditional arthrotomy (as defined as the patella dislocated out of the groove), and mini-arthrotomy (meaning that you have operated through the patellar defect if through PT autograft harvest or on the medial and lateral side of the patella but you have kept the patellar retinaculum intact and not dislocated it out of the groove).

QUESTION 38 -- How do we define PRIOR ACL tunnel technique?
We want to define whether this is a single or double tunnel. This will enable us to track failure rates separately from a one-tunnel technique versus a double-tunnel technique.

QUESTION 39 -- How do we define visualization of failed ACL graft?
We want to know, in the surgeon’s opinion at the time of arthroscopy, how the prior ACL graft appears. If it is absent, we want this noted. If the graft is present but elongated, this should be noted as well. If the majority of it is torn but the graft is present indicating some healing, then this box should be checked. The rationale behind this question is if the graft is completely absent or if it is elongated in the setting of having poor function, one could suppose that there could be a
biologic healing problem with this graft. If one has the majority of the ACL graft that is well
healed, well vascularized and is torn, one would suspect that if the patient is functioning well
there was a traumatic episode. The outcomes of these two entities may be different and this
revision ACL reconstruction prospective cohort can define whether the outcomes are linked to
ACLR graft.

QUESTION 40 -- How do we define PRIOR ACL graft type?
When defining prior ACL graft type there are basically three different types used. One is
autologous tissue or autograft, the second is allograft or allogenic tissue, and the third is
prosthetic. We want to determine if this is autograft, allograft, or prosthetic and if there is a
combination of autograft and allograft or a combination of auto- or allograft with prosthetic.

QUESTION 41 -- What do we mean by PRIOR graft source?
The source of the prior graft should be verified by the surgeon either by the surgical incisions on
the patient or the operative report. We want to define whether there was a bone-tendon-bone,
quadriiceps and patella bone taken, hamstring, or whether the allografts were achilles tendon,
tibialis anterior, or tibialis posterior. We prefer that the surgeon not check the box “Unknown”
unless there is NO way to find out the prior ACL graft. This is strongly discouraged. Finally, if
there is some unique graft used that is not listed the surgeon can check “Other”.

QUESTION 42 -- How do we define prior number of hamstring strands?
First, we would like to know from the surgeon’s review of the previous operative note the number
of strands in the hamstring construct to be filled out. If it is unknown then check “unknown”.
This may be important since in a prior systematic review of nine randomized trials of autograft
patellar tendon versus hamstring, the earlier two-stranded hamstring constructs had a greater
degree of anterior-posterior laxity than bone-tendon-bone whereas the three- to four-stranded
hamstring constructs in a later technique did not have any differences in anterior laxity. Thus, we
would like to capture this information if possible.

QUESTION 43 -- How do we define Previous Graft Harvest?
First, if there is no previous graft harvest check the box “none”. If there is previous harvest we
want to know if it is in the involved or the uninvolved knee and whether this is the patellar
tendon, hamstring, or quadriiceps. This question is important because we know from previous
work that one of the unique differences of these autograft choices was that kneeling pain was
more frequent in all the studies that evaluated excision of the tibial tubercle with a bone-tendon-
bone. Thus, if one were to evaluate revision ACL reconstruction for kneeling pain one would
have to know about the previous surgery to compare.

QUESTION 44 -- How do we define Cutaneous Numbness?
We would like to know whether the patient has an area of numbness either that is directly in
front, anterior, on the lateral side, on the medial side, or has none. This should be obvious based
upon whether there are large lateral incisions, medial incisions, or anterior incisions such as with
B-T-B.

QUESTION 45 -- How do we define CURRENT Surgical Exposure and Technique?
Just as we defined the prior exposure we are now defining current surgical exposure in the same
manner. This is a two-incision, one-incision, traditional arthrotomy, or mini-arthrotomy
technique. This may be important because revision of a two-incision by an endoscopic procedure
or revision of an endoscopic by a two-incision may be different than revising the prior surgical
technique with the same surgical technique being used. We divide endoscopic by how the
femoral tunnel is drilled, either transtibial or anteromedial portal.

Revised 2/16/2007 (NIAMS Format 6/05/02)
QUESTION 46 -- How do we define CURRENT Notchplasty?
What we want to do is to define the amount of bone that you have resected in the intercondylar area. Since it would be nearly impossible to accurately assess what the prior notchplasty was, we want you to define how much bone you currently remove. Thus, if there are osteophytes within the notch and you remove less than 5 mm we consider this small, if you remove 5 to 10 mm we consider this moderate, and large would be considered greater than 10 mm. Ideally one would be able to define where the normal notch was and how much you removed; however, we feel this is impossible to define accurately so the amount of bone you remove from the notch at this point should be considered the current notchplasty.

QUESTION 47 -- How do we define PRIOR Femoral Fixation?
In this question we want as accurately as possible to determine what the prior fixation was, particularly in reference to bioabsorbable versus nonabsorbable, to whether it was an interference screw, endobutton, suture to post, staple, or cross pin. You are allowed to check all boxes that apply and if none apply then you should check “other”. We would anticipate and encourage you to find the single best box and check this off. For example, if an interference screw was used, one would either check off the “interference screw – metal” or “interference screw – bioabsorbable”.

QUESTION 48 -- How do we define PRIOR Femoral Tunnel position?
We wish to describe three aspects of femoral tunnels. First, position is the anterior-posterior and the vertical vs horizontal position of the tunnel aperture. This can be ideal or compromised by position (either AP or vertical-horizontal) in the surgeon’s opinion. Next, consider the aperture (opening into the knee) of the femoral tunnel. This can be classified as in size of opening as either “ideal” or “enlarged”. Finally, the last consideration is the size of extraarticular surface or tunnel in femoral condyle – either “normal” or “enlarged”. In this question we classify as one of five categories:
(1) Ideal (both position and size of tunnel aperture) and the extraarticular tunnel is normal in the femoral condyle.
(2) Ideal (both position and size of tunnel aperture) but compromised as tunnel is enlarged in the femoral condyle.
The next three classification systems involve a compromised position of tunnel aperture.
(3) Compromised due to position – check this box if it is compromised ONLY due to position, either to vertical or to anterior.
(4) Enlarged – check this box if due ONLY to tunnel aperture size.
(5) Compromised due to BOTH position and size – check this box.

QUESTION 48a – How do we define the method used for the CURRENT femoral tunnel?
Check “dilation” when any form of dilation is used along with drilling. If no dilation is used, check “drilling”.

QUESTION 49 -- How do we define the CURRENT Tunnel Position after Drilling?
Just as we categorized the femoral tunnel in Question 48, we are concerned with the femoral tunnel aperture at the knee in terms of position (both AP and vertical vs horizontal) and size. Thus, a “same tunnel” means no enlargement or abnormal shape of the femoral tunnel aperture. If this is in the ideal position, check “optimal position”. If you use the same tunnel but it is compromised in AP, then check “compromised” and then check how many millimeters, in your opinion, the tunnel is off in the AP plane only.

QUESTION 50 -- How do we define CURRENT use of Femoral Tunnel Bone Graft?
We want the surgeon to define whether the femoral tunnel has been bone grafted at this procedure (“Yes”) or whether this has been staged prior to the current procedure (“Staged”), or whether none has been performed (“None”).

**QUESTION 51 – How do we define Bone Quality of Femur?**
We want the surgeon to define whether he thinks the bone quality is normal for an individual based upon that age and activity level or whether he thinks the bone quality is abnormal (i.e. soft). The surgeon must choose between these two descriptions.

**QUESTION 52 – How do we define CURRENT Femoral Fixation?**
We want the individual to check the most appropriate single box if possible. However, if more than one box needs to be checked to be accurate this is also appropriate.

**QUESTION 53 – How do we define PRIOR Tibial Fixation?**
This is analogous to defining prior femoral fixation with the addition of the “Intrafix” system which can be bioabsorbable or metal. If none of the choices is exactly accurate then “other” may be checked. Again, we would prefer that the surgeon check what he believes to be the prior tibial fixation is, either verified from the operative note or based on his experience in the OR, and we prefer that he check one box if appropriate.

**QUESTION 54 – How do we define PRIOR Tibial Tunnel Position at revision?**
As with the femur we want to determine if the position is ideal -- meaning in the location the surgeon would prefer if this was a primary ACLR and if it is ideal whether it is normal or enlarged. Similarly, if the tunnel position is compromised we want to know if this is due to position or size or both. If it is due to position, then divide by medial-lateral versus anterior-posterior.

**QUESTION 55 – How do we define CURRENT Tibial Tunnel Method?**
We want the surgeon to indicate whether he drilled it or did some dilatation. Thus, if someone did drilling and dilatation we would expect them to check off “dilatation”. “Drilling” is for a situation where ONLY drilling is done.

**QUESTION 56 – How do we define CURRENT Tibial Tunnel Position after drilling?**
As with the femur the best single box should be marked. We define the same tunnel as being the opening or aperture as it exits into the articular region of the knee. For example, an entirely new tunnel should have no overlap as it exits to the knee itself. Thus, if one were to drill a tunnel in a different starting position but the end position came out the same in the knee one would consider this “same tunnel, optimum position”. However, if one had a different starting point and the tunnel exited out and enlarged the prior tunnel one would consider this a “blended new tunnel”. For an “entirely new tunnel” this would mean that the exit point at the knee would be totally separate from the prior tunnel.

**QUESTION 57 – How do we define CURRENT Tibial Bone Graft?**
As with the femur we want to know if tibial bone graft was used at the current procedure, if it had been staged before, or none.

**QUESTION 58 – How do we define Tibial Bone Quality?**
We define tibial bone quality dichotomously between “normal” and “abnormal”. We want the surgeon to base this on prior patients of similar age and demographics.

**QUESTION 59 – How do we define CURRENT Tibial Fixation?**
We define this similarly to the femur fixation. Though the surgeon can check more than one box, we prefer that the single most appropriate box be checked when possible. The new addition for tibial fixation is obviously the Intrafix system that is bioabsorbable or metal. One can also check “Other” and appropriately define it.

QUESTION 60 – How do we define CURRENT Graft Type?
We want the surgeon to check off whether it is autograft, allograft, both, or prosthetic.

QUESTION 61 – How do we define CURRENT Graft Source?
We want the surgeon to be specific as to exactly what was the graft source.

QUESTION 61a – How do we define CURRENT Hamstring Source and Number of Strands?
If a hamstring construct has been used, either autograft or allograft, we want to know the number of strands in the final construct that is replacing the ACL graft.

QUESTION 62 – How do we define Pre-graft Tension?
We want to know whether there has been pre-graft tension applied. Answer either “yes” or “no”.

QUESTION 63 – How do we define Biologic Enhancement?
This requires either a “yes” or “no” answer. For example, one could place specific growth factors and/or autologous sources of platelets and we would like this described.

QUESTION 63a – How do we define the Location of Biologic Enhancement?
The surgeon should check all that apply.

QUESTION 64 – How do we define Graft Excursion of our ACL Revision Construct?
We define this as the number of millimeters that we feel the graft moves from full flexion to full extension.

QUESTION 65 – How do we define the Knee Position at the Time of Graft Fixation?
We want to know the degrees of hyperextension or the degrees short of extension that one applies the fixation. For example, if one applies the graft fixation in 5 degrees of hyperextension the box labeled “Positive # (Hyper-extension)” would be filled in as “05”. If one applies the graft fixation at zero degrees or neutral they would put a zero in the box labeled “Extension”. If one applies the graft fixation at 20 degrees of flexion one would put “20” in the box labeled “Extension”.

QUESTION 66 – How do we define Tension on Graft at Time of Fixation?
We want the surgeon to indicate whether manual tension is applied or if it is measured. If it is measured we want to know by what and the amount.

QUESTIONS 67 and 68 – Have we performed additional Collateral (MCL/LCL) or Posteromedial or Posterolateral Surgery? (Questions 67, 67a, 68, and 68a)
We want to define whether an MCL or posteromedial repair or reconstruction is performed. This requires a “yes” or “no” answer and the general type of repair or reconstruction as listed. Then the surgeon should indicate whether or not an LCL or posterolateral repair or reconstruction is performed and the general type of repair or reconstruction as listed.

QUESTIONS 69-74 – How do we define the Rehabilitation that is anticipated for this patient?
We expect the surgeon at the time of the ACL reconstruction to predict the major milestones that will guide this patient’s rehabilitation. These include passive range of motion, active range of motion, full weight-bearing, motion control bracing, use of an ACL de-rotation brace, and the rehab process or return to sport.

QUESTION 69 -- Do you restrict postop range of motion?
Yes or No

QUESTION 69a –
If “yes”, when do you restrict postop range of motion when do you allow full range of motion (in days)?

QUESTION 70 -- Do you restrict active range of motion postop?
Yes or No

QUESTION 70a –
If “yes”, when do you restrict active range of motion postop and when do you allow full active range of motion (in days)?

QUESTION 71 – Now, describe the full weight-bearing status without crutches or support in the postoperative period. Do you restrict this?
Yes or No

QUESTION 71a -- If you do restrict this, when do you allow full weight-bearing without support?
Using a motion control brace or immobilizer is NOT considered the use of support. What we mean by support is aids in ambulation such as single or double crutches, canes, or walkers. So we want to know when full weight-bearing occurs without the use of these aids (in days).

QUESTION 72 -- We want to know whether a motion control brace, either a double upright with hinges, or a knee immobilizer is used in the postoperative setting.
Yes or No

QUESTION 72a –
If “yes”, how long do you prescribe the motion control brace to be used?

QUESTION 73 -- The final questions in this section concern the use of an off-the-shelf or custom ACL de-rotation brace in the postoperative rehab. Do you use it?
Yes or No

QUESTION 73a –
If “yes”, how long do you use it?

QUESTION 74 -- We ask this question in evaluating return to sport after the rehab is complete. Do you use it?
Yes or No

QUESTION 74a –
If “yes”, how long do you use it?
MEDIAL AND LATERAL MENISCUS SURGERY (See Diagram, next page)

**General Introduction:** When documenting intraarticular pathology like meniscus and articular cartilage injuries and treatment, you only need to mark positive or “Yes” answers, since the database defaults to “No” or “Normal” when a box isn’t checked. Thus, you should focus on documenting the present intraarticular injuries and treatment for meniscus and articular cartilage.

**QUESTION 75a – Does the patient have a meniscal tear or prior meniscus surgery (see Question 85)?**

Yes or No

In the meniscus section we are trying to define whether a medial or lateral meniscus tear occurred, whether this is partial or complete, whether this is treated or untreated, and if treated, how it is treated, either repair or excision, and define the extent of repair. We also ask the surgeon to estimate if prior excision has been performed. Since meniscal pathology is presumed to be a highly significant variable on long-term outcomes, particularly as it relates to development of post-injury osteoarthritis, the categorization of this pathology is believed to be crucial. We suggest that the surgeon draw out the meniscal pathology on the figures for left knee and right knee showing what procedure was performed, whether it was a repair or excision, and this will make the completion of this section easier. IT SHOULD BE NOTED THAT INTRATER AGREEMENT STUDIES PUBLISHED BY DUNN IN AJSM (2004) SHOW EXCELLENT AGREEMENT ON THE MOST IMPORTANT VARIABLES WHEN DEFINING MENISCAL TEAR, WITH THE HIGHEST AGREEMENT FOR TREATMENT.

**QUESTION 75b -- How do we define Partial versus Complete?**

By partial versus complete we are talking about longitudinal tears. For example, in a tear that only exits through the femoral side of the meniscus and not through the tibial side one would consider this a partial tear. Likewise, as is common on the lateral meniscus after an ACL tear, you can have injury to the tibial side and not exit through the femoral side. When the tear in a longitudinal direction exits the femoral and the tibial side it is considered a complete tear.

**What do we mean by Longitudinal Tear?**

A longitudinal tear means that the tear direction is parallel with the circumferential peripheral fibers of the meniscus.

**QUESTION 76a, b -- How do we define Location?**

We define location based upon the diagram. We determine location in two ways. (1) Is it in the anterior half, posterior half, or both? (2) We define it in terms of its blood supply, whether this is central or peripheral. So we describe three zones: the peripheral third, the middle third, and the central third and therefore tears can cross this in several directions. For example, a radial tear can be central or can extend central-middle or can extend central-middle-peripheral. A longitudinal tear can be located in purely the middle third, the peripheral third, or in both thirds depending upon the direction of the tear. For example, a bucket handle tear can be located entirely within the middle third and these are usually excised because they are in the white-white zone without blood supply, or a longitudinal tear could be in the peripheral third in an area that has blood supply and these will commonly be repaired because of the blood supply and the potential to heal.
MOP: MENISCUS DRAWING
QUESTION 77 -- How do we define Tear Type?

We define tear type with the following specifications:

“Radial” means directly perpendicular to the circumferential fibers.

“Oblique” are flap tears which means that it is not longitudinal which means parallel to the circumferential fibers, and not perpendicular which is radial but in between those dimensions.

“Longitudinal – vertical” from the femoral down to the tibial side; these are parallel to the circumferential fibers. Thus, longitudinal tears that are relatively small can be stable or unstable. Large longitudinal tears involving the anterior and posterior horn are commonly called bucket handle tears if they can be displaced.

“Bucket handle – displaced” – Large longitudinal tears that can be easily displaced. For example, a patient presents with a bucket handle tear that can be displaced completely. Thus, if a longitudinal tear is found to be locking the knee either currently or in the past it should be classified as “bucket handle – displaced”. If one presents with a knee with a large longitudinal tear and this tear can be brought forward with a probe such that it can displace to lock the knee this is considered a bucket handle tear as well.

“Horizontal” tears can be degenerative and can be categorized and there are tears that are complex and cannot be categorized.

QUESTION 78 -- How do we define Length?

The measurement of length is really only relevant for radial, oblique, longitudinal, bucket handle, and possibly horizontal tears. Not all dimensions can be classified as millimeters. Thus, if we have a complex tear in the question above, whatever length measurement will be discounted and defaulted since this cannot be defined. We would like you to estimate within the nearest 5 mm or if possible to the nearest 1 mm how large you think the tear is.

QUESTION 79 -- Why do we define Degenerative Component?

We want to determine whether there are multiple cleavage planes or destruction of the tissue because this tear may have a less capacity to heal if you repaired it or maybe a worse prognosis for outcome. Thus, we want to surgeon to answer based on his view of the meniscus.

QUESTION 80 -- How do we define Treatment?

As shown in the published inter-rater agreement study the highest agreement among surgeons is reflected in how they would treat the meniscal tear. In the choices given “Excision” means a portion has been removed. “Repair” means you have placed some supporting device across the tear to heal it. “Abrate and trephine” means that you have not placed a mechanical device across it but you have stimulated the tear site of the meniscus to heal.

QUESTIONS 81 a, b, c, and d -- How do we Quantify Extent of Current Excision?

Obviously, Question 81 only has relevance if you have checked off “Excision” in the treatment question (Question 80) above. If you have checked any of the other choices, these questions will automatically default to “N/A”. If you checked “Excision” you MUST continue on with the following questions.

QUESTION 81a –

By using the diagram in the front of this section and drawing the tear based on its anatomic location and the amount of excised tissue, if any single compartment has over 50% of that meniscus removed it is considered “Excised”. Thus, you can define it by the posterior and anterior compartments. There are three compartments for the posterior half and three for the anterior half (central, middle, and peripheral). If you have excised only the central third
compartment in the posterior horn it is 33%, if you have excised two portions (central and middle) it is 67%, and if you have excised the entire meniscus it is obviously 100%.

QUESTION 81b –
The anterior compartment is measured and recorded in the same manner.

QUESTION 81c –
Next, we want to define the remaining meniscus tissue that is left behind. Please check the single most appropriate box.

QUESTION 81d –
Finally, we want the surgeon to make the distinction whether the circumferential fibers are intact or disrupted. What we mean by this is: in the peripheral third there are fibers of collagen that run in line with the peripheral border of the meniscus. These preserve the hoop stresses in the function of the meniscus, like a band around a wooden barrel. Check the appropriate box.

QUESTION 82 -- How do we capture the Current Meniscus Repair technique?  
This section is only to be completed if Meniscus Repair was checked in Question 80. Which technique did you use from the choices given (Question 82)?

QUESTION 83 -- What type of suture (absorbable or nonabsorbable) and/or what type of stint did you use (please write in the name of the stint)?
We define sutures as Ethibond, Tycron, PDS, or other. If you are using some implant we would classify this as “Stint absorbable”. We are also going to capture this implant information by placing the vendor label in the vendor label section. Consider any technique of meniscus repair in addition to suture as implant.

QUESTION 84 – Fill in the number of sutures used or the number of implants used.

QUESTION 85 –
Then answer whether or not, in your opinion, prior meniscus surgery has been performed. This means prior to current operation time (at earlier date). This information should be found in the previous op note but we mainly want to know what the surgeon sees at the time of this current surgery.

QUESTION 86a, b –
Based upon the surgeon’s evaluation at the time of this current surgery, please categorize the previous meniscal surgery using the same system as we used previously in the meniscus excision section. Please indicate whether one-third, two-thirds, or the entire posterior horn of the meniscus is gone. Then likewise indicate for the anterior meniscus.

This captures the first tear in the medial meniscus. If there is a second tear this can be captured in Section L.

F. LATERAL MENISCUS TEAR #1 (QUESTIONS 87-99)

QUESTION 87a, b – Does this patient have a lateral meniscus tear or prior meniscus surgery?
Yes or No
If “yes”, check the box and determine if the tear is “partial” or “complete”.

Revised 2/16/2007 (NIAMS Format 6/05/02) O-24
If “no”, proceed to Section G.

**QUESTION 88** –
Determine the location of the tear just as with a medial meniscus tear (Anterior vs Posterior and Central vs Peripheral). The lateral meniscus is categorized as was the medial meniscus PLUS one additional question. This regards location (next question).

**QUESTION 89 -- Is the tear central or adjacent to the popliteal hiatus?**
Answer simply “yes” or “no”. There is a variable size popliteal hiatus which is a watershed area for blood supply. If one draws a perpendicular line from the peripheral margin of the meniscus from the extent of that hiatus completely forward centrally from the most posterior extent of the hiatus to the most anterior extent any meniscal tear that occurs into that zone should be classified as “yes”; otherwise it would be “no”.

**QUESTIONS 90-97 --**
These questions are answered in an identical manner to Questions 77-84 in the section on Medial Meniscus Tear #1.

For a SECOND tear of the Lateral Meniscus see Section M (Questions 161-171).

For a SECOND tear of the Medial Meniscus see Section L (Questions 150-160).

The second tear of the medial meniscus and the lateral meniscus, which rarely occurs, is captured in another series of questions at the end of the articular cartilage injury section. See Section L (Medial Meniscus) and Section M (Lateral Meniscus). By “second tear” we mean, for example, an individual has, let’s say, a radial tear in the anterior horn on the lateral meniscus and a partial tear in the posterior horn. This would be two tears and should be appropriately labeled as such. One would anticipate labeling the most clinically significant tear as #1 and the least clinically significant tear as #2. Or on the medial side one could have a bucket handle tear in the peripheral third as tear #1 and a 5 mm radial component in the central third as tear #2. Thus, one could do a repair in tear #1 and do an excision in tear #2.

**QUESTIONS 160 and 171 --** The one question that is unique when comparing a second medial meniscus tear or a second lateral meniscus tear is “Was previous meniscus surgery performed prior to this date?” When referring to previous meniscus surgery this does not refer to tear #1 of the medial or the lateral side; this refers to a tear at a completely different surgical setting, thus a previous operation and an earlier time.
CATEGORIZING ARTICULAR CARTILAGE INJURY TO THE FEMORAL CONDYLES, TIBIAL PLATEAUS, AND PATELLAR TROCHELEAR REGIONS

In this category we want the surgeon to document the pathology on the arthroscopy diagrams that precede this section AND on the femoral condyle figures (Section G) for the patella (Section J), and for the trochlea (Section K) we ask that you also document on the scannable diagrams in each section for the appropriate side.

G. FEMORAL CONDYLE ARTICULAR LESIONS (QUESTIONS 100 – 121)

In each section on the femoral condyle we want the surgeon to place the worst grade by the number (1, 2, 3, or 4) based on a Modified Outerbridge Scale. DO NOT USE ROMAN NUMERALS ON THE DIAGRAM. We expect the worst grade to be placed in each box according to the following categories:

1 = Grade I (normal) – place a “1” in the box
2 = Grade II (fissures, superficial changes <50%) – place a “2” in the box
3 = Grade III (fragmentation, deep changes >50%) – place a “3” in the box
4 = Grade IV (bone) – place a “4” in the box

You are referred to the inter-rater agreement article by Marx in AJSM (2005). We want the individual specifically to categorize the location and the size of the worst grade.

QUESTIONS 101 a and b -- Where is the lesion weight-bearing?
Please say where the articular cartilage lesion is located at zero, 45, or 90 degrees. For example, an extremely large lesion that is on the complete surface of the condyle would be at zero, 45, and 90 degrees. A moderate lesion could be at 45 or 90 degrees and a small lesion would be either 45 or 90. Check ALL THAT APPLY.

For the condyles there are identical questions for the medial and the lateral femoral condyle.

QUESTION 102 -- Is an Articular Lesion present?
“Yes” or “No”
If the answer is “No” the rest of the questions in this section will default to zero and you can go straight to the next section. If the answer is “Yes” you must continue and answer the remaining questions in the section or they will be missing data points.

QUESTION 103 -- If there is a lesion present is the chondromalacia degenerative or traumatic?
Answer EACH choice “Yes” or “No”. For example, someone could have some degenerative changes on the extension surface of the lateral femoral condyle but have an acute bone bruise and articular cartilage injury superimposed on that. Thus, that person could have degenerative AND acute. In general, it will usually be one or the other but this is clarified by answering appropriately for both choices. Again these lesions are classified as Grades I-IV by number as previously described.

QUESTIONS 104-106 –
When assessing the size we want to do this in two ways. (1) Use a standardized probe for which we want the largest extent of the lesion being classified. If it is Grade IV the largest extent of Grade IV only, not to include Grades II and III in the length as well as the width. (2) We want to classify this as an estimate of whether the width is from medial to lateral 25, 50, 75, or 100%, and
MOP: ARTICULAR CARTILAGE DRAWING
finally we want to determine if this lesion how many degrees on the flexion surface does it contain. Thus, if a lesion is on the entire condyle from zero to 90 that would be 90 degrees. If this lesion is only present from the 30-60 it would be 30 degrees. REMEMBER: please draw all the pathology and chondromalacia grades but numerically score on the worst grade.

TREATMENT

QUESTION 107 –
Next we want to classify what treatment has happened to the chondromalacia. We define any debridement with a mechanical device as a “chondroplasty”, any debridement that creates bleeding as an “abrasion arthroplasty”, any drilling or microfracture as “microfracture”, any type of use of thermal device as “thermal”, and any others (“mosaicplasty”, “cell Rx”, or “allograft”) are also noted.

ARTICULAR FRACTURES

QUESTIONS 108 and 109 –
Next we want to know if any articular fractures which are linear cracks that can run from medial to lateral or anterior to posterior are present. Answer “Yes” or “No”. If they are present we want to know the number of cracks (#109) and the length in the longest dimension (#109b).

QUESTIONS 110 and 111 –
Finally, we want to know the orientation of crack (#110), whether it is “Coronal (medial to lateral)” or “Sagittal (anterior to posterior)” and then (#111) we want to know the treatment for this articular cartilage fracture from the choices given.

QUESTIONS 112-121 –
For the Medial Femoral Condyle there is exactly the same sequence of questions. For example, in the medial femoral condyle it is not uncommon to have horizontal cracks that run from medial to lateral along the flexion surface that are consistent with an unstable ACL-deficient knee that has had subluxation episodes as well as a history of locking of its meniscus. One would classify this as:

Fractures? Yes
Number of fractures
Length of the longest fracture from medial to lateral
Orientation: Medial to Lateral
Treatment, if any was performed

QUESTIONS 122-139 -- Tibial Plateaus (Lateral and Medial)
The extent of the lesions on the tibial plateaus for lateral medial side should be defined on the large knee arthroscopy diagram previously. One needs to decide again whether or not there is a lesion present, whether it is “degenerative” or “acute”, and check the appropriate grade. Then determine the size: we have divided the distance into quartiles; we want to determine the medial to lateral dimension and the anterior to posterior dimension. Again, the treatment choices are the same as for the femoral condyles. We want to look at whether there are articular cartilage fractures, the number of fractures, and their length. There is one unique aspect – the orientation of the fracture. There is a certain articular cartilage fracture in the lateral tibial plateau that outlines the inner meniscus contour. If this is present, please check this box. Then record the appropriate treatment.
The medial tibial plateau is analogous to the lateral tibial plateau.

**QUESTIONS 140-144 -- Patellar – Articular Lesions**
First, we determine whether or not there is an articular lesion present. Then we determine if the chondromalacia of the patella is degenerative or acute and then we grade with numbers only (1-4) for Grade I to Grade IV. Next, we determine treatment and whether or not there are articular cartilage fractures. We find it very helpful if one can place a number in the right or left patella based upon its location (proximal, middle, distal and lateral, central, medial) and this will give us some idea of the size and grade of the lesion and will be very helpful. We would like this box to be filled out in every patient for the right and the left knee.

**QUESTIONS 145-149 -- Trochlear – Articular Lesions**
We will define the trochlea as the region between the zero degree mark on the condyle and its most proximal extent up to the femur. We will define this into a proximal, middle, distal and lateral, central, and medial. Again, there is a diagram present. We need this filled out on every knee. There is a right knee and a left knee. We would like the worst grade to be filled out. For example, it is okay to fill out the central defect that is “4” and a medial defect that is “2” on this category. However, in Questions 146 and 147 you are going to grade only the worst grade. Let’s say you are operating on a right ACL reconstruction and there is a Grade IV defect that is in the mid-central region; however, when you look over at the more medial region this is a Grade II. You would put “4” in the central-medial box, “2” in the middle-medial box. However, when grading the questions above (#146) you would check the box for the worst lesion (Grade IV). Therefore, though we define degree of all the articular cartilage injury present, we only numerically capture, classify, and treat the worst grade.
5. Submitting, Quality Control Check, and Retention

a. Submission of forms: Performance site is required to verify the following:
   i. Patient questionnaire
      • Date of birth
      • Date of surgery
      • Today’s date
      • Patient’s age
      • Which knee (left, right, or both)
   ii. Surgeon form
      • Surgeon’s initials
      • Patient’s initials
      • Date of surgery
      • Patient’s date of birth
      • Reconstruction type (Primary—MOON; Revision—MARS)
      • Operated side (left, right, or bilateral)
   iii. Match patient questionnaire with appropriate surgeon form
      • Unique ID # match
      • Match all three secondary key variables – date of surgery, date of birth, which knee

b. Performing Quality Control Check
   i. Vanderbilt site verifies Patient Questionnaire and Surgeon Form match by ID # and three secondary key variables (date of surgery, date of birth, which knee)
   ii. Biannual random self-checks by each site

c. Retention of Study Documentation -- All forms will be maintained for twenty years.

6. Scientific Background and Publications

a. Scientific Background
   Please see Study Protocol sections: Background, Rationale and Specific Aims, Primary and Secondary Endpoints, Previous Human Studies, Inclusion/Exclusion Criteria, Study Procedures, and Statistical Considerations.

b. Publications


c. Major Presentations

Incidence of Recurrent ACL Disruption: Level 1 Evidence from a Prospective Cohort. Presented by Christopher C. Kaeding, MD, at the Annual Meeting of the AOSSM, Hershey, PA, 2006.
Q. MARS Good Clinical Practice

1. Standard Operating Procedures at Each Site
   
   a. Surgeon compliance must average >90% patients consented for Revision ACLR. This will be monitored annually.
   
   b. Surgeon/site responsible for completeness of patient questionnaire by individual specific validated outcome tool and surgeon documentation. This will be monitored and reported on an annual basis.
   
   c. Two-year follow-up for each surgeon/site must be >80% on average. This will be monitored and reported annually.
   
   d. All research personnel must complete and maintain IRB documentation which will be monitored annually.
   
   e. The MARS Research Team will meet annually to review data acquisition, presentations, publications, and update the Manual of Operating Procedures.
   
   f. Publications are reviewed on an ongoing basis for scientific content and authorship.

2. Monitoring by Coordinating Center (Vanderbilt)

Each site will have at least an annual visit throughout the course of the study. There will be additional visits when necessary, dependent on each site’s performance and the number of participants enrolled. The purpose of monitoring visits is to:

- Assure the rights and safety of participants
- Confirm that study conduct follows the guidelines of Good Clinical Practice
- Assure maintenance of required documents
- Verify adherence to the MARS Revision ACLR MOP and Study Protocol
- Monitor the quality of data collected
- Assure accurate reporting and documentation of all Adverse Events

During the monitoring visits, the data recorded on the Patient Questionnaire and Surgeon’s Forms are reviewed and verified against source documents to assure:

- Informed consent has been obtained and documented in accordance with FDA regulations and individual institution’s IRB
- The information recorded on the forms is complete and accurate
- There are no omissions in the reports of specific data elements
- Missing examinations are indicated on the forms
- Participant disposition when exiting the study is accurately recorded
R. MARS Reports

Since the MARS Revision ACLR cohort is non-interventional the Coordinating Center (Vanderbilt) will produce the following reports on an annual basis. Note the only risk to patients is confidentiality and/or violation of the consent process. By definition of the study design (prospective longitudinal cohort) no adverse events are related to the research.

Vanderbilt will produce the following reports annually:

- Screening and enrollment logs for all sites
- Patients refusing participation
- Two-year follow-up percentage with breakdown of lost to follow-up
- Adverse events
- Surgeon compliance, completeness of forms, demographics of patient population
- Any presentations and publications resulting from the study