

**JOCD Drilling Randomized Controlled Trial (RCT)**

Manual of Operations

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**SECTION A: PROTOCOL**

**A1. Overview**

[*Retro versus Trans Articular Drilling for Juvenile Osteochondritis Dissecans of the Knee: A Multicenter, Randomized Controlled Study*](http://rc-cherpprod/CHERP/Rooms/DisplayPages/LayoutInitial?Container=com.webridge.entity.Entity%5bOID%5bE636BC125E4B0A4F8D5FED00DE41BD9A%5d%5d) is designed to compare the outcomes of the two commonly employed drilling techniques, retro- and trans-articular drilling, for stable OCD lesions located on the medial femoral condyle in skeletally immature patients. This trial is registered at <http://clinicaltrials.gov/>. The figure below outlines the RCT. Details on each element are included throughout the manual.

Figure A.1 ROCK OCD RCT Schema

**SECTION B: DATA COLLECTION OVERVIEW**

Randomize just before surgery in OR

\*MRIs completed at centers where appropriate

Clinical Visits

- 6 weeks (*XR*)

- 3 months (*XR*)

- 6 months (*XR, MRI\*, Qs*)

- 1 year (*XR, Qs*)

- 2 years (*XR, MRI\*, Qs*)

Standardized postoperative physical therapy

Lesion found, during surgery, to be unstable

**END**

Surgery

-Trans-articular drilling

OR

-Retro-articular drilling

Eligible & consented

Eligible & NO consent

Ineligible

**END**

Healed

**END**

NOT Healed

Complete(d) course of Conservative Therapy

**Screen Patients for Eligibility**

* Stable JOCD lesion (*Hefti: 1, 2 or 3*)
* Skeletally immature (*open/intact physis on MRI*)

*Conservative Therapy Protocol*

*Duration: 3 months*

*Must include:*

*a) No athletic participation or activity, and*

*b) ≥6 weeks of:*

* *Cylinder casting, or*
* *Bracing, or*
* *Non-weight bearing*

**B1. Sequence of Activities**

The following section outlines the sequence of activities required to enroll and follow patients in the RCT.

**STEP 1: Patient screening and determination of eligibility**

Possibly eligible subjects should be identified by a coordinator through clinic schedule review or brought to the coordinator’s attention by an attending surgeon. The cohort of possibly eligible patients includes all patients with knee OCD under 17 for males, and under 15 for females. All patients should be screened for eligibility by a coordinator. Study forms 1A: History (patient), 1B: History (surgeon), and 1C: Screening and Eligibility, should be completed for all of these patients to collect basic information about the patients and document their eligibility. All screened patients should be entered into the ID log and assigned an ID (see Step 2).

There are several scenarios that can play out during the screening process:

1. **Patient eligible at first visit:** in this scenario, a patient meets all of the eligibility and none of the ineligibility criteria at the first visit, and is eligible for the RCT.
2. **Patient ineligible at first visit:** in this scenario, a patient does not meet at least one of the eligibility or meets at least one of the ineligibility criteria at the first visit, and is not eligible for the RCT.
3. **Eligibility cannot be determined at first visit:** in this scenario, a patient meets all of the inclusion and exclusion criteria, except for completion of the required 3-month course of non-operative therapy; therefore, they are provisionally eligible. These patients must complete therapy before their eligibility can be determined. After completion of the required therapy, patient’s final eligibility status will be determined as follows:
	1. **Eligible:** if the OCD lesion did not heal and is still stable;
	2. **Ineligible:** if the OCD lesion healed and patient no longer needs surgery;
	3. **Ineligible:** if the OCD lesion has become unstable.

See Section E1. Conservative Therapy for what is eligible conservative therapy.

**STEP 2: Assigning study IDs**

Every patient screened for this RCT should be assigned a study ID, regardless of whether they participate. Once a patient has been identified as a candidate to be screened, the research coordinator should assign the patient the next available unique study ID by recording his/her name and medical record number on the Patient ID Assignment Log (see Section. H3 Patient ID Assignment Log). The remainder of the log should be filled out when his/her final eligibility status is determined. Each patient has two possible study IDs, one for each knee. Each site will maintain its own ID Log. It should be the only study document that contains the link between the patient’s ID and, name and MRN. This log must be stored in a secure location that is separate from all patient study forms.

Patient IDs are made up of five digits and one character:

1. The first two digits represent the site number (see Figure B1 for Site IDs 9 and Surgeon IDs)
2. The next three digits are sequential and represent the patient, e.g., the first patient screened at BCH would be assigned 11-001, the second 11-002, etc.
3. The character represents the affected side (ie. If a patient has OCD of the right knee, the study ID would end in –R).

If a patient has bilateral OCD, both sides of which may be eligible for the RCT, that patient will have two Study IDs, one for forms completed for the right knee, and one for forms completed for the left knee, and will be treated as two study subjects. The first 5 digits of the study ID will be the same with the final character being -R for the right leg and -L for the left leg. If a patient is bilateral and being seen for care of both knees at one visit, please make sure that the forms filled out for the right knee are labeled with the Study ID for the right knee, not the left, and vice versa.

The Patient ID Assignment Log given to each institution contains patient IDs. As sites screen more than patients the numbers provided, add additional IDs to the Log and continue assigning them according to protocol.

Figure B.1 Site and Surgeon IDs

|  |  |  |  |
| --- | --- | --- | --- |
| **Site Name** | **Site Number** | **Surgeon Name** | **Surgeon ID** |
| Boston CH | 11 | Min Kocher  | 111 |
| Boston CH | 11 | Ben Heyworth  | 112 |
| CHOP | 12 | Ted Ganley | 121 |
| Cincinnati CH | 13 | Eric Wall  | 131 |
| Connecticut CH | 14 | Carl Nissen  | 141 |
| Kaiser LA | 15 | Jen Weiss  | 151 |
| Nashville (St. Thomas) | 16 | Allen Anderson  | 161 |
| Penn | 17 | James Carey  | 171 |
| Rady CH | 18 | Hank Chambers | 181 |
| Rady CH | 18 | Eric Edmonds | 182 |
| Rocky Mtn | 19 | John Polousky | 191 |
| Sick Kids | 20 | Lucas Murnaghan | 201 |
| St Luke's | 21 | Kevin Shea | 211 |
| Wash U | 22 | Rick Wright  | 221 |
| Wisconsin | 23 | Roger Lyon | 231 |

**STEP 3: Obtaining informed consent**

Once a patient is deemed eligible or provisionally eligible, the attending surgeon should introduce the RCT to the parents/guardians and let them know that a research coordinator will provide more detailed information. For patients who are known to be eligible, the coordinator should briefly describe the RCT and then proceed to the formal consent process. S/he should record the final consent status (consented: yes/no) on Form 1C and in the Patient ID Assignment Log. For patients who did not consent, also record the primary reason for non-participation on Form 1C. The same process should be completed for patients who are provisionally eligible, but only after non-operative therapy is completed. Since all patients in this RCT will be minors, the informed consent document must be signed and dated by a parent/guardian and the patient must sign indicating his/her assent. This consent form should be placed in a research file, separate from all other patient forms. If required by the site’s IRB, a copy should also be placed in the patient’s medical record. A second copy of the consent form should be signed and dated by all parties and given to the patient/family for their records.

**STEP 4: Study visits**

There are seven study visits we are interested in collecting data at, Visit 0 (Baseline) through Visit 6 (2 years.) Additional clinical visits may take place during the study; these are “unscheduled” and are referred to as Interim Clinical Visits. These scheduled and unscheduled visits are described below. See Figure B.2 for an overview of the visits. Procedures and details specific to these scheduled and unscheduled visits are described below. Surgeons’ clinic schedules and/or patients’ visit schedules should be monitored so as to not miss a scheduled follow-up visit. Additional tracking measures can be carried out as seen necessary by individual institutions to make sure patient visits are not missed.

Baseline: Baseline can consist of more than one visit based on the non-operative care a patient has received. The first visit of baseline will consist of the collection of demographic information and a brief medical history (Form 1A and Form 1B) and eligibility (Form 1C).

If a patient is deemed eligible at the first baseline visit, consent will be obtained, the eligibility form (Form 1C) will be completed, a physical exam will be performed (Form 2), and the patient will be asked to fill out the outcome questionnaires (Form 3 [please see Section C2. Q x Q to know which Form 3 to give a patient]). Form 4A and Form 4B will be filled out based on the x-ray and MRI used to determine the patient’s eligibility and need for surgery. The patient may get x-ray and MRI at this baseline visit or not depending on if s/he has recent images or not. Once again, the x-ray and MRI forms should be completed for the images used to determine eligibility.

If a patient is not yet eligible due to needing further non-operative care, baseline will also include the visits leading up to the point a patient is deemed eligible. At each baseline visit, a new Form 1C should be used. At the baseline visit the patient is finally deemed eligible, consent will be obtained, the eligibility form will be completed (Form 1C), a physical exam will be performed (Form 2), and the patient will be asked to fill out the outcome questionnaires (Form 3). Form 4A and Form 4B will be filled out based on the x-ray and MRI used to determine the patient’s eligibility and need for surgery. It is likely that these patients will have more than one x-ray and/or MRI, so make sure the images being used to complete forms 4A and 4B are those with which the eligibility was determined.

Once a patient is consented for the RCT, a research coordinator should enter the patient into the randomization portal using his/her log in information and answer the required eligibility questions. Instructions are below.

1. Go to: <https://rockstudygroup.research.cchmc.org/auth/login>
2. Enter your username and password. If you do not have a user name, contact Gregory Myer at greg.myer@cchmc.org
3. Select “Enroll Patient” in the top left hand corner
4. Enter the patient’s Study ID and date they were consented
5. Proceed through the questions to complete enrollment
6. If you have any trouble, contact help@bmi.cchmc.org

Visit 1 (Surgery): As part of the RCT, a patient will have surgery. A patient will be randomized to either retro- or transarticular drilling at the time of surgery. Randomization will occur in the OR, ideally after a diagnostic arthroscopy to confirm lesion stability, but before the drilling. The surgeon will log into the randomization portal to randomize the patients. Instructions are below.

1. Go to: <https://rockstudygroup.research.cchmc.org/auth/login>
2. Enter your username and password. If you do not have a user name, contact Gregory Myer at greg.myer@cchmc.org
3. Select “Patients” in the upper left hand corner
4. Find the patient being randomized (NOTE: Make sure you know the patient’s study ID as no PHI is included in the randomization system. This will be on Form 5)
5. Click on Randomize. The next screen that comes up with have the surgical procedure the patient is randomized to and key aspects of the surgery. An additional email will be generated and sent to the surgeon for records.

Each surgery will follow the agreed upon procedures (See Section E2. Surgical Procedures).

Following surgery, patients will be placed on a physical therapy regimen agreed upon by the ROCK group (See Section E3. Physical Therapy).

Visit 2 (6 Weeks, Window: 4- < 8 Weeks): This is the first follow-up visit we are interested in collecting data at. At this exam, a physical exam (Form 2), x-rays (From 4A), and a follow-up assessment (Form 6) will be completed.

Visit 3 (3 Months, Window: 2- < 4 Months): This is the second follow-up visit we are interested in collecting data at. At this exam, a physical exam (Form 2), x-rays (From 4A), and a follow-up assessment (Form 6) will be completed.

Visit 4 (6 Months, Window: 4- < 8 Months): This is the third follow-up visit we are interested in collecting data at. At this exam, a physical exam (Form 2), x-rays (From 4A), an MRI (Form 4B) (as clinically indicated and as part of standard of care) and a follow-up assessment (Form 6) will be completed. The patient should fill out outcome questionnaires (From 3).

Visit 5 (12 Months, Window: 10- <14 Months): This is the fourth follow-up visit we are interested in collecting data at. At this exam, a physical exam (Form 2), x-rays (From 4A), and a follow-up assessment (Form 6) will be completed. The patient should fill out outcome questionnaires (From 3).

Visit 6 (24 Months, Window: 22- < 26 Months): This is the last scheduled follow-up visit we are interested in collecting data at. At this exam, a physical exam (Form 2), x-rays (From 4A), an MRI (Form 4B) and a follow-up assessment (Form 6) will be completed. The patient should fill out outcome questionnaires (From 3). The patient should be closed out (Form 9B).

Interim Clinical Visits: Interim clinical visits are defined as clinical visits that are additional to the scheduled follow-up visits a patient should complete as part of this RCT. They may take place at any time. A visit should be recorded as interim if another visit in the same study visit window occurs at a time closer to when the follow-up visit is supposed to be or if a patient visits outside of a study visit window. For example, if a patient is seen at 4.5 months post-surgery and at 6.5 months post-surgery, the visit at 4.5 months should be recorded as interim as the 6.5 month visit is closer to when Visit 4 is supposed to occur. At these visits, Form 4A and Form 6 should be completed.

At each visit, if there is indication for close-out as outlined on Form 9B, that form should be filled out. Based on the follow-up assessment, a new Form 7: Adverse Event, and/or Form 8: Secondary Surgery should be completed as appropriate. All adverse events, new, ongoing, or ended, should be recorded at each clinic visit as needed. A patient may end up with several adverse event forms completed throughout the follow-up period. If the only adverse event noted at a clinic visit is noted as “resolved”, a new Form 7 for that clinic visit should still be completed.

Figure B.2 Overview of Visits and Forms by Visit

**Trial Only**

**Trial / Registry**

**Baseline (Visit 0)**

**6 Weeks (Visit 2)**

**3 Months (Visit 3)**

**6 Months (Visit 4)**

**1 Year (Visit 5)**

**2 Years (Visit 6)**

Pre-Consent

Post-Consent

1A: History (Patient)

1B: History (Surgeon)

1C: Screening & Eligibility (Coordinator)

5: Surgery (Surgeon)

*8: Secondary Surgery (Surgeon)*

2: PE (Surgeon)

4A: X-ray (Surgeon)

6: Follow-up (Surgeon)

2: PE (Surgeon)

4A: X-ray (Surgeon)

6: Follow-up (Surgeon)

2: PE (Surgeon)

3A or 3B: Outcome Q (Patient)

4A: X-ray (Surgeon)

4B: MRI (Surgeon)**5**

6: Follow-up (Surgeon)

9B: Closeout (Coordinator)

1 Record data from PE performed at visit when decision was made to perform surgery

2 Patient should complete questionnaire at visit when decision was made to perform surgery

3 Record data from x-ray taken at visit when decision was made to perform surgery

4 MRI required for all Registry and RCT patients

5 MRI completed if clinically indicated or standard of care for clinical center

Form 7:Adverse Event and Form 8: Secondary Surgery should be completed as necessary

**Interim Visit (Visit 7)**

4A: X-ray (Surgeon)

6:Follow-up (Surgeon)

2: PE (Surgeon)**1**

3A or 3B: Outcome Q (Patient)**2**

4A: X-ray (Surgeon)**3**

4B: MRI (Surgeon)**4**

 **Surgery (Visit 1)**

2: PE (Surgeon)

3A or 3B: Outcome Q (Patient)

4A: X-ray (Surgeon)

4B: MRI (Surgeon)**5**

6: Follow-up (Surgeon)

2: PE (Surgeon)

3A or 3B: Outcome Q (Patient)

4A: X-ray (Surgeon)

6: Follow-up (Surgeon)

**STEP 5: Closeout**

Patients meet the criteria for RCT closeout if/when either of the following events occurs. 1) A patient completes the RCT, e.g., completes Study Visit 6. 2) A patient is withdrawn from the RCT for reasons outlined on Form 9B or other. To close-out a patient, fill out Form 9B. Patients additionally need to be closed out through the randomization portal before Form 9B is completed or at the time Form 9B is completed by a research coordinator. Instructions are below.

1. Go to: <https://rockstudygroup.research.cchmc.org/auth/login>
2. Enter your username and password.
3. Select “Close Out Patients” in the top left hand corner
4. Find the patient being close out and under “Actions” select “Close-Out”

**B2. Visit Protocols**

The following table outlines the details of what needs to be completed and when for each visit. The numbers for each part of each visit indicate the order in which events should occur.

Figure B.3 Protocol by visit (NOTE: This protocol may have to be adjusted to fit your clinic)

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Patient** | **Research Coordinator** | **Surgeon** |
| **Baseline Visit(s)** |
|  Before visit | \*\*Patient may already have usable x-rays and MRs | 1. Identify potential subjects2. Enter patient into Patient ID Assignment Log and give Study ID3. Put labeled Form 1A in patient chart4. Give labeled Form 1B, 2 to surgeon | 1. Identify potential subjects |
|  During visit | \*\*Patient may need x-ray and MR to determine eligibility1. Complete Form 1A5. Consent7. Complete Form 3 | 1. Determine eligibility using Form 1C, some may be completed prior to visit4. Obtain consent if/when eligible6. Give patient labeled Form 3 | 1. Determine eligibility using Form 1C2. Complete physical exam according to Form 23. Mention RCT to patient |
|  After visit |  | 1. Complete Form 1C if not already completed2. Enter patient into randomization portal | 1. Complete Forms 1B, 2, and 4A and 4B based on images used to determine eligibility and need for surgery |
| **Visit 1: Surgery** |
|  Before surgery |  | 1. Give surgeon labeled Form 5 |  |
|  During surgery |  |  | 1. Randomize patient after diagnostic arthroscopy through randomization portal |
|  After surgery |  |  | 1. Compete Form 5 |
| **Visit 2: 6 Weeks** |
|  Before visit |  | 1. Give surgeon labeled Forms 2, 4A, 6 |  |
|  During visit | 1. Get x-ray |  | 1. Complete physical exam according to Form 22. Complete follow-up exam according to Form 6 |
|  After visit |  |  | 1. Complete Forms 2 and 6 (if not already done) and 4A for x-ray obtained at visit |
| **Visit 3: 3 Months** |
|  Before visit |  | 1. Give surgeon labeled Forms 2, 4A, 6 |  |
|  During visit | 1. Get x-ray |  | 1. Complete physical exam according to Form 22. Complete follow-up exam according to Form 6 |
|  After visit |  |  | 1. Complete Forms 2 and 6 (if not already done) and 4A for x-ray obtained at visit |
| **Visit 4: 6 Months** |
|  Before visit |  | 1. Give surgeon labeled Forms 2, 4A, 4B, 62. Put labeled Form 3 in patient chart |  |
|  During visit | 1. Get x-ray, MRI2. Complete Form 3 |  | 1. Complete physical exam according to Form 22. Complete follow-up exam according to Form 6 |
|  After visit |  |  | 1. Complete Forms 2 and 6 (if not already done) and 4A and 4B for x-ray and MRI obtained at visit  |
| **Visit 5: 1 Year** |
|  Before visit |  | 1. Give surgeon labeled Forms 2, 4A, 62. Put labeled Form 3 in patient chart |  |
|  During visit | 1. Get x-ray2. Complete Form 3 |  | 1. Complete physical exam according to Form 22. Complete follow-up exam according to Form 6 |
|  After visit |  |  | 1. Complete Forms 2 and 6 (if not already done) and 4A for x-ray obtained at visit  |
| **Visit 6: 2 Years** |
|  Before visit |  | 1. Give surgeon labeled Forms 2, 4A, 62. Put labeled Form 3 in patient chart |  |
|  During visit | 1. Get x-ray, MRI2. Complete Form 3 |  | 1. Complete physical exam according to Form 22. Complete follow-up exam according to Form 6 |
|  After visit |  | 1. Complete 9B for closeout | 1. Complete Forms 2 and 6 (if not already done) and 4A and 4B for x-ray and MRI obtained at visit  |
| **Visit 7: Interim Visit(s)** |
|  Before visit |  | 1. Give surgeon labeled Forms 4A, 6 |  |
|  During visit | 1. Get x-ray |  | 1. Complete physical exam according to Form 22. Complete follow-up exam according to Form 6 |
|  After visit |  |  | 1. Complete Form 6 (if not already done) and 4A for x-ray obtained at visit  |

**SECTION C: FORM OVERVIEW**

**C1. Form Overview**

All doctors and research coordinators should make themselves familiar with the forms and when each form should be completed so as not to miss any of the data collection points.

**FORM 1A: History**

Used at: First Baseline visit (can be completed without consent)

Completed by: Patient (in waiting room)

**FORM 1B: History**

Used at: First Baseline visit (can be completed without consent)

Completed by: Surgeon (during/after visit)

**FORM 1C: Screening and Eligibility**

Used at: Completed for each Baseline visit (can be completed without consent). This means multiple Form 1Cs may be completed for a patient depending on if the patient is eligible at the first baseline visit or needs more non-operative care before eligibility can be determined

Completed by: Research Coordinator with input from Surgeon (should be used as a guide to eligibility during all baseline visits; completed at each visit a patient has while determining eligibility)

**FORM 2: Physical Exam**

Used at: Baseline, Visit 2, Visit 3, Visit 4, Visit 5, Visit 6

Completed by: Surgeon (should be used as a guide for physical exam during visits; completed during/after visit)

\*\*NOTE: For Baseline, complete only at the baseline visit a patient is consented

**FORM 3: Outcome Questionnaires**

Used at: Baseline, Visit 4, Visit 5, Visit 6

Completed by: Patient (in waiting room)

 \*\* NOTE: For Baseline, give to patient when consented

**FORM** **4A: X-Ray**

Used at: Baseline, Visit 2, Visit 3, Visit 4, Visit 5, Visit 6, and any Interim Visits (Visit 7)

Completed by: Surgeon (after visit)

\*\* NOTE: For Baseline, complete on the x-ray used to determine eligibility

**FORM** **4B: MRI**

Used at: Baseline, Visit 4, Visit 6

Completed by: Surgeon (after visit)

\*\* NOTE: For Baseline, complete on the MRI used to determine eligibility. Some institutions may not include MRIs as part of standard of care at all time points, so fill out as clinically necessary

**FORM 5: Surgery**

Used at: Visit 1

Completed by: Surgeon (can be used as a guide during surgery; completed after surgery)

**FORM 6: Follow-up**

Used at: Visit 2, Visit 3, Visit 4, Visit 5, Visit 6, and any Interim Visits (Visit 7)

Completed by: Surgeon (can be used as a guide during the visit; completed during/after visit)

**FORM 7: Adverse Event**

Used at: Any visit necessary

Completed by: Surgeon (can be used as a guide during the visit; completed during/after visit).

 \*\*\*NOTE: One should be completed for every visit an adverse event is noted, ongoing, or resolved

**FORM 8: Secondary Surgery**

Used at: Any surgery necessary

Completed by: Surgeon (completed after surgery)

**FORM 9B: Close-out**

Used at: Any visit necessary OR at Visit 6

Distribution: Research coordinator holds on to, surgeon may have a copy as a guide

Completed by: Research coordinator (after visit)

**C1a. Labeling study forms**

All forms should be given to the patient or surgeon with Study ID (see section B1, STEP 2) filled in and patient sticker on. If not patient sticker is readily available, the patient name should be written legibly on the patient name line.

**C2. Q x Q**

NOTE: All forms should be completed for the knee that is being addressed at the appointment and is associated with the Study ID. If the patient has bilateral knee OCD and is receiving care for both knees at one appointment, make sure the appropriate forms for the follow-up visit for each knee are completed. Make sure the patient, doctor, and coordinators are filling out the forms for the knee linked to the Study ID.

**Form 1A: History Form (Patient)**

RESEARCH COORDINATOR TO COMPLETE BEFORE FORM GIVEN TO PATIENT

**A1.** Fill in the Patient ID from the ID Assignment Log. This is unique to the patient and patient side (see Section B1, Step 2).

**Patient Name:** Fill the patient name in or place a patient label in the box.

**A2.** This form is only completed for the first visit of baseline; therefore the Baseline box is already checked.

**A3.** Fill in the month, day, and year of the patient’s clinic visit.

PATIENT FILLS OUT (directed at patient)

**B1.** Fill in the month, day, and year you were born.

**B2.** Select your gender, male or female.

**B3.** Select “Yes” if you have any Hispanic or Latino background, otherwise select “No”.

**B4.** Select all of the races that you feel apply to yourself and specify the race you are referring to if “Other” is selected.

**B5.** Indicate if anyone in your immediate family has/had OCD and how many of each immediate family member has/had OCD when an option. Note the difference between “No” and “Don’t Know”.

**B6.** Select “Yes” if you have ever been diagnosed with OCD in any joint. This includes the elbow, ankle, etc. Otherwise select “No”. If the answer to B6 was yes, please indicate which joint you had OCD in for a.

**B7.** Answer each question for the Right and the Left leg separately. Only answer b. and c. if the answer to a. is “Yes” for the indicated leg. For c., injuries include, but are not limited to, twisting injuries, direct blows, falls onto, etc.

**B8.** This refers to any treatment you may have received for the knee being addressed at the visit. Only complete a. and b. if you answer “Yes”. For a., “people” refers to any of the listed entities in part b. and others that you can specifically identify. If you have seen two chiropractors and a physical therapist for example, you should check chiropractor and physical therapist for b. and write in “3” for a.

**Form 1B: Patient History (Surgeon)**

RESEARCH COORDINATOR TO COMPLETE BEFORE FORM GIVEN TO PATIENT:

**A1.** Fill in the Patient ID from the ID Assignment Log. This is unique to the patient and patient side (see Section B1, Step 2).

**Patient Name:** Fill the patient name in or place a patient label in the box.

**A2.** This form is only completed for the first visit of baseline; therefore the Baseline box is already checked.

**A3.** Fill in the month, day, and year of the patient’s clinic visit.

**A4.** Fill in the Surgeon ID of the treating surgeon as indicated in Figure B.1 Site and Surgeon IDs found in Section B.1 Step 2.

SURGEON FILLS OUT

**B1.** Fill in the patient’s height in centimeters measured at visit.

**B2.** Fill in the patient’s weight in kilograms measured at visit.

**B3.** This question is important! Indicate the side of the OCD lesion being examined. Select “Right” or “Left” if the patient ONLY has right or left knee OCD. If the patient has OCD on both sides, only select “Both”, not all three options. Unless the patient is bilateral, this answer should match the last character of the Patient ID, i.e. if the ID is 11-001-L, the answer should be left. Only answer a. if the answer to B3. is “Both”. For a., select the side that is being addressed for the RCT. This answer should match the last character of the patient ID, i.e. if the ID is 11-001-L, the answer should be Left. **All questions after this point refer to the knee indicated in B3. or B3a if the answer to B3 is both.**

**B4.** Indicate the location of the OCD lesion. To be eligible for the RCT, the lesion must be located on the medial femoral condyle.

**B5.** If this is the first visit that a patient is being diagnosed with OCD, use the current date. If the patient has received a diagnosis of OCD previously either by the attending physician or someone else, do the best to accurately record that date.

**B6.** Knee pathology can include any injury or pathology to the knee in question. Please describe briefly if the answer is “Yes”.

**B7.** Indicate any prior knee surgery on the knee in question, not the contralateral knee. Please describe briefly if the answer is “Yes”.

**PLEASE OBTAIN THE OPERATIVE NOTE(S) IF THE PATIENT HAS HAD PRIOR SURGERY.**

**B8.** If the patient has had any past intra-articular corticosteroid injections for pain in the knee of interest, please indicate such.

**B9.** This question is important for eligibility. Non-operative therapy options are described by the options given by B9a. Only complete a. if the answer is “Yes” to B9. If the answer is “Yes” to B9., fill in how many weeks of each treatment the patient has undergone. For those with multiple options, select the option that best describes the treatment.

**B10.** Bone age is not on the x-ray or MRI form so make sure to fill it in here.

**Form 1C: Screening and Eligibility (Coordinator)**

RESEARCH COORDINATOR TO COMPLETE AT BASELINE VISIT(S):

**A1.** Fill in the Patient ID from the ID Assignment Log. This is unique to the patient and patient side (see Section B1, Step 2).

**Patient Name:** Fill the patient name in or place a patient label in the box.

**A2.** This form can be completed for at any of the Baseline visits; therefore the Baseline box is already checked.

**A3.** Fill in the month, day, and year of the patient’s clinic visit. Since a patient might not be eligible at the first visit of baseline, make sure to complete a new Form 1C for each following Baseline visit and record the date of each visit.

**B1.** Select “Yes” if there is a diagnosis of knee OCD (stable or unstable).

**B2.** Select “Yes” if the lesion is on the medial femoral condyle as determined by x-ray or MRI, as gleaned from medical record notes (from a previous x-ray or MRI), or as indicated by the attending surgeon.

**B3.** Select “Yes” if the lesion is considered stable as ascertained from MRI.

**B4.** Select “Yes” if the patient is skeletally immature as ascertained from MRI.

**B5.** Select “Yes” once a patient has completed the required non-operative therapy as outlined in the RCT protocol. Form 1B can be used to help answer this eligibility question.

**B6.** Select “Yes” if the patient has any concomitant knee pathology on the same side as the OCD lesion. Form 1B can be used as a guide to help answer this eligibility question.

**B7.** If the surgeon no longer recommends surgery for the lesion because the lesion has healed sufficiently after a course of non-operative therapy, then select “Yes”.

**B8.** Select “Yes” if the patient has had any surgery on the same side as the OCD lesion. Form 1B can be used as a guide to help answer this eligibility question.

**B9.** If the patient has any metabolic bone disorder that would change their risk of getting OCD or change the course of treatment and healing a patient would undergo, indicate “Yes”. This includes osteoporosis, rickets, Paget’s disease, or other bone abnormalities.

**B10.** Select “Yes” if the patient has sickle cell disease as ascertainable from the patient, family, or medical chart.

**B11.** If the patient has any history of prolonged (defined as >6 months or >5 courses) corticosteroid or chemotherapy treatment as ascertained from the patient, family, or medical chart, select “Yes”.

**B12.** Based on the answers to B1- B11, determine if this patient is eligible. Answers in grey indicate a patient is ineligible. If the only grey answer is to B5 (“No” selected), then the patient may still be eligible at a later time point. If any of the other shaded answers on the form are checked, the patient is not eligible and will not ever be eligible.

**B13.** Complete this question once the patient is determined to be eligible. If “No” consent, make sure to indicate why as part of B14. If “Yes”, fill in the date the patient was consented in a.

**B14.** Only complete if the answer to B13 was “No”. Select the one main reason the patient chose not to participate.

**Form 2: Physical Exam Form**

RESEARCH COORDINATOR TO COMPLETE BEFORE FORM GIVEN TO SURGEON:

**A1.** Fill in the Patient ID from the ID Assignment Log. This is unique to the patient and patient side (see Section B1, Step 2).

**Patient Name:** Fill the patient name in or place a patient label in the box.

**A2.** This form can be completed for any visit. Select the box the visit corresponds to.

**A3.** Fill in the month, day, and year of the patient’s clinic visit.

**A4.** Fill in the Surgeon ID of the treating surgeon as indicated in Figure B.1 Site and Surgeon IDs found in Section B.1 Step 2.

SURGEON FILLS OUT

**B1.** For sub-sections 1-4, fill out accordingly as determined by your assessment of the knee of interest. For 5, range of motion, complete as follows:

Record values for hyperextension/zero point/flexion (e.g. 10 degrees of hyperextension, 150 degrees of flexion = 10/0/150; 10 degrees of flexion to 150 degrees of flexion = 0/10/150).

Passive range of motion should be measured with a goniometer.

**B2.**

**1.** Select one answer from the row. An effusion is assessed by ballotting the knee. A fluid wave (less than 25 cc) is graded mild, easily ballotteable fluid – moderate (25-60 cc), and a tense knee secondary to effusion (greater than 60 cc) is rated severe.

**GROUP 1 GRADE.** Give an overall group grade for Group 1. The overall group grade should correspond to the worst grade within the group with answers in column A being the most normal, and answers in column D being the least normal.

**2.** Extension and flexion grades for the knee of interest should be compared to that of the contralateral knee. Notice answers should be the differences between the affected and unaffected knee, so both sides should be measured and the difference recorded.

**GROUP 2 GRADE.** Give an overall group grade for Group 1. The overall group grade should correspond to the worst grade within the group with answers in column A being the most normal, and answers in column D being the least normal.

**3.** Patellofemoral (anterior) crepitation is elicited by extension against slight resistance. Medial and lateral compartment crepitation is elicited by extending the knee from a flexed position with a varus stress and then a valgus stress (i.e., McMurray test). Grading is based on intensity and pain. Notice each measure should be the difference between the affected and unaffected knee, so both sides should be measure and the difference recorded.

**4.** Only complete if the lesion appears to be healed. Record the answer for the affected leg as a percent of what the unaffected leg can do. The patient is asked to perform a one leg hop for distance on the index and normal side. Three trials for each leg are recorded and averaged. A ratio of the index to normal knee is calculated.

**B3.** The final evaluation is the worst group grade given for any of the above sections.

**C1.** Asses the patient’s gait by observing patient walk up and down a straight hall way. Complete for both sides.

\*\*\* For additional information on how to fill out Section B, please see <http://www.sportsmed.org/Research/IKDC_Forms/>. The last page of the IKDC includes instructions for the knee examination.

**From 3A, 3B, 3C: Outcome Questionnaires**

If a patient is under the age of 18, s/he should fill out Form 3A.

If a patient is 18 to 25, s/he should fill out Form 3B.

If a patient is 25 or older, s/he should fill out Form 3C.

RESEARCH COORDINATOR TO COMPLETE BEFORE FORM GIVEN TO PATIENT:

**A1.** Fill in the Patient ID from the ID Assignment Log. This is unique to the patient and patient side (see Section B1, Step 2).

**Patient Name:** Fill the patient name in or place a patient label in the box.

**A2.** This form can be completed for several visits. Select the box the visit corresponds to.

**A3.** Fill in the month, day, and year the questionnaire was given to the patient.

The remainder of the questionnaire will be completed by the patient according to the instructions given. Please make sure to have someone available to answer any questions the patient may have.

**Form 4A: X-Ray**

If this form is being completed for baseline, make sure to complete it using the x-rays that were used to determine the patient’s eligibility and need for surgery. If multiple forms were completed during the baseline process, we are only interested in the last one completed (i.e. the form completed on the images used to determine final eligibility).

**Form 4B: MRI**

If this form is being completed for baseline, make sure to complete it using the MRI that was used to determine the patient’s eligibility and need for surgery. If multiple forms were completed during the baseline process, we are only interested in the last one completed (i.e. the form completed on the images used to determine final eligibility).

**Form 5: Initial Surgery**

RESEARCH COORDINATOR TO COMPLETE BEFORE FORM GIVEN TO SURGEON:

**A1.** Fill in the Patient ID from the ID Assignment Log. This is unique to the patient and patient side (see Section B1, Step 2).

**Patient Name:** Fill the patient name in or place a patient label in the box.

**A2.** This form can only be completed for the surgical visit, so the surgery box is already checked.

**A3.** Fill in the month, day, and year of the patient’s surgery.

**A4.** Fill in the Surgeon ID of the treating surgeon as indicated in Figure B.1 Site and Surgeon IDs found in Section B.1 Step 2.

**A5.** Remember, these forms are used for the both the RCT and the OCD Registry, so make sure to indicate if the patient is part of the RCT or not. Do not fill out section B if the patient is not in the RCT.

SURGEON FILLS OUT

**B1.** Only complete this question if the patient is in the RCT. This information will be given to the surgeon once the patient is randomized on the screen in the randomization portal and via email.

**B2.** Only complete this question if the patient is in the RCT. Even if the answer is “No”, the patient may remain in the RCT based on the intention to treat principle, however make sure to indicate why the surgery indicated by randomization was not performed.

**C1.** Select the surgical approach(es) used during the procedure. Both may be selected.

**C2.** For the surgery performed, multiple answers may be selected. For those that have sub-questions, make sure to fill out each part of the surgical option. For incision questions included for trans-articular drilling, retro-articular drilling, transarticular fixation, and resurfacing procedure, indicate the location of the incision and size in millimeters only if the incision and diagnostic arthroscopy portal site are not the same.

**C3.** If fluoroscopy was used at any point during the surgery, select “Used” and indicate the number of minutes it was used and the number of images taken. Otherwise select “Not Used”

**C4.** If a tourniquet was inflated at any point during the procedure, select “Used” and record the number of minutes it was inflated. Otherwise select “Not Used”. This can be ascertained from the anesthesia record if not known.

**D1.** This needs to be determined intraoperatively. If the answer is “No” and the patient is enrolled in the RCT, the patient is no longer eligible and must be unenrolled from the RCT and the surgeon must complete From 9B: Registry Closeout.

**D2.** Answer “Yes” if the lesion required fixation, not just drilling. If the answer is “Yes” and the patient is enrolled in the RCT, the patient is no longer eligible and must be unenrolled from the RCT and the surgeon must complete From 9B: Registry Closeout.

**D3.** If the lesion was initially stable but due to operative intervention it was destabilized or displaced, please indicate “Yes” and fill out a. indicating how far, in millimeters, it was moved.

**D4.** Indicate “Yes” if there were any inadvertent chondral injuries, including iatrogenic creation of a grade 3 or 4 cartilage lesion other than at the site or margin of the lesion. Minor iatrogenic chondral injuries or scuffing may happen in surgery, however if a grade 3 or 4 lesion is made, this should be noted. If the answer is yes, indicate how many of these lesions were made, and the size of the largest injury.

**D5.** This can include any type of adverse event relating to the OCD lesion or surgery, including blood loss, destabilization of the lesion, etc. If the answer is “Yes”, describe the incident. Anything that occurred during surgery that you think is notable should be recorded here.

**D6.** If there was anything notable about the lesion or knee that was observed during the surgery and is not elsewhere recorded on a form, this is the place to describe it.

**Form 6: Follow-up**

RESEARCH COORDINATOR TO COMPLETE BEFORE FORM GIVEN TO SURGEON:

**A1.** Fill in the Patient ID from the ID Assignment Log. This is unique to the patient and patient side (see Section B1, Step 2).

**Patient Name:** Fill the patient name in or place a patient label in the box.

**A2.** This form can be completed for several visits. Select the box the visit corresponds to.

**A3.** Fill in the month, day, and year of the patient’s clinic visit.

SURGEON FILLS OUT

**B1.** Select medication a patient is taking for pain related to OCD, if any. Note the “None” option. Specify if “Other”.

**B2.** Select all forms of nonoperative treatment a patient underwent / did since the last visit. Make sure to indicate the sub-categories when available. For physical therapy, it is important to know the dates so we can calculate how long a patient did PT for. If it is ongoing, do not fill out the ended date. The date started should be the same on all Form 6s completed for a patient.

**B3.** The patient will have x-rays at each follow-up visit, so based on the x-ray from the visit, please fill out the status of the lesion as compared to the previous examination of the lesion. “Not Healing” indicates the lesion is static.

**B4.** Answer each of the sub-categories based on the physical assessment. If the patient needs another surgery, make sure to fill out Form 8: Secondary Surgery when the surgery occurs. These questions are important as they help define the length of the healing process.

**C1.** Select “Yes” if the patient has had any complications due to the surgery s/he underwent for his/her OCD lesion, due to any other event that affected the knee of interest, or any event that adversely affected the health of the patient not necessarily related to the patient’s knee. Use Form 7: Adverse Event, for an idea of the complications of interest.

**Form 7: Adverse Event**

RESEARCH COORDINATOR TO COMPLETE BEFORE FORM GIVEN TO SURGEON:

**A1.** Fill in the Patient ID from the ID Assignment Log. This is unique to the patient and patient side (see Section B1, Step 2).

**Patient Name:** Fill the patient name in or place a patient label in the box.

**A2.** This form can be completed for several visits. Select the box the visit corresponds to.

**A3.** Fill in the month, day, and year of the patient’s clinic visit.

SURGEON FILLS OUT

**B1.** For each complication a person is found to have at a single clinic visit, the complication should be noted as should whether it is a new adverse event, an ongoing adverse event (i.e. has been noted on a Form 7 for a previous visit), or is resolved. If the complication is resolved, the date ended should be filled in as accurately as possible (i.e. if a patient says s/he stopped having pain 3 days before the visit, the date ended should be three days earlier than the date indicated by date of visit). A new Form 7 should be completed at each visit an adverse event is noted, ongoing, or first resolved.

**B2.** If the complication warrants surgery, indicate such and complete Form 8 when appropriate.

**Form 8: Secondary Surgery**

RESEARCH COORDINATOR TO COMPLETE BEFORE FORM GIVEN TO SURGEON:

**A1.** Fill in the Patient ID from the ID Assignment Log. This is unique to the patient and patient side (see Section B1, Step 2).

**Patient Name:** Fill the patient name in or place a patient label in the box.

**A2.** This form can only be completed for surgery, so the surgery box is already checked.

**A3.** Fill in the month, day, and year of the patient’s surgery.

**A4.** Fill in the Surgeon ID of the treating surgeon as indicated in Figure B.1 Site and Surgeon IDs found in Section B.1 Step 2.

SURGEON FILLS OUT

**B1.** Indicate any and all reasons the patient underwent a secondary surgery related to his/her knee OCD.

**B2.** Select the surgical approach(es) used during the procedure. Both can be selected.

**B3.** For the surgery performed, multiple answers can be selected so check all that apply. For those that have sub-questions, make sure to fill out all associated questions. The answer(s) to B3 should relate to B1, i.e. if “Removal of Implant” is selected for B1 then it should also be noted as part of B3. For incision questions included for trans-articular drilling, retro-articular drilling, transarticular fixation, and resurfacing procedure, indicate the location of the incision and size in millimeters only if the incision and diagnostic arthroscopy portal site are not the same.

**C1.** This needs to be determined intraoperatively. RCT patients can remain enrolled in the study even if the answer is “No” for secondary surgeries.

**C2.** Answer “Yes” if the lesion required fixation, not just drilling. RCT patients can remain enrolled in the study even if the answer is “Yes” for secondary surgeries.

**C3.** If the lesion was initially stable but due to operative intervention it was destabilized or displaced, please indicate “Yes” and fill out a. indicating how far, in millimeters, it was moved.

**C4.** Indicate “Yes” if there were any inadvertent chondral injuries, including iatrogenic creation of a grade 3 or 4 cartilage lesion other than at the site or margin of the lesion. Minor iatrogenic chondral injuries or scuffing may happen in surgery, however if a grade 3 or 4 lesion is made, this should be noted. If the answer is yes, indicate how many of these lesions were made, and the size of the largest injury.

**C5.** This can include any type of adverse event relating to the OCD lesion or surgery, including blood loss, destabilization of the lesion, etc. If the answer is “Yes”, describe the incident. Anything that occurred during surgery that you think is notable should be recorded here.

**C6.** If there was anything notable about the lesion or knee that was observed during the surgery and is not elsewhere recorded on a form, this is the place to describe it.

**Form 9B: RCT Closeout**

RESEARCH COORDINATOR TO COMPLETE:

**A1.** Fill in the Patient ID from the ID Assignment Log. This is unique to the patient and patient side (see Section B1, Step 2).

**Patient Name:** Fill the patient name in or place a patient label in the box.

**A2.** This form can be completed for any visit. Select the box the visit corresponds to.

**A3.** Fill in the month, day, and year the form was completed.

**B1.** Record whether the patient completed the RCT or not. A patient counts as having completed the RCT if s/he completed a 2 year follow-up visit and all associated forms are complete. If the answer is “Yes”, continue to B2. If the answer is “No”, select the one primary reason the patient did not complete the RCT as part of **a**.

**B2.** Fill in the date it was found the patient needed to be closed out of the RCT. This is the date the patient completed the study (i.e. the date of Visit 6), the patient was found to no longer be eligible for the study, or the date it was requested the patient was withdrawn. This form should be completed and the patient closed out in the randomization portal on the same day or prior to completion.

**SECTION D: DATA MANAGEMENT GUIDE**

**D1. Form Flow**

Below are the steps for general data management and flow. Figure D1 shows a more detailed version by form and visit.

**STEP 1: Complete forms**

Complete each form as specified in Section C1 and C2.

**STEP 2: Send forms**

Boston Children’s Hospital will serve as the Data Coordinating Center for the time being. Original forms for RCT subjects will be sent to Boston Children’s Hospital **DEIDENTIFIED**. Do not send forms 1A, 1B, or 1C that were completed for patients who ended up not being eligible. Hold on to those and store as appropriate. Do not send a copy of the consent form. Make sure to make copies of all forms to keep for your own records (ie. Boston CHwill have a copy and each institution will have a copy for subjects from the institution).

To deidentify:

If you put a patient label on the form, black out the label and make sure there are no other pieces of identifying information written on the sheet (i.e. did the patient put his/her name anywhere else on the form? Did a coordinator or surgeon put the patient’s name anywhere else on the form?)

Forms for each subject should be sent to Boston CH at several time points.

**Time 1:** After all baseline visit(s) are completed and the patient is enrolled in the RCT. This mailing should include the following:

1. Form 1A
2. Form 1B
3. Form 1C
4. Form 2 (completed for the baseline visit a patient was determined to be eligible)
5. Form 3 (completed for the baseline visit a patient was determined to be eligible)
6. Form 4A (competed for the x-ray eligibility and surgery were decided upon)
7. Form 4B (competed for the MRI eligibility and surgery were decided upon)

**Time 2+:** After each subsequent visit. This mailing should include all forms completed for each study visit for a subject from surgery through closeout, which covers any and all follow-up visits and associated forms.

Forms should be mailed to:

Patty Connell / Kyna Donohue

Children’s Orthopaedic Surgery Foundation

Hunnewell 2

300 Longwood Avenue

Boston, Massachusetts 02115

Forms can also be emailed to:

 Kyna.Donohue@childrens.harvard.edu

 CC: Patricia.connell2@childrens.harvard.edu

**STEP 3 (done by DCC only):**

Boston Children’s Hospital will be in charge of data entry for all institutions. We will be using RedCAP as a data management system until Teleforms is up and running. RedCAP is an online based data collection and storage system that each site will have access to. It is fully HIPPA compliant. Each site will sent de-identified forms to BCH. A BCH study coordinator will be responsible for recording all data into the RedCap database.

Figure D.1 Data Flow by Visit and Form

**POST-CONSENT**

**Form 1C (R, finish), 2 (S), 4a (S), 3 (P), 4A (S), 4B (S)**

**Consent (P, R)**

Send deidentified copies to Boston CH

Send deidentified copies to Boston CH for CONSENTED PATIENTS ONLY

**Screen Patients for Eligibility**

ID Assignment Log (R)

**FORMS: 1a**- History (patient)  **4b-** X-Rays **7-** Adverse Event

 **1b-** History (surgeon)  **4c-** MRI **8-** Secondary Surgery

 **1c-** Screening and Eligibility  **5a-** Surgery  **9b-** Close out

 **2-** Physical Exam  **5b-** Randomization and Surgery

 **3-** Questionnaires **6-** Follow-up

**KEY: P-** Patient fills out

 **S-** Surgeon fills out

 **R-** Research staff fills out

**Not Eligible**

**END**

**Eligible**

**CONTINUE**

**Mail 1**

Give copy to patient, put copy in MR, keep hard copy for records, can remain identifiable.

Keep hard copies for records, can remain identifiable.

Keep hard copy of ID Log for research records

Keep hard copies for records, can remain identifiable.

Send deidentified copies to Boston CH

Keep hard copies for records, can remain identifiable

**PRE-CONSENT**

**Form 1A (P), 1B (S)**

**Visit 0: Baseline**

 **As completed:**

**Form 2(S), 3(A,B,C)(P), 4A(S), 4B(S), 5A(S), 6(S), 7(S), 8(S), 9B(R)**

**Mail 2+**

**SECTION E: STANDARD PROCEDURES**

**E1. Conservative Therapy**

All patients will be required to complete a course of non-operative therapy before surgical treatment can be offered. The standardized therapy agreed upon by the group requires:

1. Three continuous months of avoidance of athletic activity/participation AND
2. Minimum of six weeks of:
	1. cylinder casting, OR
	2. locked extension hinged-knee bracing OR
	3. non-weight bearing with crutches, OR
	4. some combination of the above 3 options

**E2. Surgical Procedures**

Below is a brief outline of the trans-articular and retro-articular drilling techniques.

Additionally, please see the power point presentation and video put together by Dr. Hank Chambers.

***Trans-articular drilling:***

* + Drilling under arthroscopic visualization, directly through the articular cartilage, with no additional drilling in ‘retro-articular’, ‘extra-articular’, or trans-condylar (through the intercondylar notch) fashion
	+ Use of a 0.045 K-wire for drilling
	+ A minimum 4 wire passes per square centimeter (to insure adequate disruption of sclerotic bone margin of OCD lesion), with a maximum of 5 wire passes per square centimeter (to prevent unnecessary disruption of the articular cartilage)

***Retro-articular drilling:***

* + Drilling must be performed under AP and lateral fluoroscopic guidance, as described by Edmonds et al. and Boughanem et al., with no additional drilling in ‘trans-articular’, or intra-articular trans-condylar fashion
	+ Use of a 0.062 K-wire for drilling
	+ Minimum of 4 wire passes per square centimeter (to insure adequate disruption of sclerotic bone margin of OCD lesion) with no maximum number of wire passes (as additional wire passes are not theorized to be disruptive to the health of the articular cartilage, as described in previous techniques)

**E3. Physical Therapy**

See protocol on next page (template Rx form).



patient label

patient label

**ROCK PT Protocol Following Operative Management for**

**Juvenile Osteochondritis Dissecans of the Knee**

**Diagnosis: Stable MFC OCD lesion of the knee**

**Procedure date: \_\_ / \_\_ / \_\_\_\_ S/P: OCD drilling**

**NOTE:** Time frames below are provided for reference, but should not be used as criteria to progress each patient to the subsequent phase of rehabilitation. A decision to progress each patient to the next phase should be made solely on the ability to demonstrate the noted progression criteria within each phase.

**WEIGHT BEARING PROTOCOL**

**Week 0-4:** NWB

**Week 4-6:** TDWB

**Week 6-12:** If MD clears following XR, should be PWB progression to FWB

PLEASE DO NOT ADVANCE WEIGHT BEARING UNTIL SEEN IN THE OFFICE FOR VISITS

**ACUTE PHASE (post-op weeks 0-6)**

**Weight Bearing Restrictions:** TDWB

**ROM:** Full ROM without limitations

**Modalities:** As needed to assist with muscle activation, effusion control and pain management

**PRE:** Progression of acute phase strengthening to include initiation and progression of closed kinetic chain exercises within guidelines of WB restrictions

**Criteria to progress to Sub-Acute Phase:**

1. ROM = WNL
2. Can execute supine SLR w/o extensor lag
3. No effusion and pain with exercise

**NEUROMUSCULAR STRENGTHENING PHASE (post-op weeks 6-12)**

**Weight Bearing Phase:** Progression to FWB as tolerated (TDWB to PWB to FWB recommended over 1-2 wks)

**ROM:** No restrictions

**Modalities:** PRN

**PRE:** Progression of sub-acute strengthening to include FWB closed kinetic chain interventions

**Criteria to Progress to Return to Activity Phase**

1. ROM WNL
2. No residual pain or effusion with activity
3. Quadriceps strength deficit less than 20% of contralateral limb

**RETURN TO ACTIVITY (when healing achieved)**

**Strengthening:** Continue with a progression of NM strengthening PRE’s

**Agility:** Initiate agility, jogging and light impact activities in conjunction with return to activity goals. Progress to plyometric activities consistent with return to sport goals

**Criteria to Progress to Sports/Activity:**

1. Quadriceps strength within 10% of contralateral limb
2. Performance on functional hop testing within 10% of contralateral limb
3. Successful completion of a return to activity/function progression.

**Additional Instructions:**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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**SECTION F: ROCK CONTACT LIST**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Institution** | **Investigator** | **Email Address** | **Research Contact** | **Email** |
| **Tennessee Orthopaedic Alliance in Nashville (St. Thomas)** | Allen F. Anderson  | AndersonAF@tnortho.com (615) 383-2693 | Sara Hollis (Administrator)Janet Trimble (practice manager) | sara.hollis@stthomas.orgtrimblejt@toa.com |
| **Boston Children's Hospital** | Benton E. HeyworthMininder S. Kocher  | Benton.Heyworth@childrens.harvard.edu (617) 355-6021Mininder.kocher@childrens.harvard.edu (617) 355-8423 | Kyna DonohueAdam Nasreddine | kyna.donohue@childrens.harvard.eduadam.nasreddine@childrens.harvard.edu |
| **Connecticut Children's Medical Center** | Carl W. Nissan Matt Milewski | cnissen@ccmckids.org (860) 284-0220mdmilewski@gmail.com |  Matthew Solomito | Msolomito@connecticutchildrens.org |
| **Cincinnati Children's Hospital Medical Center** | Eric J. Wall Greg Myer | Eric.Wall@cchmc.org (513) 636-4787Greg.Myer@cchmc.org513.636.1246 | Emily EismannNicole BrinkmanAmy Pohlman | Emily.Eismann@cchmc.orgAmy.Pohlman@cchmc.org |
| **Rady Children's Hospital San Diego** | Hank G. ChambersEric W. Edmonds Andrew Pennock | hchambe1@san.rr.com (858) 966-6789EWedmonds@rchsd.org(858) 966-6789apennock@rchsd.org  | Joanna Roocroft | jroocroft@rchsd.org |
| **Univeristy of Pennsylvania** | James L. Carey | James.Carey@uphs.upenn.edu | Annamarie HoranShannon Marcoon | Annamarie.Horan@uphs.upenn.eduShannon.Marcoon@uphs.upenn.edu |
| **Kaiser Permanente Los Angeles** | Jennifer M. Weiss  | jennifermweiss@yahoo.com | (no research staff) |   |
| **Youth Sports Institute Rocky Mountain Hospital for Children** | John D. Polousky  | johnpolousky@msn.com(720) 979-0840 | Scott Rubinstein | Scott.Rubinstein@HealthONEcares.com |
| **St. Luke's Intermountain Orthopaedics** | Kevin G. Shea  | kshea@slhs.org, kgshea@aol.com (208) 489-4203 | Noah Archibald-Seiffer | archiban@slhs.org |
| **The Hospital for Sick Children** | M. Lucas Murnaghan  | lucas.murnaghan@sickkids.ca(416) 823-4902 |   |   |
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**SECTION G: FORMS**

On the following pages you will find all finalized forms for printing and distributing.

**SECTION H: APPENDICES**

**H1. References**

Boughanem, J., R. Riaz, et al. (2011). "Functional and Radiographic Outcomes of Juvenile Osteochondritis Dissecans of the Knee Treated With Extra-Articular Retrograde Drilling." Am J Sports Med **39**(10): 2212-2217.

Edmonds, E., J. Albright, et al. (2010). "Outcomes of extra-articular, intra-epiphyseal drilling for osteochondritis dissecans of the knee." Journal of Pediatric Orthopedics **30**(8): 870-878.

Kocher, M., L. Micheli, et al. (2001). "Functional and Radiographic Outcome of Juvenile Osteochondritis Dissecans of the Knee Treated with Transarticular Arthroscopic Drilling." The American Journal of Sports Medicine **29**(5): 562-566.

**H2. IRB Documents**

On the following pages, you will find the finalized consent form, the approved protocol, and the approval letter from your institutions’ IRB.

**H3. PATIENT ID ASSIGNMENT LOG**

On the following pages you will find the patient ID assignment log to be completed for all screened patients. Add sheets as necessary with consecutive patient IDs.

Each patient ID consists of two parts. The first two digits (\_\_ \_\_ - ) refer to the institution a patient is being treated at. For example, all patients seen at Boston Children’s Hospital will start with 11. The next three digits ( - \_\_ \_\_ \_\_ ) are sequential and represent the patient. The last character corresponds to the side of interest (either “R” or “L”).

Once a patient is identified as possibly eligible, enter the patient name and MRN into the ID log and indicate the side of interest once known. Notice two IDs are given for each patient, one for the right leg and one for the left leg. Only bilateral patients will use both IDs assigned to them. Once a patient is seen in clinic, complete the rest of the log. Notice the two sections corresponding to the registry and the RCT. Under the RCT section, once the patient has been entered into the online randomization system, check the “Randomization Initiate?” box.

**H4. INSTITUTION SPECIFIC PROTOCOLS**

In this section, you will find procedures and protocols specific to your institution for consenting patients, who to contact in clinic about patients, etc.