Standard Operating Procedure (SOP):

Creation and Verification of Custom Image Sets from the Osteoarthritis Initiative (OAI)

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1. Purpose

This SOP defines the standardized process for creating, verifying, and approving **custom image sets derived from Osteoarthritis Initiative (OAI) imaging archives**. Because image extraction is operationally performed by a single Image Curator, this SOP emphasizes **structured, multi-step verification strategies** to ensure completeness, accuracy, and traceability.

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2. Scope

This SOP applies to:

- All custom image sets generated from OAI imaging repositories (e.g., MRI, radiographs)
- Image pulls created for research, teaching, method development, validation studies, or external collaborations
- Personnel responsible for selecting, extracting, organizing, and validating image files

This SOP does **not** cover image interpretation, scoring, segmentation, or downstream image analysis.

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3. Definitions

- **Image Pull**: The extraction and organization of image files from the OAI archive based on predefined criteria
- **Specification Document (Spec)**: Written documentation defining inclusion criteria, image types, visits, knees, and identifiers (Appendix A)
- **Structural Verification**: Validation that folder and file structures match the planned specification
- **Content Verification**: Validation that the images correspond to the correct participant, knee, visit, and image type
- **Gold Standard Image Set**: The finalized, approved image set released for use

4. Roles and Responsibilities

Role	Responsibility
Image Curator	Performs image selection, extraction, organization, and verification
Lead Investigator / Project Lead	Reviews verification documentation and approves the final image set

Note: All technical tasks may be performed by a single individual, but verification must be explicitly documented.

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5. Required Documentation

- Approved image pull specification
- Image pull log (dates, tools, source locations)
- Code or scripts used to create the image pull (e.g., SAS)
- File containing the command-line code used to execute the image transfer (e.g., Excel, text, or script file)
- Verification outputs (folder listings, counts, cross-checks)
- Discrepancy and resolution log (if applicable)
- Final image set approval documentation
- Version control records
- Approval of the Gold Standard Image Set

All documentation must be stored in the project's designated directory.

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6. Image Pull Specification

Before initiating an image pull, a specification must be finalized and approved (Appendix A). At minimum, it must define:

- Participant IDs
- Side (left/right knee)
- Visit(s) (e.g., baseline, 12m, 24m)
- Image modality and sequence (e.g., MRI sagittal DESS, PA fixed-flexion radiograph)
- Expected folder and naming conventions
- Total expected image count (if feasible)

- Unique project identifier and version number for the image set

No image extraction may begin without an approved specification from the requester and the Lead Investigator.

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7. Image Extraction Procedure

The Image Curator shall:

1. Identify source imaging file location using the OAI index files (e.g., contents##.csv) or the MRI## datasets (interim visits only).
2. Create the command-line code to transfer the images from their source location to a project-specific final image set location.
3. Extract images according to the approved specification using the command-line code
4. Organize images into a standardized folder hierarchy, typically reflecting:
    - Participant ID
    - Knee (left/right)
    - Visit
    - Image type or sequence
5. Maintain an image pull log documenting:
    - Date of pull
    - Source location
    - Filters or scripts used
    - Any deviations from the specification

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8. Verification Procedures

Because independent dual programming is not feasible for image pulls, **verification relies on multiple complementary checks**.

8.1 Structural Verification (Folder-Level QC)

The Image Curator must verify that the folder structure exactly matches the specification.

Recommended steps include:

- Use command-line tools to generate a complete directory listing of the final image set
- Confirm that all expected combinations of:
    - Participant ID
    - Knee
    - Visit
    - Image type

  are present and correctly labeled
- Any mismatch between expected and observed folder structure must be resolved before proceeding to content verification.

Example strategy:

- Generate a recursive folder list
- Compare folder names against the planned specification table and command-line code for transfer
- Confirm absence of unexpected folders or naming deviations

Outputs (e.g., .txt directory listings) must be saved and archived.

8.2 Content Verification (Image-Level QC)

The following content checks must be performed, when technically feasible:

- Spot-check images across participants, visits, and knees to confirm correct modality and anatomy
- Verify embedded metadata (where available) matches:
    - Participant ID
    - Side
    - Visit date or visit code
- Confirm image counts per folder match expectations (e.g., number of image files)

Any discrepancies must be documented.

8.3 Completeness Checks

The Image Curator must verify:

- All specified participants are present
- No extra participants are included
- All required visits, knees, and image types are included for each participant
- Missing images are expected and justifiable (e.g., missed clinic visit)

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9. Discrepancy Handling

Any discrepancy identified during verification must be:

1. Logged with description and suspected cause
2. Resolved by re-pulling, renaming, or removing images as appropriate
3. Re-verified using the same procedures
4. Documented as resolved prior to approval

No unresolved discrepancies are permitted in the final image set.

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10. Final Image Set Approval

Upon completion of verification:

- The image set is designated as the **Gold Standard Image Set**
- Final approval is documented by the Lead Investigator or Project Lead
- The image set is:
    - Locked (i.e., file permissions are changed to read-only for general users, with write access restricted to designated custodians)
    - Archived
    - Released for approved use

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11. Deviations

Any deviation from this SOP must:

- Be documented with justification
- Be approved by the Lead Investigator
- Include an assessment of potential impact on data integrity

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12. Training Requirements

Personnel performing image pulls must:

- Be trained on this SOP
- Demonstrate familiarity with OAI imaging structure and naming conventions
- Maintain documentation of SOP training
- Refresher training is required when major SOP revisions occur

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13. Revision History

Version	Date	Description	Approved By
1.0	February 5, 2026	Initial release	Jeffrey Driban

Appendix A

Specification Document Template

Requester:
Project Title:
Project Number:

Eligibility Criteria

OAI Variable	Thresholds/Criteria
Example: P02SEX	*P02SEX = 2 [Female]*

File Location/Name with Participant IDs (side):

Side: ☐ Right ☐ Left ☐ Bilateral ☐ See file above

Image Modality/Sequence and Visits:

Image Modality	00	12	18	24	30	36	48	72	96
Radiograph: Bilateral Fixed-Flexion Knee	☐	☐	☐	☐	☐	☐	☐	☐	☐
Radiograph: Lateral Knee	☐	☐							
Radiograph: AP Pelvis	☐	☐					☐		☐
Radiograph: PA Bilateral Hand	☐						☐		
Radiograph: PA Dominant Hand	☐						☐		
Radiograph: Full Limb		☐		☐		☐	☐		
MRI: AX MPR	☐	☐	☐	☐	☐	☐	☐	☐	☐
MRI: COR MPR	☐	☐	☐	☐	☐	☐	☐	☐	☐
MRI: COR T1 3D FLASH	☐	☐	☐	☐	☐	☐	☐	☐	☐
MRI: COR IW TSE	☐	☐	☐	☐	☐	☐	☐	☐	☐
MRI: SAG 3D DESS	☐	☐	☐	☐	☐	☐	☐	☐	☐
MRI: SAG IW TSE	☐	☐	☐	☐	☐	☐	☐	☐	☐
MRI: SAG T2 MAP	☐	☐	☐	☐	☐	☐	☐	☐	☐
MRI: AX T1 Thigh	☐	☐	☐	☐	☐	☐	☐	☐	☐
MRI: Locator Knee	☐	☐	☐	☐	☐	☐	☐	☐	☐
MRI: Locator Thigh	☐	☐	☐	☐	☐	☐	☐	☐	☐

Number of participants:
Number of knees:
Number of knee-visits:
Total number of image folders (excluding repeat scans):

Expected folder and naming conventions:
For example: D:/project_name/image_sequence/ParticipantID_side/Visit/images

Other Requirements:

By signing below, the undersigned agree that this document constitutes the approved and complete specifications for the requested custom image pull from the Osteoarthritis Initiative (OAI). These specifications will serve as the authoritative reference for image selection, extraction, and verification. Any changes require documented approval by both parties.

Signatures

Requesting Party

Name: _____

Title / Affiliation: _____

Signature: _____

Date: _____

OAI CORE Knowledgebase

Name: _____

Title / Affiliation: _____

Signature: _____

Date: _____