



## Data Collection Worksheet

**Please Note:** The Data Collection Worksheet (DCW) is a tool to aid integration of a PhenX protocol into a study. The PhenX DCW is not designed to be a data collection instrument. Investigators will need to decide the best way to collect data for the PhenX protocol in their study. Variables captured in the DCW, along with variable names and unique PhenX variable identifiers, are included in the PhenX Data Dictionary (DD) files.

### Part I: Study of Osteoporotic Fractures (SOF) Fractures and Falls History: History of Fractures Questionnaire

#### FAMILY HISTORY OF BROKEN BONES AND FRACTURES

Clinic use only

ID

Date

1. Has a **doctor** ever said that you had a broken or fractured bone? (MARK ONE BOX.)

Yes

No PLEASE GO TO QUESTION 2

Dont Know PLEASE GO TO QUESTION 2

**IF YES**, please write down the names of all the bones you have broken (for example, "wrist" or "spine") and your age when you broke that bone.

Broken Bone	Age When Broken

**HAS A DOCTOR EVER TOLD YOU THAT YOU HAD:**

2. Osteoporosis, sometimes called thin or brittle bones?

Yes

No PLEASE GO TO QUESTION 3

Dont Know PLEASE GO TO QUESTION 3

IF YES, how old were you when a doctor first told you this? I was\_\_\_\_years old.

3. Fracture of the spine or fracture of the vertebrae?

Yes

No

Dont Know

IF YES, how old were you when a doctor first told you this? I was\_\_\_\_years old.

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## Part II: Framingham Osteoporosis Study Fracture Assessment Form

Note: The PhenX Skin, Bone, Muscle and Joint Working Group recommends that this form be completed by personnel trained in performing medical records review.

### HIP FRACTURE FORM

DATE HIP FRACTURE OCCURRED: \_\_\_\_/\_\_\_\_/\_\_\_\_ (Month/Day/Year)

1. SOURCE(S) OF HIP FRACTURE CONFIRMATION:

1.1. Orthopedic notes

0  No

1  Yes

1.2. X-ray report

0  No

1  Yes

1.3. Discharge summary

0  No

1  Yes

1.4. OR report

0  No

1  Yes

1.5. ER notes

0  No

1  Yes

1.6. Other \_\_\_\_\_

0  No

1  Yes

2. HIP FRACTURE SIDE:

1  Right

2  Left

9  Unknown

3. HIP FRACTURE LOCATION:

1.0

Unknown

1.1

Intertrochanteric

1.2

Femoral neck (subcapital)

1.3

Other \_\_\_\_\_

4. HIP FRACTURE TREATMENT:

1  Open Reduction Internal Fixation (ORIF or pinning)

2  Arthroplasty/hemiarthroplasty (femoral head replacement)

3  Other \_\_\_\_\_

4  Cast or other immobilization

5 [ ] None

9 [ ] Unknown

5. OTHER FRACTURE(S) OCCURED AT SAME TIME:

0 [ ] No

1 [ ] Yes

9 [ ] Unknown

6. CIRCUMSTANCES OF HIP FRACTURE:

1 [ ] Fall from standing height or less

2 [ ] Motor vehicle accident or fall from greater than standing height

3 [ ] Other

9 [ ] Unknown

7. LOCATION OF FALL OR TRAUMA:

1 [ ] Outside

2 [ ] Inside

3 [ ] Other \_\_\_\_\_

8 [ ] n/a \_\_\_\_\_

9 [ ] Unknown

8. TIME OF DAY FRACTURE OCCURRED:

1 [ ] Daytime (6am-6pm)

2 [ ] Night (6:01pm to 5:59am)

3 [ ] Other \_\_\_\_\_

9 [ ] Unknown

9. DEATH OCCURED DURING HIP FRACTURE HOSPITALIZATION:

0 [ ] No

1 [ ] Yes

8 [ ] n/a (no hospitalization)

9 [ ] Unknown

10. DETAILED CIRCUMSTANCES OF HIP FRACTURE:

1 [ ] **Fall from standing height or less**-includes most injuries due to tripping over something, slips in the shower or bathtub, or falling out of a chair or bed (unless standing on it), in which the participant lands on the surface at the same height as the surface he/she was standing on

2 [ ] **Falls on stairs, steps or curbs**-includes all falls during change of level, such as stepping up or down stairs, steps, or curbs

3 [ ] **Fall from more than standing height, but NOT on stairs**-includes falls from heights such as off a ladder or while standing on a table or chair, off a porch, out of a window, etc.

4 [ ] **Minimal trauma other than a fall**-includes vertebral fractures associated with coughing, stepping down a step, etc., and rib or other fractures associated with turning over in bed, etc.

5 [ ] **Moderate trauma other than a fall**-includes collisions with objects during normal activities (e.g. stub toe, hit hand against door frame, walking into door), twisting or turning ankle (or ankle fractures).

6 [ ] **Severe trauma other than a fall**-includes motor vehicle accidents, struck by a car, hit by rapidly moving projectile (golf ball, golf club), assault

7 [ ] **Pathologic fracture**-usually associated with cancer in bone

8 [ ] **Unknown/Dont know**

11. DATE DATA RETRIEVAL COMPLETED: \_\_\_\_/\_\_\_\_/\_\_\_\_ (Month/Day/Year)

12. DATE OF ADJUDICATION BY MD FRACTURE COORDINATOR: \_\_\_\_/\_\_\_\_/\_\_\_\_  
(Month/Day/Year)

13. FINAL ADJUDICATION BY ENDPOINTS COMMITTEE REQUIRED:

0 [ ] No

1 [ ] Yes

14. DATE OF ADJUDICATION BY ENDPOINTS COMMITTEE: \_\_\_\_/\_\_\_\_/\_\_\_\_  
(Month/Day/Year)

15. Comments (not for data entry):

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**NON-HIP FRACTURE FORM**

DATE FRACTURE OCCURRED: \_\_\_\_/\_\_\_\_/\_\_\_\_ (Month/Day/Year)

**16. SOURCE(S) OF FRACTURE CONFIRMATION:**

**16.1. Orthopedic notes**

0  No

1  Yes

**16.2. X-ray report**

0  No

1  Yes

**16.3. Discharge summary**

0  No

1  Yes

**16.4. OR report**

0  No

1  Yes

**16.5. ER notes**

0  No

1  Yes

**16.6. Other \_\_\_\_\_**

0  No

1  Yes

**17. FRACTURE SIDE:**

1  Right

2  Left

3 [ ] Axial (vertebral, pelvis, nasal, sacrum, sternum, skull)

9 [ ] Unknown

**18. FRACTURE LOCATION:**

(see fracture location codes, write in) \_\_\_\_\_

**19. FRACTURE TREATMENT:**

1 [ ] Open Reduction Internal Fixation (ORIF or pinning)

2 [ ] Arthroplasty/hemiarthroplasty (femoral head replacement)

3 [ ] Other \_\_\_\_\_

4 [ ] Cast or other immobilization

5 [ ] None

9 [ ] Unknown

**20. OTHER FRACTURE(S) OCCURED AT SAME TIME:**

0 [ ] No

1 [ ] Yes

9 [ ] Unknown

**21. CIRCUMSTANCES OF FRACTURE:**

1 [ ] Fall from standing height or less

2 [ ] Motor vehicle accident or fall from greater than standing height

3 [ ] Other

9 [ ] Unknown

**22. LOCATION OF FALL OR TRAUMA:**

1 [ ] Outside

2 [ ] Inside

3 [ ] Other \_\_\_\_\_

8 [ ] n/a \_\_\_\_\_

9 [ ] Unknown

23. TIME OF DAY FRACTURE OCCURRED:

- 1 [ ] Daytime (6am-6pm)
- 2 [ ] Night (6:01pm to 5:59am)
- 3 [ ] Other \_\_\_\_\_
- 9 [ ] Unknown

24. DEATH OCCURRED DURING FRACTURE HOSPITALIZATION:

- 0 [ ] No
- 1 [ ] Yes
- 8 [ ] n/a (no hospitalization)
- 9 [ ] Unknown

25. DETAILED CIRCUMSTANCES OF FRACTURE:

1 [ ] **Fall from standing height or less**-includes most injuries due to tripping over something, slips in the shower or bathtub, or falling out of a chair or bed (unless standing on it), in which the participant lands on the surface at the same height as the surface he/she was standing on

2 [ ] **Falls on stairs, steps or curbs**-includes all falls during change of level, such as stepping up or down stairs, steps, or curbs

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5 [ ] **Moderate trauma other than a fall**-includes collisions with objects during normal activities (e.g. stub toe, hit hand against door frame, walking into door), twisting or turning ankle (or ankle fractures).

6 [ ] **Severe trauma other than a fall**-includes motor vehicle accidents, struck by a car, hit by rapidly moving projectile (golf ball, golf club), assault

7 [ ] **Pathologic fracture**-usually associated with cancer in bone

8 [ ] **Unknown/Dont know**

26. DATE DATA RETRIEVAL COMPLETED: \_\_\_\_/\_\_\_\_/\_\_\_\_ (Month/Day/Year)

27. DATE OF ADJUDICATION BY MD FRACTURE COORDINATOR: \_\_\_\_/\_\_\_\_/\_\_\_\_



(Month/Day/Year)

28. FINAL ADJUDICATION BY ENDPOINTS COMMITTEE REQUIRED:

0 [ ] No

1 [ ] Yes

29. DATE OF ADJUDICATION BY ENDPOINTS COMMITTEE: \_\_\_\_/\_\_\_\_/\_\_\_\_  
(Month/Day/Year)

30. Comments (not for data entry):

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#### FRACTURE LOCATION CODES

- 1.0 - Hip (USE HIP FRACTURE FORM)
  - 1.1 - femoral neck
  - 1.2 - intertrochanteric
  - 1.3 - other
- 2.0 - Wrist (unspecified)
  - 2.1 - distal radius (Colles; Smith)
  - 2.2 - distal ulna
  - 2.3 - both distal radius and ulna
- 3.0 - Skull
- 4.0 - Facial bones (includes jaw, nose, cheek)
- 5.0 - Neck
  - 5.1 - first cervical vertebra
  - 5.2 - second cervical vertebra
  - 5.3 - third cervical vertebra
  - 5.4 - fourth cervical vertebra
  - 5.5 - fifth cervical vertebra
  - 5.6 - sixth cervical vertebra
  - 5.7 - seventh cervical vertebra
  - 5.8 - multiple cervical vertebrae
- 6.0 - Shoulder
  - 6.1 - clavicle or collar bone

- 6.2 - scapula (shoulder blade)
- 7.0 - Arm (unspecified)
  - 7.1 - humerus (upper arm)
  - 7.2 - elbow
  - 7.3 - radius a/o ulna, proximal or mid shaft
- 8.0 - Hand
- 9.0 - Fingers
- 10.0 - Other small bones in wrist
- 11.0 - Ribs
- 12.0 - Chest/Sternum
- 13.0 - Thoracic Spine (unspecified)
  - 13.1 - first thoracic vertebra
  - 13.2 - second thoracic vertebra
  - 13.3 - third thoracic vertebra
  - 13.4 - fourth thoracic vertebra
  - 13.5 - fifth thoracic vertebra
  - 13.6 - sixth thoracic vertebra
  - 13.7 - seventh thoracic vertebra
  - 13.8 - eighth thoracic vertebra
  - 13.9 - ninth thoracic vertebra
  - 13.10 - tenth thoracic vertebra
  - 13.11 - eleventh thoracic vertebra
  - 13.12 - twelfth thoracic vertebra
  - 13.13 - multiple thoracic vertebrae
- 14.0 - Lumbar Spine (unspecified)
  - 14.1 - first lumbar vertebra
  - 14.2 - second lumbar vertebra
  - 14.3 - third lumbar vertebra
  - 14.4 - fourth lumbar vertebra
  - 14.5 - fifth lumbar vertebra
  - 14.6 - multiple lumbar vertebrae
- 15.0 - Pelvis
- 16.0 - Tailbone/Coccyx/Sacrum
- 17.0 - Leg (unspecified)
  - 17.1 - femur (not hip)
  - 17.2 - patella
  - 17.3 - tibia
  - 17.4 - fibula
  - 17.5 - both tibia/fibula
- 18.0 - Ankle (includes distal tibia and fibula)
- 19.0 - Foot/Metatarsal

- 20.0 - Toes
- 21.0 - Heel/Os Calcis

## **Fracture Adjudication**

When data retrieval for a reported fracture has been completed, the individual investigating the reported fracture will attach all relevant materials to the fracture form and complete the form. The packet will then be passed on to Dr. (FILL IN NAME) for review and fracture adjudication. Dr. (FILL IN NAME) will decide if the reported fracture should be coded as a "fracture" or a "non-fracture". Dr. (FILL IN NAME) may determine there is not sufficient evidence to determine fracture status. In this case, the packet will be returned to the field coordinator for further investigation.

If Dr. (FILL IN NAME) decides an additional opinion on fracture status is warranted, he/she may send the fracture in question to the Endpoints Committee for final adjudication. The Committee, comprised of Drs. (FILL IN NAME OF PHYSICIAN, FILL IN NAME OF SECOND PHYSICIAN) and a consulting orthopedic surgeon, will review the fracture information and come to a final decision on the status of the reported fracture.

If a reported fracture is deemed a true "fracture" by Dr. (FILL IN NAME) or the Endpoints Committee, the fracture form will be sent to be entered into the official fracture database. Those coded as a "non-fracture" will be stored in the field coordinators office.

Protocol source: <https://www.phenxtoolkit.org/protocols/view/170901>