

Study data declaration

Completed and signed before study data is sent. Every item below is a reason a study has had to stop and go back.

1 STUDY

Study title

Institution

Department

Investigator

Osteo3d reference

Ethics committee reference

Date of approval

2 BEFORE THE DATA IS SENT

APPROVALS

- ☐ Ethics committee approval, or a documented waiver, is in hand and its reference is recorded.
- ☐ The approval covers the use the data is being sent for, including analysis by an external party.
- ☐ Where consent was taken, it is checked against the use now intended.

DE-IDENTIFICATION

- ☐ Patient name, identifiers, dates of birth and accession numbers are removed from every file.
- ☐ Free-text description fields are checked. Names are routinely typed into study and series descriptions at the scanner.
- ☐ Folder and file names are checked. A name in a path identifies a patient as surely as a tag does.
- ☐ The key linking pseudonyms to patients is held at your institution and is not sent with the data.
- ☐ Where head or face imaging is involved, a decision is recorded on whether pixel data is shared at all.

IMAGING

- ☐ The series is the one the study needs, not simply the largest series in the folder.
- ☐ Slice thickness supports the measurement. Thin bone-kernel reconstruction is required for bone morphometry.
- ☐ The region of interest is fully covered, including the contralateral side where comparison is planned.
- ☐ Every subject is acquired to the same protocol, or the departures are recorded per subject.
- ☐ Original unprocessed series are included alongside any corrected reconstruction.

ORGANISATION AND TRANSFER

- ☐ One folder per subject, named by study identifier only.
- ☐ A subject list is supplied, carrying identifiers and grouping but no patient identity.
- ☐ Archives are readable and complete, and a sample has been opened and checked.
- ☐ The transfer route is agreed in writing before any data moves.

An item that cannot be ticked is a finding, not a delay. Where something here cannot be satisfied, say so. It usually changes the design rather than stopping the study.

3 DECLARATION

The signatories below confirm:

1. The imaging supplied with this form has been de-identified at this institution.
2. The key linking study identifiers to patients is held at this institution and has not been shared with Osteo3d.
3. The ethics committee approval referenced above covers analysis of this data by an external party.
4. This is a study. The work is not for the care of an individual patient.
5. The imaging is ours to share for this purpose, and sharing it breaches no undertaking given to the participants.

4 SIGNATURES

INVESTIGATOR

Name

Designation

Signature

Date

GUIDE OR SUPERVISOR

Name

Designation

Signature

Date

HEAD OF DEPARTMENT

Name

Designation

Signature

Date

Institutional stamp

Return the signed form with the data to contactus@osteo3d.com · +91-9900265669