Standard Operating Procedures for CORTICES Registry - Antegrade rigid intramedullary nailing of tibial diaphyseal fractures

When entering your patient data, you will be asked to enter a new or existing Record ID. Please use your 2-digit Unique Site Number (shown below) for your site's data.

SITE #	SITE	SITE #	SITE
20	Boston Children's	30	Le Bonheur Children's/Campbell Clinic
21	Levine Children's	31	Lurie Children's
22	Children's Atlanta	32	Nationwide Children's
23	Children's Colorado	33	Rady Children's
24	Scottish Rite for Children	34	Seattle Children's
25	Children's LA USC	35	St. Louis Children's
26	Children's Philadelphia	36	Texas Children's
27	Cincinnati Children's	37	Vanderbilt Children's
28	CS Mott Children's	38	UCSF Benioff Children's Hospital
29	Gillette Children's		

To generate your REDCap Record IDs, please use the following format (below), where 'S' is the 2-digit site code and 'P' is the 3-digit record ID. The IDs should be sequentially recorded.

S S – P P P

2-digit Unique **Site** Number

3-digit Sequential **Patient** ID Number

For example, BCH's first patient would have a REDCap ID of "20-001". BCH's twentieth patient would have a REDCap ID of '20-020'. It is crucial that sites use the correct site ID to avoid duplicate REDCap IDs.

***Note:** If you were a site involved with testing this REDCap and inputted training data (**BCH, WUSTL, Vanderbilt, Colorado, Nationwide, Campbell Clinic, Rady San Diego, Lurie Children's**), please review all fields for your test patients as the REDCap was changed. You may keep the same Record ID for the test patient, but the data must be re-validated.

CPT/ICD9/ICD10 Codes Search Query

CPT 27759: *Treatment of tibial shaft fracture (with or without fibular fracture) by intramedullary implant, with or without interlocking screws and/or cerclage*

CPT procedural codes are the same for flexible and rigid, so must look in OP report or x-ray to specify that we are finding patients who had surgery with a rigid intramedullary nail (IMN)

Although we know that CPT codes work for BCH and WashU we want to ensure that we collect all the patients that we have please also check the following diagnostic codes:

ICD codes:

ICD 9 Codes

823.2	823.8
823.20	823.80
823.22	823.82
823.3	823.9
823.30	823.90
823.32	823.92
823.4	824.4
823.40	824.8

ICD 10 Codes

S82.222A	S82.222B	S82.242B	S82.291C
S82.192B	S82.231A	S82.251A	S82.292A
S82.201A	S82.231B	S82.251B	S82.292B
S82.201B	S82.232A	S82.251C	S82.302A
S82.201C	S82.232B	S82.252A	S82.841A
S82.202A	S82.235A	S82.252B	S82.492B
S82.202B	S82.241A	S82.262A	S89.121A
S82.222A	S82.242A	S82.291A	

Data Entry Phases: Will go through these phases of data entry for the study

Phase 1- XRAYS: Coordinators will query the medical record using CPT codes, look through x-rays and determine if participant has a Rigid Tibia Nail.

Phase 2- PIs Work: Coordinators will send list/excel of participants with a Rigid Nail to PIs to determine Open/Closed Physis, grade of physis (0,1,2), and if eligible the PIs will enter Radiographic Measurements, Skeletal Maturity Age and additional PI specific data entry points

Phase 3- Chart Data: This information will be sent back to Coordinators for entry and additional chart review questions will be inputted through REDcap

Phase 1: XRAY Rigid Nail Identification

Coordinators will look through x-rays and determine if participant has a Rigid Tibia Nail

For X-rays a singular nail will be shown for rigid nails and two nails in an almost X shape will be shown for flexible nails, **flexible nails make the patient ineligible.**

Figure 1: Rigid Nail

Figure 2: Flexible Nails (to be excluded)

OP Report:
To identify rigid nails, look for nails that are stated as being at least 7-8 mm in diameter or say rigid on the report. Also look for reports that specify only one nail being used.
Some examples of common manufactured rigid nails are Smith and Nephew IMN Trigen.

For flexible nails look for nail that are 2 to 4 mm in diameter, two nails will be used during surgery may also be called an elastic nail ex elastic titanium nail 3.5 mm. These will not be included in our data.

Common Manufacturer for flexible IMN nail is Synthes nail (be careful not to confuse with Synthes nail kit)
Note that growing rods, retrograde rush rods and rods that are hooked are not to be included. There will be some surgeries with screws only, those are also to be excluded.

Phase 2: PI Work

Coordinators will send list/excel of participants with a Rigid Nail to PIs to determine Open/Closed Physis, grade of physis (0,1,2), and if eligible the PIs will enter Radiographic Measurements, Skeletal Maturity Age and additional PI specific data entry points

After all patients with rigid nails have been identified by the coordinator, these IDs must be sent to a PI. Determining whether a patient is skeletally immature by identifying an open physis may be difficult and subjective.

PI/designated individual must review all potentially eligible patients. An excel sheet template is provided to allow ease of eligibility screening for the PI.

This excel sheet will be used obtain the necessary radiographic measurements (See “Radiographic Measurements” section of the guide). If the PI is not doing the measurements, they need to determine who they are delegating the task to. (The designate must also attend all relevant trainings necessary for collecting skeletal age by use of the Skeletal Maturity App). Once the PI has determined which patients have open physes the coordinator will begin REDCap data entry.

Study-Specific Definitions

Looking for patients with an open physis which are classified as skeletally immature

Open physis

For this study, we will use lateral tibial physis fusion as the definition for an open physis that determines skeletal immaturity. This will be determined by use of the Skeletal Age App to grade lateral tibial physis fusion (TIB-Q). Gradings of 0 will be included and a grading of 1 or 2 will be excluded.

Included

Grade 0 (Absent fusion): Radiolucent gap between epiphysis and metaphysis visible thorough entire lateral proximal tibia

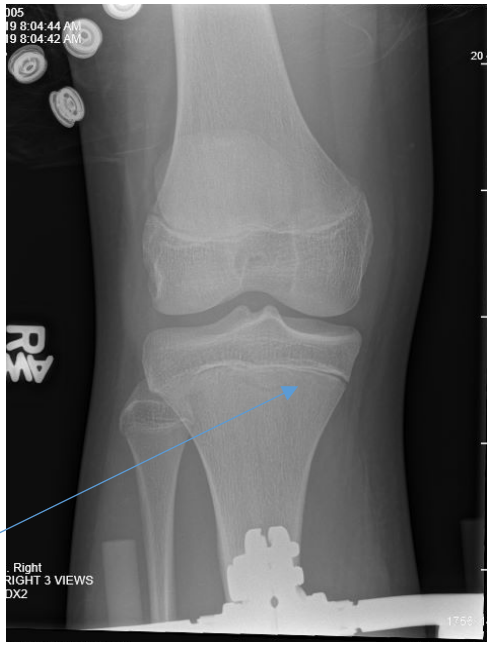
Excluded

Grade 1 (Incomplete fusion): Gap between epiphysis and metaphysis only visible laterally

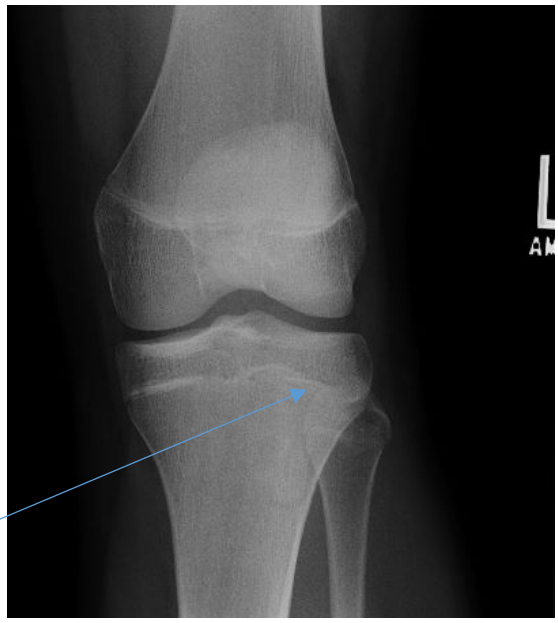
Grade 2 (Complete fusion): Gap between epiphysis and metaphysis is completely gone

Skeletal maturity: complete closure of the physis x-ray
X-ray examples of closed vs open physis

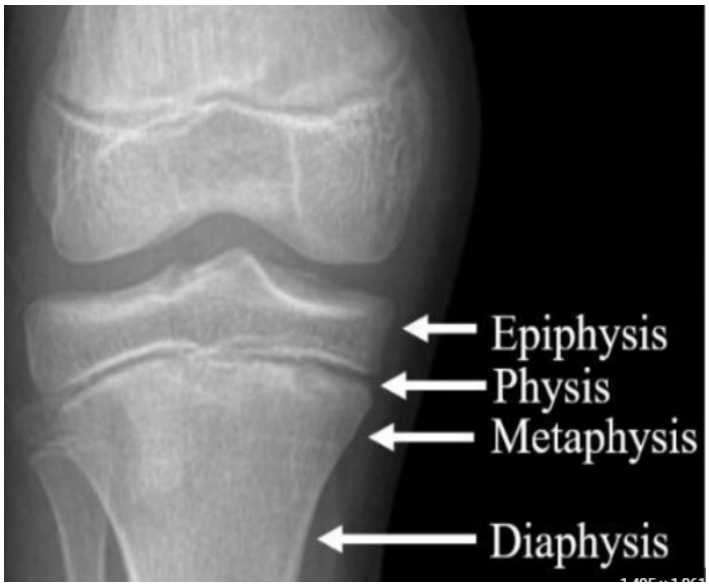
Skeletal Immaturity- open physis (TibQ 0)



Skeletal Immaturity- partially open physis (TibQ 1)



Skeletal Maturity- closed physis (TibQ 2)



Tibia shaft
The tibial shaft (body) is the straight segment of the tibia between the expanded proximal and distal ends.
Diaphysis

The long tubular midportion of bone that ends in the metaphysis, the flared portion of bone that is separated from the epiphysis by the growth plate or physis.

Phase 3: Coordinator Chart Data Entry

This information will be sent back to Coordinators for entry and additional chart review questions will be inputted through REDcap

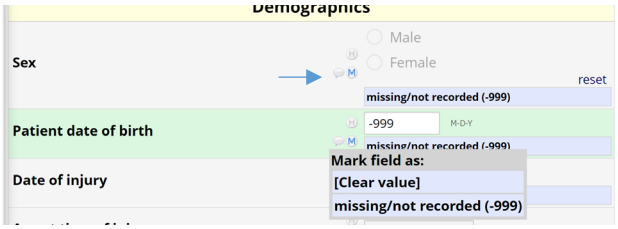
Form Completion Technique

All data is to be entered directly into REDCap from the medical records.

When entering data, please follow the rules below:

1. Mark REDCap page status for each form as appropriate:
    a. **Incomplete (RED):** Data not fully entered
    b. **Complete (GREEN):** Data is fully entered

2. Use missing code field (no fields/questions should be left blank in order to be considered Complete)
    a. -999 = missing/not recorded
        i. In instances where a field is not found in the medical record, or a measurement could not be done, please click the M icon next to the variable options and then choose **"missing/not recorded (-999)".** Once the missing data code is chosen, the question becomes greyed out.



Eligibility - REDCap

The inclusion and exclusion criteria for the study are as follows:

Inclusion:

- Participant younger than 18 years at presentation
- Diagnosed with tibial shaft or diaphyseal fracture with open physis as identified by physician (*Defined as Skeletal Age App Tib-Q type 0)
- Treated with antegrade rigid tibial intramedullary nail (can include patients that previously had internal fixation and then came back for rigid nail)
- Presented at or transferred to a CORTICES-participating institution between January 2010 and May 2025 (transfer refers to patients that did not present initially at CORTICES institution, but were transferred and received surgery at CORTICES institution).

Exclusion:

- Patient is missing first AP and lateral of tibia obtained post-operatively
- Patient has flexible rods, growing rods, retrograde rush rods and rods that are hooked
- Patients that only treatment was a nail removal at a CORTICES institution

If any of the inclusion criteria are not met or if any of the exclusion criteria are met, the patient is not eligible for further data collection. Answer "No" to the final question on this instrument and do not proceed. Otherwise, answer "Yes" and proceed to Data instrument.

Data Entry

Demographics

Patient sex

- Indicate whether patient is Male or Female
    - Menarche
      If Female, indicate if the patient is pre-menarchal, post-menarchal, or select missing/Not recorded field" if the answer is unattainable.

Race

- Check all that apply

Neighborhood Atlas ADI Score

- Go to https://www.neighborhoodatlas.medicine.wisc.edu/mapping. Enter state and change ADI Score to National Percentiles. Enter patient's full home address and record NATIONAL Percentile ADI Score only.
    - If the patient's home address at the time of injury is known (sometimes specified in Discharge Paperwork), use that information. Otherwise, use the location on file for the patient.

Patient date of birth

- Enter in the MM/DD/YYYY format

Date of Injury

- Enter in the MM/DD/YYYY format

Age at time of injury

- Calculated field- will display the age after date of birth and date of injury have been entered

Height

- Enter the patient's height at presentation (measurement within 6 months of presentation)

Weight

- Enter the patient's weight at presentation (measurement within 6 months of presentation)

BMI

- Calculated- will display after height and weight are entered

Injury Characteristics

Mechanism of injury

- Select the reported mechanism of injury.
    - If "Other," please specify in the open text field

MVA/MCA/ATV: MVA: Motor Vehicle Accident High impact, MCA: Motorcycles and moped Accident, All Terrain Vehicle Accident.

Auto-ped: Automatic vehicle vs. pedestrian, includes non-motorized bicycle vs. car, and children struck on skateboards and non-motorized scooters.

Sports

Fall from height: fall from greater than the height of the person

Other: Any mechanism not otherwise included

Date of surgery

- Enter in the MM/DD/YYYY format

Age at time of surgery

- Calculated field- will display after date of birth and date of surgery are entered

Time from injury

- Calculated field- will display after date of injury and date of surgery are entered

Surgical technique

- Indicate if the patient received an open or closed reduction (should be found in op note)

Nail technique

- Indicate the nail technique used (should be found in op note)
  - Using the search tab in the op notes, use the words "suprapatellar, infrapatellar, and extraarticular lateral" to find the technique used. If you cannot determine the method enter "–999" in the other section.

Nail diameter

- In cm (should be found in op note)

Nail length

- In cm (should be found in op note)

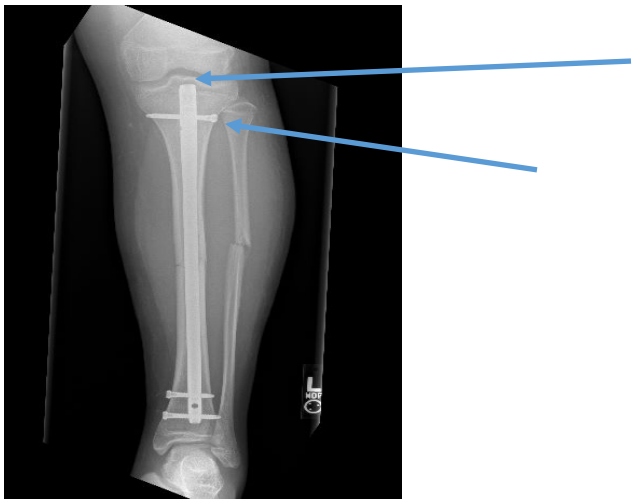
Nail manufacturer

- Should be found in op note

Nail location

- Select the location of the nail (should be found in op note)
  - Do interlocking screws cross physis? (proximal tibia physis)
    If "above physis" is selected, indicate whether the interlocking screws cross the physis

    In the example below, the top arrow shows the nail above the physis, and the bottom arrow points towards a screw that is below the physis and does not cross it.



Was there a **LEFT** hand xray obtained within 3 months of injury?

- If yes, then calculate hand bone age using Greulich/Pyle
  - Would be in radiologist or op note

Was there an ipsilateral or contralateral knee radiograph obtained within 3 months of injury?

- If yes, then calculate Modified Fels/Liu bone age using Skeletal age app
  - https://apps.apple.com/us/app/whats-the-skeletal-maturity/id1564285837
  - Use the link provided above and follow the instructions to calculate bone age.

Fracture location

- Select location of the fracture

Fracture characteristics

- Select the fracture type using the below criteria

Transverse	Fracture line runs perpendicular to the bone axis
Spiral	Fracture line wraps around the bone; there may be 2 superimposed fracture lines and a fracture corner
Oblique	Fracture line is at an angle from the transverse plane; single fracture line
Comminuted	Fracture that is in 3 or more pieces

(should be in op note)

Was it an open fracture?

- In the op note, if the fracture site was opened to achieve reduction, then it is considered open reduction. If done without opening the fracture site (with or without clamps) then it would be considered a closed reduction.
  - Can look for keywords/phrases such as “small incision made over medial aspect of tibia” or “incision over fracture site”

Fibula fracture

- Indicate if there was a fibula fracture (OP Note)
  - Location

    If there was, enter location of fibula fracture

OTA Classification

- Use the figure provided in REDCap to determine OTA classification

Associated injuries

- Select any associated injuries that apply
  - If “Other,” please specify in the open text field

Date of x-ray depicting radiographic healing

- Enter in the MM/DD/YYYY format
  - (should be indicated in radiology or clinic note on the date images were obtained)

Time for radiographic healing

- Calculated field- will display after date of surgery and date of x-ray depicting radiographic healing are entered

Post-op immobilization

- Enter any applicable post-op immobilization
  - If “Other,” please specify in the open text field
- For how long in cast/splint?
- For how long in boot?

- For how long in Other immobilization?
- For any post-op immobilizations selected, enter length of time in “weeks”

Date patient regained full weight bearing without assistance

- Enter in the MM/DD/YYYY format

Time to full weight bearing without assistance

- Calculated field- will display after date of surgery and “date patient regained full weigh bearing without assistance” are entered

Complications?

- Indicate if there were any complications

Complications

  - If yes, select any complications that apply
  - If “Other,” please specify in the open text field

Only list complications that are POST TREATMENT. Both deep and superficial infections are included. NV = nerve or vessel injury. Do not include Compartment syndrome or hardware removal as complications.

Return to OR for HWR

- Indicate whether patient returned to OR for HWR (hardware removal)
- Indicate whether they returned to a CORTICES institution or outside for the removal

Date of Surgery

- Enter in the MM/DD/YYYY format

Full return to normal activities and sports??

- Indicate if patient returned to activities and sports
  During last visit check note for mention of returning to normal activities
- If yes, then indicate if the activities/sports were at the same level as before the injury
- Select “Unknown” if it cannot be found

Last date of follow-up after injury

- Enter in the MM/DD/YYYY format

Radiographic Measurements

Coordinators will have PI’s fill out this section

We recommend having the PI fill out this section after determining if the patient is eligible with an open physis

Did patient reach skeletal maturity by the last postoperative visit?

Skeletal Immaturity

Skeletal Maturity

- X-ray on the left depicts an unclosed physis (skeletal immaturity) and the one on the right shows closure of the physis (skeletal maturity)
    - Date skeletal maturity was observed
    - Enter in the MM/DD/YYYY format
    - How many months between injury and skeletal maturity?
    - Calculated field- display after “date of injury” and “date skeletal maturity was observed”

Date of final post op visit:

- Enter the last date the patient was evaluated post op

First Ap and lateral of tibia obtained post-operatively [2 months to 4 months post-op]

- Enter
    - Date of First Post-OP AP X-ray
    - Date of First Post-OP LAT X-ray
    - MPTA
    - LDTA
    - PPTA
    - ADTA

AP and lateral of tibia obtained after skeletal maturity (closure of proximal tibial physis).

- Enter
    - Date of AP X-ray
    - Date of LAT X-ray
    - MPTA
    - LDTA
    - PPTA
    - ADTA

If patient was skeletally immature at last postop visit [2 months to 4 months post-op]: latest AP and lateral of tibia

- Enter
    - Date of AP X-ray

- Date of LAT X-ray
- MPTA
- LDTA
- PPTA
- ADTA

Was a standing AP of both lower extremities obtained within 2 months – 4 months post-op?

- Enter

Date of Left X-ray

- Enter

Date of Right X-ray

- Enter

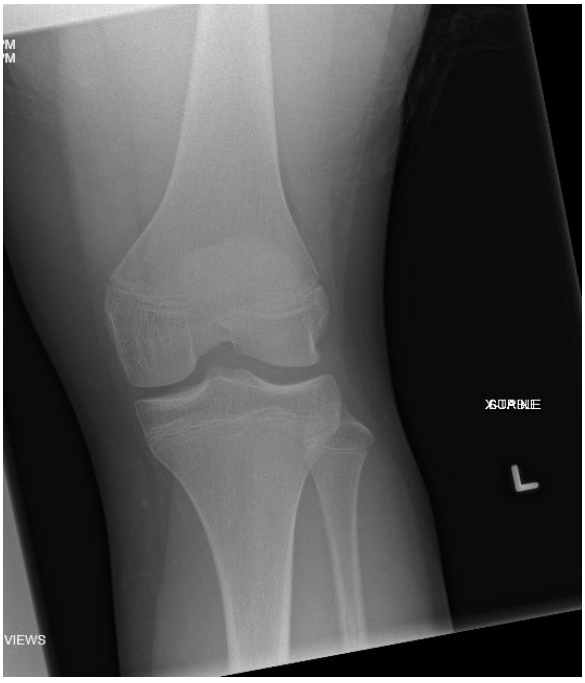
Was a standing AP of both lower extremities obtained after skeletal maturity was reached?

- Enter
  - Date of Left X-ray
  - Date of Right X-ray
  - MPTA left
  - MPTA right
  - LDTA left
  - ADTA right
  - AP standing hips to ankles
  - Leg length discrepancy
  - MAD (mechanical axis deviation)

Supplemental Examples

Skeletal Immaturity (TibQ 0)

Skeletal Maturity (TibQ 2)



Skeletal Immaturity (TibQ 1)

Skeletal Maturity (TibQ 2)