Protocol Title:	**ROCK Osteochondritis Dissecans of the Knee – Cohort of patients with confirmed diagnosis.**
Principal Investigator: (Study Doctor)	**James L. Carey, MD** University Of Pennsylvania Department of Orthopaedic Surgery Weightman Hall, 235 S. 33rd St., 1st Fl. Philadelphia, Pa 19104 **(215) 615-4400**
Emergency Contact:	Ask For The Orthopaedic Surgery Resident On Call **215 406-6525**
Subject Initials:	_____--_____--_____ First Middle Last
Sex/Age	☐ **Male** ☐ **Female Date of Birth or Age today_____**
Subject number	_____

Why am I being asked to volunteer?

You or your child are/is being invited to participate in a research study because your doctor has determined that you have/your child has osteochondritis dissecans or focal articular cartilage defects of the knee. We will refer to these conditions as 'OCD' in the rest of this document. Your participation is voluntary which means you can choose whether or not you want to participate. If you choose not to participate, there will be no loss of benefits to which you are otherwise entitled. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. The research team is going to talk to you about the research study, and they will give you this consent form to read. You may also decide to discuss it with your family, friends, or family doctor. You may find some of the medical language difficult to understand. Please ask the study doctor and/or the research team about this form. If you decide to participate, you will be asked to sign this form.

What is the purpose of this research study?

We are inviting you to participate in this research study because you are/your child has been diagnosed with OCD of the knee. The purpose of this research study is to obtain longterm follow-up information in order to learn about how people do over time after undergoing surgical or non-surgical treatment for OCD, including the return to activities, pain, and

additional treatment or surgery. This study is being conducted by the Research in OsteoChondritis of the Knee (ROCK) group, which is an organization of surgeons at institutions around the United States and internationally who are working together to improve patient care through research.

How long will I be in the study?

If you agree to take part in this study, your direct involvement will last for the amount of time needed to complete a series of short questionnaires at five separate times, approximately 15-20 minutes for each time. You will be asked to complete these questionnaires once at your initial visit, and then at regularly scheduled clinic visits at two, five, ten, and twenty-five years after the initial questionnaire. If you're unable to come back to clinic for follow-up at these time points, surveys will be emailed/mailed to you. If you have a clinic visit scheduled in between time points, you will be asked to complete the surveys at that time. You will not, however, be asked to complete them any more frequently than 12 week intervals.

How many other people will be in the study?

Approximately 300 people will take part in this study at Penn. Approximately 3,000 subjects are expected to participate in this study nationwide. It will take about 50 years to complete the entire study.

What am I being asked to do?

You will be asked to complete questionnaires regarding your knee OCD and its effect on your daily activities. Questions focus on function, symptoms, and overall quality of life. We will also ask you to provide contact information for someone else who may help us to locate you in the future if we are not able to contact you. Any questions that you would prefer not to answer may be skipped. You will complete the first questionnaire at your initial appointment here at Penn Orthopaedics.

You will also be asked to complete the questionnaires at two years, five years, ten years, and twenty-five years after you start treatment. If you cannot make it back to clinic, these questionnaires will be emailed/mailed to you from Penn Orthopaedics and can be answered online or returned in the postage-paid envelope provided. Study staff from Penn Orthopaedics will also contact you by telephone and/or email before the questionnaire is mailed to confirm your address and to ask about any additional surgeries or interventions you may have had.

Your physician at Penn Orthopaedics will complete an in-depth evaluation form that provides the details of your OCD lesion at your initial visit and at your clinical follow-up visits. If you undergo surgical treatment, your surgeon will also complete an in-depth form providing the details of your OCD lesion and what he/she found during your surgery. Completion of these evaluation forms does not require procedures beyond those that are done as part of any routine examination. However, it does mean we will use information from your medical record in this research. We will access information related to the diagnosis and treatment of your OCD, including information about the nature of your lesion, your current level of pain and function of your knee, and any treatment you have previously received for your knee.

At two years, five years, ten years, and twenty-five years after enrollment, study personnel at Penn will again be checking your medical records to see if you have had any additional surgery or interventions here at Penn. It may also be necessary for us to access your medical record for information about the initial surgery, if applicable, as well as subsequent knee injuries or surgeries, complications, additional treatment and physical therapy notes, X-rays or other images, and outcome measures for pain and functionality.

We will keep your contact information in a registry of patients with injuries like yours in case we might want to contact you for a future study. Agreeing to be in this study does not mean you would have to agree to be in any future studies. You will be asked to sign another consent document for any future studies.

What are the possible risks or discomforts?

This study does not involve any additional procedures that are not part of standard clinical care so the physical risks from participating in this study are not greater than what would be encountered during standard care. You/your child will receive the same care as a patient who is not in the study. The only differences will be that you/your child will be asked to fill out questionnaires and the study doctor will fill out additional forms for research purposes.

Risks to confidentiality and privacy

All human research studies pose a risk to confidentiality and privacy. The study team will do everything possible to minimize these non-physical risks. All patients participating in this study will get a unique study ID, and only the research staff at Penn will know the link between your/your child's name and study ID, and therefore to your/your child's personal information. The primary site for this study is the University of Pennsylvania. The information collected here will only be shared with other sites in a de-identified format.

General risk statement

You may experience some or none of the risks mentioned above. In addition, unforeseeable and/or unknown risks/discomforts may occur as a result of your participation in this study. Every effort will be made to ensure that these hazards are avoided.

What if new information becomes available about the study?

During the course of this study, we may find more information that could be important to you. This includes information that, once learned, might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available. If you wish to be added to a mailing list to receive a copy of any publications that result from this study, please provide your preferred contact information to the coordinator.

What are the possible benefits of the study?

You/your child will not likely receive any direct benefit from participating in this study. we hope that, in the future, other people might benefit from this study because data collected in this study may help physicians and therapists gain a better understanding of how patients are affected by OCD of the knee and provide an improved standard of care as a result.

What other choices do I have if I do not participate?

The alternative to participating in this study is not to participate.

Will I be paid for being in this study?

You will not be compensated for your participation in this study.

Will I have to pay for anything?

You and/or your health insurance may be billed for the costs of medical care during this study if these expenses would have happened even if you were not in the study.

When is the Study over? Can I leave the Study before it ends?

This study is expected to end after all participants have completed all visits, and all information has been collected. This study may also be stopped at any time by your physician, because:

- The Principal Investigator feels it is necessary for your health or safety.
  - Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- The Principal Investigator has decided to stop the study.

If you decide to participate, you are free to leave the study at anytime. Withdrawal will not interfere with your future care.

Who can see or use my information? How will my personal information be protected?

Your study information will be collected for this trial and will be disclosed to the study team at the University of Pennsylvania. The University of Pennsylvania will be collecting data from all people who participate in this study. We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

What information about me may be collected, used or shared with others?

If you agree to participate in this study, the following information will be collected for study purposes.

- Name, address, telephone number, email or other electronic contact method if preferred by participants, date of birth
- All elements of dates for dates directly related to an individual, including birth date, admission date, discharge date, surgical procedure date, clinic visit dates
- Social Security number (The collection of your social security number is to help us locate you for follow-up. The collection of your social security number, for research purposes other than payment, is strictly optional and is not required for participation in the study)
- Personal and family medical history
- Results from a physical examinations, tests or procedures, images from X-Rays, CT scans or MRIs
- Reports from the Emergency Room, Pathology, the laboratory, operations, Radiology

- Progress notes, EKGs, discharge summaries, consultations
- Inpatient and Outpatient clinical records,
- Information in the medical record
- Self-reported racial/ethnic background

What is an Electronic Medical Record?

An Electronic Medical Record (EMR) is an electronic version of the record of your care within a health system. An EMR is simply a computerized version of a paper medical record. If you are receiving care or have received care within the University of Pennsylvania Health System (UPHS) (outpatient or inpatient) and are participating in a University of Pennsylvania research study, results of research-related procedures (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in your existing EMR maintained by UPHS.

If you have never received care within UPHS and are participating in a University of Pennsylvania research study that uses UPHS services, an EMR will be created for you for the purpose of maintaining any results of procedures performed as part of this research study. The creation of this EMR is required for your participation in this study. In order to create your EMR, the study team will need to obtain basic information about you that would be similar to the information you would provide the first time you visit a hospital or medical facility (i.e. your name, the name of your primary doctor, the type of insurance you have). Results of research procedures performed as part of your participation in the study (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in this EMR.

Once placed in your EMR, these results are accessible to appropriate UPHS workforce members that are not part of the research team. Information within your EMR may also be shared with others who are determined by UPHS to be appropriate to have access to your EMR (e.g. health insurance company, disability provider, etc).

Why is my information being used?

Your information is used by the research team to contact you during the study. Your information and results of tests and procedures are used to:

- do the research
- oversee the research
- see if the research was done right.

Who may use and share information about me?

The following individuals may use or share your information for this research study:

- The investigator for the study and the study team
- Other authorized personnel at Penn (including the following):
    - The University of Pennsylvania Institutional Review Board (IRB)
    - The University of Pennsylvania Office of Human Research (OHR)

Who, outside of the School of Medicine, might receive my information?

<u>Oversight organizations</u>

- The Office of Human Research Protections (OHRP)
- Regulatory Agencies (i.e. Food and Drug Administration – FDA)

- The Research in OsteoChondritis Dissecans (ROCK) study group, comprised of surgeons at institutions across the country and internationally

Once your personal health information is disclosed to others outside the School of Medicine, it may no longer be covered by federal privacy protection regulations. The Principal Investigator or study staff will inform you if there are any additions to the list above during your active participation in the trial. Any additions will be subject to University of Pennsylvania procedures developed to protect your privacy.

How long may the School of Medicine use or disclose my personal health information?

Your authorization for use of your personal health information for this specific study does not expire. Your information may be held in a research database. However, the School of Medicine may not re-use or re-disclose information collected in this study for a purpose other than this study unless:

- You have given written authorization
- The University of Pennsylvania's IRB grants permission
- As permitted by law

Can I change my mind about giving permission for use of my information?

Yes. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the investigator for the study. If you withdraw your permission, you will not be able to stay in this study.

What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study. By signing this document you are permitting the School of Medicine to use and disclose personal health information collected about you for research purposes as described above.

Who can I call with questions, complaints or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on page one of this form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Office of Regulatory Affairs with any question, concerns or complaints at the University of Pennsylvania by calling (215) 898-2614.

When you sign this form, you are agreeing to take part in this research study. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Your signature also means that you are permitting the University of Pennsylvania

to use your personal health information collected about you for research purposes within our institution. You are also allowing the University of Pennsylvania to disclose that personal health information to outside organizations or people involved with the operations of this study.

A copy of this consent form will be given to you.

You are asked to provide your/your child's social security number on the questionnaires that are retained by the research team. The collection of your social security number is to help us locate you for follow-up. The collection of your social security number, for research purposes other than payment, is strictly optional and is not required for participation in the study. We may also use your social security number to locate you for follow-up using commercial search engines, such as Equifax, or web based social networking sites such as Facebook. (Initial your choice below)

____ I allow you to collect and use my/my child's social security number for the purposes outlined above.

____ I do NOT allow you to collect or use my/my child's social security number for the purposes outlined above.

Name of Subject (Please Print)	Signature of Subject	Date
Name of Parent/Guardian Providing Consent for Child	Signature of Parent/Guardian	Date
Description of relationship to subject		
Name of Person Obtaining Consent (Please Print)	Signature of Staff	Date