Radiographic Procedure Manual for Examinations of the Knee, Hand, Pelvis and Lower Limbs

Osteoarthritis Initiative: A Knee Health Study
RADIOGRAPHIC PROCEDURE MANUAL FOR:

OAI

PROTOCOL:

Osteoarthritis Initiative: A Knee Health Study

Version 2.1
August 2006
Dear Clinic Coordinator and Radiographic Technologist,

The OAI requires that the Clinic Coordinator and Radiographic Technologist read and fully understand the Radiographic Procedure Manual for the OAI study protocol. This requirement should be completed before imaging any participant in the OAI study. Additional requirements for OAI certification are listed in section 2.2 of the manual.

Please have all applicable study personnel sign and date this form to confirm completion of this requirement. The first time a clinic coordinator or technologist has completed this requirement, the form should be faxed or mailed to Andrey Semyonov at Synarc:

Andrey Semyonov  
OAI  
Synarc, Inc.  
575 Market Street, 15th Floor  
San Francisco, CA 94105

Principal Investigator: ________________________________

Site Number: ________________________________

<table>
<thead>
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<th>Who is responsible for submitting packages to Synarc?</th>
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<td>O Clinic Coordinator</td>
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All new personnel for this study must comply with this requirement as well.

- - - DO NOT REMOVE THIS PAGE – SEND A PHOTOCOPY ONLY- - -
Dear Clinic Coordinator and Radiographic Technologist,

The OAI requires that the Radiographic Technologist read and fully understand the Radiographic Procedure Manual for the OAI study protocol prior to the start of each new visit. This requirement should be completed before imaging any participant at the new follow-up visit.

Please have all applicable study personnel sign and date this form to confirm completion of this requirement. When a technologist completes this requirement subsequent to the initial certification, i.e., prior to the start of a follow-up visit, this form should be mailed or faxed to Alisa Boyd:

Alisa Boyd  
SF Coordinating Center  
185 Berry Street  
Lobby 4, Suite 5700  
San Francisco, CA 94107-1762

Principal Investigator: ____________________________
Site Number: ____________________________

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<tr>
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1.0 INTRODUCTION

The purpose of this manual is to standardize the radiograph acquisition and assessment procedures among the centers participating in the OAI study:

Osteoarthritis Initiative: A Knee Health Study

All radiologists and technologists contributing to this study are expected to have had appropriate theoretical and practical training in general radiography. Study personnel should also satisfy all local requirements for radiology licensing and registration. For the safety of participants and technologists alike, an understanding of radiation risks and radiation safety procedures is also required. Qualified radiology personnel at each clinical site are the first step toward the successful use of radiography in the OAI study. The procedure manual is designed for the clinic coordinator, the radiographic technologists, and the radiologists involved in this study. The goal of this manual is to define a standard approach to take radiographs which produce images of sufficient quality for achieving the study goals.

It is not our position that the techniques proposed in this manual are the only ones to yield acceptable results. Rather, we are providing guidelines for uniform data collection with the goal of making the results of all participating study sites consistent and comparable. This is a key to the success of any multi-center study.

This manual, taken alone, should not be considered as sufficient training in the proper technique for acquiring radiographs. All sites involved in this study will get specific training from Synarc. If there is a need to train additional technologists, please contact Synarc.

Questions regarding this manual should be directed to:

Andrey Semyonov  
OAI  
Synarc, Inc.  
575 Market Street, 15th Floor  
San Francisco, CA 94105 USA

Telephone: 415-817-8987  Fax: 415-817-8999
Email: andrey.semyonov@synarc.com

Technical questions should be directed to:

Pamona Radjpaul  
Telephone: 415-817-7954

HOURS: 8.00 am – 5.00 pm (Pacific Time)
STUDY INTRODUCTION

2.1 Protocol Overview

The Osteoarthritis Initiative (OAI) cohort study is a multi-center, longitudinal, observational study of osteoarthritis (OA) focusing primarily on knee OA. The main focus of the OAI will be on knee OA because this is the site where OA symptoms most frequently cause significant loss of function and disability. OAI’s primary objectives are to evaluate radiographic and MRI joint images as biomarkers for osteoarthritis and explore their potential as surrogate endpoints for clinical studies and treatment trials of knee OA. Because joint images are a central focus of OA, high quality radiographs acquired according to the standard protocols are critical to the success of the study. The OAI joint images will become part of a shared resource that will be available to researchers around the world.

5000 women and men between the ages of 45-79 are being recruited and enrolled at 5 clinical centers in four U.S. cities. The study is comprised of three subgroups: 1) those with clinically significant knee OA who are at risk of disease progression, 2) individuals who are at high risk of developing clinically significant knee OA, and 3) a normal control group. The baseline assessments consist of an initial eligibility assessment by telephone, a screening clinic visit and an enrollment clinic visit. There are four planned annual follow-up visits. Joint imaging biomarkers (magnetic resonance imaging and radiography) and biochemical and genetic markers (from blood and urine) are collected at baseline and at all follow-up visits. Participants are followed for changes in the clinical status of the knee and other joints, including worsening and onset of symptoms and disabilities, worsening and onset of knee structural abnormalities, and changes in other imaging and biochemical markers of OA.

2.2 Summary of Responsibilities

The role of the investigator site and radiology facility will be to:

- Complete the x-ray technologist certification requirements
  - Read and fully understand the OAI Radiographic Procedure Manual and submit the completed Sign-Off form to Synarc.
  - Receive training in the OAI radiographic protocol by Synarc, Inc. staff or another x-ray technologist certified for the study.
    - Technologists must be directly trained by Synarc, Inc. to be certified for taking fluoroscopy guided knee films.
  - Receive an OAI staff ID number from the study clinic coordinator and provide Synarc, Inc. with this OAI staff ID.
  - Pass central review of first 10 images of each type acquired according to the OAI protocol. After certification, a sample of each technologist's images will be reviewed centrally.
  - Procedure manuals should also be reviewed and signed off on annually by certified technologists using the "Radiographic Technologist's Sign-Off form found at the beginning of the study manual. Please fax this form to Alisa Boyd (415-514-8150) at the San Francisco Coordinating Center.
• Perform radiographic examinations of the left and right knee, bilateral or dominant hand, pelvis, full limb and lateral knee according to the procedures detailed in this manual.

• Review radiograph quality and obtain repeats as necessary before the participant leaves the radiology suite. Make comments on the transmittal form and the parameter log about any difficulties during the imaging process.

• Send original radiographs and transmittal forms to Synarc, Inc. as soon as possible after the radiographs are taken (preferably on at least a weekly basis).

• Maintain a permanent archive copy at the site of all film-based and digital x-ray examinations submitted to Synarc, Inc. for the duration of the study.

The role of Synarc, Inc. will be to:

• Train the technologists who are taking radiographs for the OAI.

• Review the quality of radiographs and request repeats as necessary. For non-fluoroscopy knees, pelvis, and hand radiographs a subset of films will be centrally reviewed (20% overall, but a higher percent initially). 100% of fluoroscopy-guided knee and full limb films will be centrally reviewed.

• Fax the quality review information to the Clinic Coordinator within 5 working days of receiving exams

• E-mail notification of the repeat request to the site within 5 working days of receipt and return the original exam (if hardcopy film) to the site for review when performing the repeat exam.

It is expected that the majority of examinations received will be of acceptable quality. If any problems are detected, however, Synarc, Inc. will notify the responsible site, suggest possible causes of the problem, and offer potential solutions to assist the site in producing a good quality repeat exam. The clinical site should try to avoid these errors in future exams. Acquisition of acceptable quality radiographs is the responsibility of the radiology facility.
2.3 Inclusion & Exclusion Criteria

2.3.1 Major Inclusion Criteria

- Men and women ages 45-79.

- All ethnic groups are eligible for the study, with an expected 23% of the cohort from ethnic minority groups.

- Participants must have knee pain or risk factors for knee OA.

- Participants must have a complete set of acceptable quality radiographs at baseline.

2.3.2 Major Exclusion Criteria

- Rheumatoid Arthritis (RA) or inflammatory arthritis, defined as self-report of a physician diagnosis and history of using any RA-specific prescription medications.

- Unlikely to demonstrate measurable loss of joint space during the study, defined as severe joint space narrowing in both knees on the baseline knee radiograph.

- Bilateral total knee joint replacement or plans to have bilateral knee replacement.

- Unable to undergo a 3.0 Tesla MRI exam of the knee because of contraindications.

- Positive pregnancy test.

- Unwilling to sign informed consent.

2.4 Schedule of Radiographic Examinations and Participant Subcohorts

The radiographs acquired for a participant will differ depending in their subcohort assignment and visit. To know which kind of x-ray(s) to obtain for a particular participant, review the Data from Prior Visits Report for that particular visit. (see X-ray Administrative Overview, Attachment A for examples of Data from Prior Visits Reports.)
2.4.1 Participant Cohorts and Schedule of Radiographic Examinations

The OAI participants are split into three cohorts. The progression cohort (Pr) consists of participants with symptomatic knee OA at the beginning of the study. The incidence cohort (Inc) consists of participants who do not have symptomatic knee OA at the beginning of the study, but who have a high risk of developing knee OA. The normal control cohort consists of participants who do not have knee symptoms or radiographic evidence of tibiofemoral knee OA at the beginning of the study.

The radiographs acquired for a participant will differ depending in their subcohort assignment and visit. To know which kind of x-ray(s) to obtain for a particular participant, review the Data from Prior Visits Report for that particular visit. (See X-ray Administrative Overview, Attachment A for examples of Data from Prior Visits Reports.)

2.4.2 Procedure for Repeat Exams

Repeat exams should be performed as quickly as possible. Ideally, radiographs of insufficient quality should be identified by the radiology technologist at the time of acquisition and repeated immediately.

Synarc, Inc. will also centrally review radiographs for quality and require repeats when quality is inadequate. To facilitate this, Synarc, Inc. will send a “Repeat Request” form via email to the Clinic Coordinator indicating the need and reason for a repeat exam within five working days of receiving the x-rays. This email allows the site to schedule the participant for the exam while the originals are in transit back to the site. Synarc, Inc. will return the original exam (if hardcopy film), along with a copy of the emailed “Repeat Request” form to the site for review when taking the repeat exam. Repeat exams should be taken within 2 weeks of the original radiograph.
3.0 TECHNIQUE AND EXAMINATION PROCEDURES FOR RADIOGRAPH ACQUISITION

In this section the specific requirements for the radiographic examination are presented. Because of the need to assess small changes over time, the quality criteria for radiographs in a study are stricter than in standard clinical practice. The most reliable evaluations of the radiographs require adherence to uniform acquisition and quality standards by all study sites involved.

General Comments on Radiographic Technique

If you are unable to satisfy any of the required elements, please contact Synarc, Inc. to discuss alternatives before you begin performing exams.

Contact: Andrey Semyonov
Tel. 415-817-8987 Fax 415-817-8999
Email: andrey.semyonov@synarc.com

Conventional radiographic equipment with exposure of radiographic film is recommended. Digital radiographic equipment may be used if it satisfies the requirements of the procedures described in this manual and passes a test run of submission to Synarc. Study centers that plan to use digital x-ray equipment will be contacted by Synarc, Inc. to arrange for a test run of data submission. Radiographic equipment used in this study should be in good working order and a regular quality assurance program that includes regular checks to ensure the equipment is performing properly and safely.

It is preferred that each study center use a single x-ray unit for each acquisition protocol for the duration of the study. Changing equipment can add unnecessary variability to the data. If it becomes necessary to change equipment at some time during the study, please contact Synarc, Inc. as soon as possible before this change occurs.

Please follow standard radiation protection practices. Appropriate collimation of the x-ray beam and use of a lead apron to shield the gonads should minimize radiation dose to the participant.

Before each radiographic examination, prepare the following:

- Have positioning aids present in the procedure room
- Explain the examination procedure to the participant
- Have the Transmittal Form(s) ready to fill in
- Have study supplies ready to label the radiographs immediately
- IMPORTANT: To ensure participant confidentiality and HIPPA compliance, the biographical information flashed onto the film or entered into the digital image header should include the participant study identifier (patient ID and acrostic), not the participant’s name or date of birth.
3.1 Radiographic Supplies and Forms

Listed below are radiographic supplies and forms for use for radiographic examinations:

- A hand positioning aid for consistent positioning of the hand and wrist is provided on transparencies and in this manual in section 3.4.1.
- X-ray jackets and padded mailers (if conventional film x-ray), CDs and jewel cases (if digital x-ray) and adhesive x-ray labels for films, electronic media, and jackets (see Appendix II) will be supplied by Synarc, Inc. and must be used for all participants.
- “SynaFlexer” Plexiglass positioning frame for reproducible foot fixation and knee flexion for the knee and pelvis exams.
- The Data from Prior Visits Report. This report lists which images to obtain for each participant at the current visit. See X-ray Administrative Overview, Attachment A.
- The X-ray Transmittal Form (see Appendix III) must be completed for each participant visit in which x-rays are taken. Keep a photocopy of this form in the participant’s chart and send the original along with the radiographs to Synarc. Transmittal forms are available as PDFs on the OAI website under the Documents and Forms link.
- The X-ray Parameter Log (see section 3.2 and Appendix IV) must be completed for each participant visit in which x-rays are taken. Keep this form in the participant’s chart. Do NOT send this form to Synarc.
- The Screening Knee X-ray Reading Form (included in the Screening Visit Workbook) must be completed by a validated radiologist at the site for each screening visit knee x-ray. This form should be scanned into the OAI data system. In addition, send a photocopy of this form to Synarc, Inc. along with the screening knee x-rays for each participant. Any additional comments on the reading form that the site radiologists noted should be added to the comments section of the transmittal form. Please be sure to file the original form in the participant’s chart.
- X-ray tracking forms. There is an “X-ray tracking form” for each type of x-ray examination: PA knee, Fluoro knee, lateral knee, hand, pelvis, and full limb examinations. These are scannable data collection forms that originate at the clinic and accompany the participant to x-ray and are returned to the clinic for data entry. They are described in the X-ray Administrative Overview.

3.2 X-ray Parameter Log

The primary quality assurance goal for the subsequent radiographs is to maintain consistent high image quality throughout the study. Therefore, it is essential that an x-ray Parameter Log be kept with all the imaging parameters (kVp, mAs, etc.) used for each participant. Since parameters may vary slightly from participant to participant, consistent technique can be assured only if this log is referred to at each visit. Please see log in Appendix IV. The Parameter Log is also available on the OAI website under Documents and Forms / Study Forms / X-Ray and MRI Parameter Logs. The Parameter Log must be kept in the participant’s chart. The clinic coordinator should pull the Log and send it with the participant each time they have x-rays taken. The same Parameter Log should be used for all visits for a
particular participant. If the parameters recorded do not produce a good quality image, vary the settings as needed to achieve good quality and re-record these settings on the Parameter log.

To control variables that may interfere with evaluation of the films, use the same equipment and the same equipment setup for a given participant for the duration of the study. If it becomes necessary to change equipment at some time during the study, contact Synarc, Inc. before this change occurs.
3.3 Bilateral PA Fixed Flexion Knee Radiograph

Radiographs of both the right and left knees will be acquired using this protocol in all participants at screening, 12 months, 24 months, 36 months, and 48 months. For all radiographs, please concentrate on image quality and optimum positioning of the participant since follow-up radiographs will be compared to baseline radiographs to evaluate progression of the disease.

3.3.1 Bilateral PA Fixed Flexion Knee Radiographic Technique

Exposure Technique

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<td>Film Size</td>
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<td>KVp Range</td>
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<tr>
<td>Other</td>
<td>Use Right/Left Lead Markers</td>
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Examination Procedure

At the beginning of each week the x-ray tube should be calibrated to ensure that a 10 degree caudal (toward the feet) angle as indicated by the tube angle indicator is actually 10 degrees. Angle the tube so that it is at 10 degrees caudal according to the dial. Place the inclinometer on the top of the x-ray tube so that its base is aligned with the long axis of the tube. Read off the actual degrees of the beam angle. If not 10 degrees caudal, adjust the beam angle so that the inclinometer reads 10 degrees. Mark this spot on the x-ray tube. This will be the “10 degree” beam angle that is used in the study. Record results on the inclinometer calibration form.

Positioning the Participant

- The anterior wall of the SynaFlexer positioning frame (provided by Synarc) must be in direct contact with the bucky, cassette holder or reclining table top of the radiographic unit such that there is no angle or gap between them. Lower the bucky or cassette holder so that the center of the film will be at the level of the participant’s tibiofemoral joint line. Position the center line of the positioning frame to the center of the bucky or cassette holder.
- Position the participant in a standing upright position on the frame facing the bucky, cassette holder or reclining table top.
• The great toes of both feet are placed in contact with the anterior wall of the frame (Fig. 3.3.1).

• Both feet are fixed in external rotation by pressing the inner aspects of the foot and heel against the V-shaped support on the base of the frame (Fig. 3.3.1).

• Both knees are flexed until they touch the anterior wall of the frame. This fixes the angulation of the tibias.

• With the great toes and knees still touching the anterior wall, both thighs are also pressed directly against the wall to fix the angulation of the femurs (Fig. 3.3.1).

• Gently push the participant forward with your hand in the small of the back to ensure firm contact of both thighs with the wall of the frame. IMPORTANT: the toes, knees and thighs must all be in firm contact with the wall of the frame in order for knee flexion to be reproduced exactly on follow-up radiographs.

• Body weight is distributed equally between the two legs.

• Shield the participant’s gonads with a half apron.

**Positioning the X-ray Tube and Film Comments**

• Angle the x-ray tube to 10° caudal.

• Without altering the beam angle or the vertical position of the beam, reposition the beam so that it is centered midway between the two knees at the level of the joint line, defined by the horizontal skin crease of the popliteal fossa.

  o If it is difficult to identify the knee crease in obese subjects, ask them to increase the flexion of the knees determine the knee crease and then return them to the proper flexion for imaging (pressing the thighs against the anterior wall of the frame). If this maneuver does not help, try to feel the tibial tuberosity and inferior rim of patella, and center the beam between these two anatomical structures. Mark the skin with a felt pen if necessary. Remember that beam centering above or below the knee crease will alter the projection of the tibial rims and the joint space on the radiograph and deteriorate the reproducibility of serial measurements. Accordingly, precise beam centering and angulation is critical to the success of the study.

• Collimate to the size of the film.

• Use small lead Right/Left markers and place them on the cassette close to the knees but where they will not obscure the knees or the location for study label. Properly collimated images will include the entire femoral and tibial metaphyses, the head of the fibula, at least 5 metal beads of the SynaFlexer, and the Right/Left markers.

• Expose both knees on one film and approximately equidistant from the center of the film. See special remarks for participants with varus deformity (“bow legs”).
Special Remarks

- For participants with asymmetric “bow legs”, it may be necessary to position the frame slightly to one side so that the midpoint between the knees is centered on the film. Both knees should be completely visible on the image, with the lateral femoral and tibial bone margins visible without the use of a high intensity light. In extreme cases, it will be necessary to image each knee separately in order to get an adequate coverage of each knee. When imaging an individual knee, center the knee on the film and center the beam on the knee (not on the column of beads). Be sure the beads are visible on the film (See the first example in section 3.3.2).

- If a participant was difficult to position or has a special consideration, please relay that information to Synarc, Inc. in the “comments” section of the Transmittal Form. Synarc, Inc. may decline to request a repeat if the participant’s knee posed a difficult positioning situation that would most likely not be corrected with another attempt.

- To assist with participant confidentiality, the biographical information flashed onto the films or entered into the digital image header should include participant study identifiers only, not the participant’s name. The flash region may be covered with the self-adhesive study label, but do not apply multiple layers of labels. Please refer to Appendix II for further detail on film labeling.

![SynaFlexer](image)

**Figure 3.3.1**— SynaFlexer for reproducible feet fixation and knees flexion. The frame is positioned with its anterior wall in direct contact with the bucky, cassette holder or reclining table top such that both knees are centered on the film. With the great toes touching the anterior wall of the frame, both feet are fixed in external rotation by pressing them against the V-shaped support on the base of the frame. Body weight is distributed equally between the two legs. Both knees and thighs are pressed against the anterior wall of the frame in order to fix flexion of the knees. The x-ray beam is angled 10° caudal and centered at the level of the joint line midway between the two knees.
Figure 3.3.2— Proper participant positioning and beam angulation for radiography of the knees. The left panel shows proper positioning against a bucky. The right panel shows proper positioning with a reclining table unit.

3.3.2 Criteria for Assessing Quality of Bilateral PA Fixed Flexion Knee Radiographs

Common Mistakes

- Incorrect beam angle determined by the position of the SynaFlexer beads.
- Incorrect exposure technique used causing over or underexposure of the image
- Side marker not visualized on the film.

Criteria of good quality bilateral knee radiographs

- Both knees are exposed on one film.
- Both knees should be completely visible on the film. This includes the femoral and tibial metaphyses as well as the proximal fibula. If either knee is partly cut off, repeat with better centering of the knees relative to the film. In the case of severe varus deformity, image each knee separately.
- Optimum exposure to visualize the medial and lateral sides of the knee joint, including bone margins, and soft tissue should be clearly visible without the use of a high intensity light.
- The cortex of the tibial plateau floor should be clearly delineated.
- The articular surface of the medial femoral condyle must be sharply delineated.
• Medial tibia plateau should be flat; ideally with the anterior and posterior tibial margins superimposed.
  
  o There are some cases where the tibial margins may not be aligned even on a properly acquired image, however if the x-ray beam has not been correctly angled and/or the beam not correctly centered at the joint line, this may cause poor alignment of the tibial plateau rims and should be corrected.

• Beam angle is 10 degrees and centered at the level of the knee joint line as indicated by the position of the SynaFlexer beads.

• At least 5 beads from each column of the SynaFlexer frame should be clearly visible on the film.

• Right/Left side markers are present on film.
3.3.3 Examples of Bilateral PA Fixed Flexion Knee Projection

For examples of acceptable and unacceptable quality posterioranterior knee radiographs, see the following pages.

**Bilateral PA Fixed Flexion Knee – Acceptable**

![Acceptable Bilateral PA Fixed Flexion Knee Image]

An image with good contrast. The cortical rims of the tibial plateaus are clearly delineated and at least 5 beads from each row of the SynaFlexer frame are visualized.
The cortical rims can be poorly aligned even when the participant has been positioned in the SynaFlexer correctly and the x-ray beam has been angled and centered properly. However, if the tibial rims are poorly aligned due to incorrect beam angulation (determined by the position of the double row of beads on the SynaFlexer at the level of the joint space) or the knees are incorrectly centered on the film, then a repeat may be requested.
Bilateral PA Fixed Flexion Knee – Unacceptable

This is a poor quality bilateral knee image due to incorrect beam angulation (> 10 degrees, determined by the position of the SynaFlexer beads at the level of the joint space) and incorrect centering of the knees.
The tube angle is too shallow as indicated by the parallel position of the SynaFlexer beads in the two columns at the level of the joint space. When the tube is angled 10° caudal per the study protocol, the columns of beads near the right knee will appear lower than the column of beads near the left knee producing a “staggered” appearance (Refer to the example on page 20.) The central ray should always be set to 10° caudal, and then centered on the popliteal fossa. Check the x-ray tube weekly with the inclinometer to determine the accuracy of the tube head reading. Record the results in the log book. Contact Synarc if the inclinometer and tube angle setting disagree.
3.4 Hand Radiograph

For the OAI study, posterioanterior (PA) radiographs will be taken for the dominant hand (or both hands at selected sites) at Enrollment and 36 Months or 48 Months. For all radiographs, please concentrate on image quality and optimum positioning of the participant since follow-up radiographs will be compared to baseline radiographs to evaluate progression of the disease.

3.4.1 Hand Radiographic Technique

Exposure Technique

The film should be exposed to optimally depict trabeculae and joint spaces.

<table>
<thead>
<tr>
<th>Radiographic Table</th>
<th>Central ray perpendicular to point midway between the head of the 2\textsuperscript{nd} and 3\textsuperscript{rd} MCP joint.</th>
<th>Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>FFD</td>
<td>40”</td>
<td>Required</td>
</tr>
<tr>
<td>kVp</td>
<td>50-55 kVp</td>
<td>Required</td>
</tr>
<tr>
<td>mAs</td>
<td>Dependent on Film/Screen system 7-13 mAs</td>
<td>Recommended</td>
</tr>
<tr>
<td>Focal Spot</td>
<td>Small</td>
<td>Required</td>
</tr>
<tr>
<td>Collimation</td>
<td>Full size of the film</td>
<td>Required</td>
</tr>
<tr>
<td>Cassette</td>
<td>10” x 12” (single hand); 11” x 14” (bilateral)</td>
<td>Recommended</td>
</tr>
<tr>
<td>Film</td>
<td>Single emulsion film. Please make sure the film is loaded with the emulsion side (dull) to the screen.</td>
<td>Recommended</td>
</tr>
<tr>
<td>Lead Markers</td>
<td>Use Right/Left lead markers</td>
<td>Required</td>
</tr>
</tbody>
</table>

Examination Procedure for Single Hand

*Positioning the Participant*

- Explain the procedure to the participant.
- Ask participant to remove all rings and jewelry from hand and wrist.
- Place the participant comfortably in a chair next to the table. The surface of the table should be slightly lower than the participant’s shoulder: approximately the level of the axilla ([Fig. 3.4.1](#)).
- Flex the elbow approximately 90° ([Fig. 3.4.1](#)).
- Place the palm, wrist and entire forearm flat against the cassette. A sandbag may be placed across the forearm to help stabilize it.
- Center the transparent “Hand Positioning Aid,” (see example found in this section) on the cassette and place the participant’s dominant hand and wrist on it.
• Position the hand in slight ulnar deviation so that the index finger falls along a straight line through the radius (Fig. 3.4.2).
• Spread the fingers slightly apart, as on “Hand Positioning Aid.”
• The palm and wrist should be kept firmly in contact with the cassette. This usually requires conscious effort on the part of the participant as there is a natural tendency to supinate the forearm and flex the knuckles lifting the radial side of the hand and wrist off the cassette. Therefore, please tell the participant to make an effort to keep the hand flat. A sandbag across the forearm helps to stabilize the arm.

Examination Procedure for Bilateral Hands (designated sites only)

Positioning the Participant

• Ask participant to remove all rings and jewelry from hand and wrist.
• Place the participant comfortably in a chair next to the table. The surface of the table should be slightly lower than the participant’s shoulder: approximately the level of the axilla (Fig. 3.4.1).
• The elbow should be flexed approximately 90° (Fig. 3.4.1).
• The entire forearm should be flat against the x-ray table (i.e., the wrist should not be extended). A sandbag may be placed across the forearm to help stabilize it.
• Center the transparent Hand Positioning Aid, (next page) on the half side of the cassette to be exposed and rest the participant’s hand on it.
• Position the cassette in a landscape position and mask the side that will not be exposed with lead. The right hand should be exposed on the right side of the film and the left hand should be exposed on the left side of the film so that when the film is entirely exposed, both hands will be displayed with the fingers pointing in the same direction. IMPORTANT: The cassette will need to be turned around after the right hand exposure when the participant turns to place their left hand on the table. If the cassette is not turned around, the hands will be displayed pointing in opposite directions (see the last example in section 3.4.3).
• Center each hand on the half side of the film with the metacarpophalangeal joints mid-line and the forearm parallel to the short axis of the cassette. Make sure the entire wrist is included.
• Use the Hand Positioning Aid to place the hand in slight ulnar deviation so that the index finger falls along a straight line through the radius (Fig. 3.4.2.) and spread fingers slightly.
• Keep the palm and wrist in firm contact with the cassette. This usually requires conscious effort on the part of the participant as there is a natural tendency to supinate the forearm and flex the knuckles lifting the radial side of the hand and wrist off the cassette. Therefore, please tell the participant to make an effort to keep the hand flat. A sandbag across the forearm helps to stabilize the arm.
Figure 3.4.1 — Proper Participant Positioning (right hand radiograph). The participant is seated beside a table at the level of the axilla with the arm resting on the table, the elbow bent 90°, and the forearm parallel to the thigh.

Figure 3.4.2 — Proper Positioning of the Hand Unilateral: The hand is centered on the film with the palm and forearm pressed firmly against the cassette, the index finger aligned with the radius along the long axis of the cassette, and the fingers spread slightly. The x-ray beam should be centered between the 2nd and 3rd knuckles (⊗). A sandbag across the forearm helps stabilize the arm. Unilateral hand exposed on One Film: In the case of both hands acquired separately on the same film, the cassette (11” x 14”) should be positioned in a landscape position with the side that is not exposed being masked with lead. The right hand should be exposed on the
right half side of the film and the left hand should be exposed on the left half side of the film so that when the film is entirely exposed, both hands will be displayed with the fingers pointing in the same direction.

![Figure 3.4.3— Proper Positioning. Ensure firm contact between the film cassette and the participant’s hand. This requires mild effort by the participant; however, the participant should not press so hard as to cause trembling.](image)

If the participant has difficulty maintaining this position, you can place a sandbag across the forearm to help prevent movement. Make sure the sandbag is not on the film. If you use tape to immobilize the hand or straighten arthritic fingers, please use paper tape as other tapes may show up on the film.

![Figure 3.4.4— Improper Positioning. If the table level is not high enough (arm is insufficiently abducted) or if the participant does not consciously press hand and wrist against the cassette, the wrist will tend to rise off the film. This leads to image blurring, geometric magnification and superimposition of anatomy.](image)

**Positioning the X-ray Tube and Film Comments (Single and Bilateral Hand)**

- Center the beam between the 2nd and 3rd metacarlo-phalangeal joints (knuckles) ([Fig. 3.4.2](image)). The central ray should be at 90 degrees to the plane of the film ([Fig. 3.4.5](image)).
• Collimate to the size of the film (single hand radiograph) or to the half size of the film (in the case of bilateral hands radiographs). In order to optimize the radiologist’s ability to identify subtle pathological changes, the entire film must be exposed to produce a black background against which to view the anatomy. There should be no white margins on the films.

• Use small lead right/left markers and place them on the film where they will not be obscured by the study label, preferably on the lateral side of the hand. Place the markers right side up, so they can be read without reorientation of the radiograph.

Figure 3.4.5— Beam Centering. The x-ray beam should be centered between the 2nd and 3rd metacarpophalangeal joints and perpendicular to the film surface. This will image the joints tangentially. Improper beam centering will result in overlapping joint margins.

Special Remarks

• To assist with participant confidentiality, the biographical information flashed onto the films or entered into the digital image header should include participant study identifiers, not the participant’s name. The flash region may be covered with the self-adhesive study label, but do not apply multiple layers of labels. Please refer to Appendix II for further detail on film labeling.

• If a participant was difficult to position or had a special consideration, please relay that information to Synarc, Inc. in the “comments” section of the Transmittal Form. Synarc, Inc. may decline to request a repeat if the participant’s knee posed a difficult positioning situation that would most likely not be corrected with another attempt.

3.4.2 Criteria for Assessing Quality of Hand Radiographs

Common Mistakes

• Both hands acquired with a single exposure produce incorrect alignment of the forearm, incorrect beam centering, superimposition and blurred contours of the joints.

• Hands incorrectly positioned for the bilateral film. Fingers should be pointing in the same direction.

• Poor positioning of the participant:
- Supination of the forearm (the forearm and the palmar surface of the hand should be pressed flat against the cassette, see Fig. 3.4.3 and Fig. 3.4.4).

- Not using the “Hand Positioning Aid” leading to:
  - Incorrect alignment (the index finger should fall along a straight line passing through the radius and parallel to the long edge of the cassette).
  - Fingers and thumb too close together.

- Improper beam centering will result in overlapping joint margins in a hand otherwise properly positioned.
- Incorrect exposure technique used causing over or underexposure of the image.

**Criteria of Good Quality Hand Radiographs**

- All jewelry (rings, watches, bracelets, etc.) should be removed if possible.
- **The hand should be centered on the film with the index finger aligned with the radius along the long axis of the cassette.** The fingers should be slightly spread apart and the thumb slightly extended. Proper projection of the ulnar styloid (without superimposition) will indicate the wrist was kept flat against the cassette.
- Complete anatomical coverage of the entire hand is required, including the distal radius, ulna and the radiocarpal joint.
- Optimum exposure to visualize and evaluate of all joints of interest, including bone margins, and the trabeculae and joints should be clearly visible without the use of a high intensity light.
- The x-ray beam should be centered exactly between the 2nd and the 3rd metacarpophalangeal joints (knuckles) with no angulation. Improper beam centering will result in overlapping joint margins in a hand otherwise properly positioned.
- Each hand is exposed separately.
- Proper collimation to the size of the film.
- Left/Right side marker should be present on the film.
3.4.3 Examples of Hand Projection

For examples of acceptable and unacceptable quality posteroanterior hand radiographs, see the following pages.

Hand – Acceptable

Good exposure technique used. Hand and wrist visualized. Fingers and thumb are well separated. The index finger is aligned with the radius. No overlapping of contours of the
MCP’s (indicating proper beam centering). Correct orientation of the ulnar styloid (indicates that the wrist is flat).

**Hand – Acceptable**

Good bilateral hand film (both hands acquired separately on the same film). Both hands and wrists are completely depicted. Both hands are displayed with the fingers pointing in the same direction.
Finger deformities: For mild cases, try to improve alignment by taping the fingers with paper tape. In severe cases where positioning is impossible to correct (as the example above) please do the best that you can.
Hand – Unacceptable

This hand is incorrectly positioned because the fingers and thumb are not well separated. The index finger is not aligned with the radius. The side marker is not visualized on the film. This situation can be avoided by using the hand positioning aid consistently.
Hand – Unacceptable

This hand was incorrectly positioned diagonally across film and the light field was collimated. Failure to expose the entire film resulted in white borders, which transmits excessive light and impairs the radiologist’s ability to analyze the image accurately.
Hand – Unacceptable

Both hands on one film acquired with a single exposure leads to incorrect alignment of the index finger to the radius of the hand and wrist and supination of the forearm. The fingers are not separated and the beam has been incorrectly centered in the middle of the film. This causes distortion of the joint spaces which can lead to inaccurate image analyses.
3.5.1 Pelvic Radiographic

For the OAI study, anterioposterior (AP) radiographs will be taken of the pelvis at Enrollment and 36 Months or 48 Months. For all radiographs, please concentrate on image quality and optimum positioning of the participant since follow-up radiographs will be compared to baseline radiographs to evaluate progression of the disease.

3.5.1 Pelvic Radiographic Technique

The film should be exposed to provide optimal visualization of the articular surfaces of the pelvis.

Exposure Technique

<table>
<thead>
<tr>
<th>Imaging System</th>
<th>Bucky</th>
<th>Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>FFD</td>
<td>40”</td>
<td>Required</td>
</tr>
<tr>
<td>kVp Range</td>
<td>70-80 kVp</td>
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</tr>
<tr>
<td>mAs</td>
<td>Dependent on Film/Screen System</td>
<td></td>
</tr>
<tr>
<td>Focal Spot</td>
<td>Large</td>
<td>Required</td>
</tr>
<tr>
<td>Collimation</td>
<td>Full Size of the Film</td>
<td>Required</td>
</tr>
<tr>
<td>Cassette</td>
<td>14”x 17”</td>
<td>Recommended</td>
</tr>
<tr>
<td>Film/Screen Combination</td>
<td>Standard/regular film</td>
<td>Recommended</td>
</tr>
<tr>
<td>Lead Markers</td>
<td>Use Right/Left Lead Markers</td>
<td>Required</td>
</tr>
</tbody>
</table>

Examination Procedure

Examination Preparation

- Explain the procedure to the participant.
- Ensure clothing and foreign objects (i.e. zippers) are removed from participant’s pelvic region as necessary. Use a drape sheet or a patient gown to cover the participant’s pelvic region.
- Instruct the participant to remove their shoes.

Positioning the Participant

- Place the anterior wall of the SynaFlexer in direct contact with the bucky, cassette holder or reclining table top of the radiographic unit. ([Fig. 3.5.1](#)).
- Participant is standing upright on the frame, facing the X-ray tube with the back against the bucky.
- The heels of both feet are placed in contact with the anterior wall of the frame ([Fig. 3.5.1](#)).
- Both feet are fixed in internal rotation against the V-shaped support on the base of the frame.
• Heels and medial aspects of the feet are in close contact with the frame.
• Body weight is distributed equally between the two legs.
• Ask the participant to hold still during exposure.
• Place a side marker on the film.

Figure 3.5.1—SynaFlexer for reproducible feet fixation. The frame is positioned with its anterior wall in contact with the bucky (or cassette holder or reclining table top). With the heels touching the anterior wall of the frame, both feet (in diagram above right) are fixed in 5° internal rotation by placing the medial side of the heel and forefoot directly against the V-shaped support on the base of the frame. Body weight is distributed equally between the two legs.

Positioning the X-ray Tube and Film Comments

• Center the x-ray beam perpendicular to the plane of the film two inches above the symphysis pubis (at the level of the greater trochanter). The symphysis pubis is identified by manual palpation.
• Collimate to the size of the film and include iliac bones entirely.
• Use small lead right/left side markers and place them on the film where they will not be obscured by the study label, preferably on the lateral side.

Special Remarks
To assist with participant confidentiality, the biographical information flashed onto the films or entered in the digital image header should include participant study identifiers, not the participant’s name. The flash region may be covered with the self-adhesive study label, but do not apply multiple layers of labels. Please refer to Appendix II for further detail on film labeling.

If a participant was difficult to position or has a special consideration, please relay that information to Synarc, Inc. in the “comments” section of the Transmittal Form. Synarc, Inc. may decline to request a repeat if the participant’s knee posed a difficult positioning situation that would most likely not be corrected with another attempt.

3.5.2 Criteria for Assessing Quality of Pelvic Radiographs

Common Mistakes

- Incorrect beam centering causing superimposition of the joints.
- Incorrect exposure technique used causing over or underexposure of the image
- No markers are visualized on the film. If the marker is overexposed, please remark the film before submitting to Synarc, Inc.

Criteria of good quality pelvic radiographs

- Central ray is centered two inches above symphysis pubis.
- The entire pelvis is depicted, including both hip joints and iliac bones (see the first example in section 3.5.3).
- Optimum exposure to visualize clear delineation of the hip joints of interest, including the trabeculae, and soft tissue should be clearly visible without the use of a high intensity light.
- Right/Left side markers are on the film.
- Correct exposure of the film.
3.5.3 Examples of Pelvic Projection

For examples of acceptable and unacceptable quality pelvic radiographs, see the following pages.

Pelvis – Acceptable

This is an acceptable pelvis radiograph because it is properly exposed and centered.
Pelvis – Unacceptable

The iliac bones and right greater trochanter are clipped due to incorrect centering of the pelvis to the film.
Pelvis – Unacceptable

The radiograph is underexposed causing inadequate visualization of the hip joints. Furthermore, the side marker is not present on the image.
3.6 Unilateral PA Fixed Flexion Knee Radiograph with Fluoroscopy (Fluoro) –

Radiographs of the right and left knees will be acquired separately using the fluoroscopy-guided technique. For all radiographs, please concentrate on image quality and optimum positioning of the participant since follow-up radiographs will be compared to baseline radiographs to evaluate progression of the disease.

Please note: if a participant has a total knee replacement in one knee, do not acquire a fluoroguided x-ray for that knee.

3.6.1 Fixed Flexion Fluoro Guided Knee Radiographic Technique

Exposure Technique

<table>
<thead>
<tr>
<th>Imaging System</th>
<th>Bucky</th>
<th>Recommended</th>
</tr>
</thead>
<tbody>
<tr>
<td>Focus-Film Distance (FFD)</td>
<td>47”</td>
<td>Required</td>
</tr>
<tr>
<td>Film Size</td>
<td>10” x 12”</td>
<td>Required</td>
</tr>
<tr>
<td>Film/Screen Speed</td>
<td>400</td>
<td>Required</td>
</tr>
<tr>
<td>KVP Range</td>
<td>65-70 kVp</td>
<td>Recommended</td>
</tr>
<tr>
<td>mAs</td>
<td>7-13 mAs (variable)</td>
<td>Recommended</td>
</tr>
<tr>
<td>Focal Spot</td>
<td>Small</td>
<td>Required</td>
</tr>
<tr>
<td>Densitometer</td>
<td>1 to 1.2</td>
<td>Recommended</td>
</tr>
<tr>
<td>Beam Centering</td>
<td>Joint line</td>
<td>Required</td>
</tr>
<tr>
<td>Beam Angulation</td>
<td>Aligned with medial tibial plateau</td>
<td>Required</td>
</tr>
<tr>
<td>Other</td>
<td>Use Right/Left Lead Markers</td>
<td>Required</td>
</tr>
<tr>
<td>Other</td>
<td>Fluoroscopic equipment with variable x-ray beam angulation</td>
<td>Required</td>
</tr>
</tbody>
</table>

Examination Procedure

Positioning the Participant

- Participant positioning is exactly the same as for bilateral PA fixed-flexion knee radiographic technique. (Section 3.3).
- Place the anterior wall of the SynaFlexer direct contact with the upright table top of the fluoroscopy unit. Lower the cassette holder so that the center of the film will be at the level of the participant’s tibiofemoral joint line.
- Participant is standing upright on the frame facing the anterior wall.
- Center the knee of interest to the cassette.
- The great toes of both feet are placed in contact with the anterior wall of the frame, (Fig. 3.6.2).
• Both feet are fixed in external rotation by pressing the inner aspects of the foot and heel against the V-shaped support on the base of the frame (Fig. 3.6.2).

• Body weight is distributed equally between the two legs.

• Both knees are flexed until they touch the anterior wall of the frame. This fixes the angulation of the tibias.

• With the great toes and knees still touching the anterior wall, both thighs are also pressed directly against the wall to fix the angulation of the femurs (Fig. 3.6.2).

• Gently push the participant forward with your hand in the small of the back to ensure firm contact of both thighs with the wall of the frame. **IMPORTANT:** the toes, knees and thighs must all be in firm contact with the wall of the frame in order for knee flexion to be reproduced exactly on follow-up radiographs.

• The participant’s gonads are shielded with a half apron.

**Positioning the X-ray Tube and Film Comments**

• Center the beam to the back of the knee at the level of the joint line, defined by the horizontal skin crease of the popliteal fossa.

• Starting with a horizontal beam at zero degrees, increase the angle caudally under fluoroscopy to achieve superimposition of the midpoint of anterior and posterior rims of the medial tibial plateau (see Fig. 3.6.1 below).

![Figure 3.6.1](image)

**Figure 3.6.1**—In the example shown above, the beam was angled at 5° (left panel), 10° (middle panel), and 15° (right panel): for this knee, the 10° angulation is optimal for clear delineation of the medial joint space, and shows superimposition of the medial tibial rims.

• Expose the knee when the anterior and posterior rims are optimally aligned. The medial tibia plateau should be flat and the vertical distance between the anterior and posterior tibial margins at the center of the medial tibial plateau should not be greater than approximately 1 mm (see Fig. 3.6.1 and Fig. 3.6.3).

• Fluoroscopic exposure per knee should be in the 5-10 second range.

• At least 5 of the metal beads in the positioning frame must be visible on the radiograph.

• Collimate to the size of the film.
• Use small lead Right/Left markers and place them on the cassette close to the knee but where they will not obscure the knees or the location for the study label.

• In contrast to the non-fluoro technique, each knee is imaged separately with the fluoro technique.

• Repeat the process for the other knee.

Special Remarks

• To assist with participant confidentiality, the biographical information flashed onto the films should include participant study information only, not the participant’s name. The flash region may be covered with the self-adhesive study label, but do not apply multiple layers of labels. Please refer to Appendix II for further detail on film labeling.

• If a participant was difficult to position or had a special consideration, please relay that information to Synarc, Inc. in the “comments” section of the Transmittal Form. Synarc, Inc. may decline to request a repeat if the participant’s knee posed a difficult positioning situation that would most likely not be corrected with another attempt.

Figure 3.6.2—SynaFlexer for reproducible feet fixation and knees flexion. The frame is positioned with its anterior wall in direct contact with the bucky, cassette holder or reclining table top such that knee of interest is centered on the film. With the great toes touching the anterior wall of the frame, both feet are fixed in external rotation by pressing them against the V-shaped support on the base of the frame. Body weight is distributed equally between the two legs. Both knees and thighs are pressed against the anterior wall of the frame in order to fix flexion of the knees. The horizontal x-ray beam is centered at the level of the femorotibial joint line of the knee of interest, and angled under fluoroscopic control until the anterior and posterior rims of the medial tibial plateau superimpose. The radiograph is acquired with this beam angulation.
3.6.2 Criteria for Assessing Quality of Fixed Flexion Fluoroscopy Guided Knee Radiographs

- Each knee is exposed on a separate film.
- Each knee must be centered on the film.
- The medial tibia plateau should be flat; the vertical distance between the anterior and posterior tibial margins at the center of the medial tibial plateau should not be greater than about 1 mm (see Fig. 3.6.3).
- Optimum exposure to visualize the delineation of the articular cortex of the medial femoral condyles, tibial plateaus and the soft tissue should be clearly visible without the use of a high intensity light.
- The entire joint, including the femoral and tibial metaphyses and the head of the fibula, must appear on the film.
- Each image is collimated to the size of the film
- At least 5 metal beads of both columns of beads in the positioning frame must be visible.
- Right or left side markers are present on both films.

Figure 3.6.3—A closer look at the medial joint space: The distance between the anterior and posterior tibial margins at the center of the medial tibial plateau (distance between arrows) should be less than about 1 mm and the cortex of the tibial plateau floor should be sharply delineated.
3.6.3 Examples of Fixed Flexion Fluoroscopy Guided Knee Projection

For examples of acceptable and unacceptable quality fixed flexion fluoro guided knee radiographs, see the following pages.

**Fixed Flexion Fluoro Guided Knee – Acceptable**

Good quality posterior-anterior knee radiograph. The knee is well depicted with the anterior and posterior rims of the medial tibial plateau. The image is marked. There is at least 5 beads of both columns of beads of the SynaFlexer frame are visible.
Although this is a good quality posterior-anterior knee radiograph (the medial tibial plateau is flat), this image is unacceptable because the beads of the SynaFlexer are not visible.
Poor positioning and incorrect tibial alignment. The anterior and posterior rims of the medial tibial plateau are not superimposed and are more than 1 mm apart.
The anterior and posterior rims of the medial tibial plateaus are not superimposed. Furthermore, the side marker and SynaFlexer beads are not visible on the image.

Good quality repeat
Fixed Flexion Fluoro Guided Knee – Unacceptable

Poor Quality: underexposed, beads not visible on radiograph.
3.7 PA Semi-flexed Knee Radiograph with Fluoroscopy (Fluoro)

Radiographs of the right and left knee will be acquired separately using the fluoroscopy-guided technique. For all radiographs, please concentrate on image quality and optimum positioning of the participant since follow-up radiographs will be compared to baseline radiographs to evaluate progression of the disease.

If a participant has a total knee replacement in one knee, do not acquire a fluoro-guided x-ray for that knee.

3.7.1 Semi-Flexed Fluoro Guided Knee Radiographic Technique

Exposure Technique

<table>
<thead>
<tr>
<th>Table Cell 1</th>
<th>Table Cell 2</th>
<th>Table Cell 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Imaging System</td>
<td>Bucky</td>
<td>Required</td>
</tr>
<tr>
<td>Focus-Film Distance (FFD)</td>
<td>47”</td>
<td>Required</td>
</tr>
<tr>
<td>Film Size</td>
<td>10” x 12”</td>
<td>Required</td>
</tr>
<tr>
<td>Film/Screen Speed</td>
<td>400</td>
<td>Required</td>
</tr>
<tr>
<td>kVp Range</td>
<td>65-70 kVp</td>
<td>Recommended</td>
</tr>
<tr>
<td>mAs</td>
<td>7-13 mAs (variable)</td>
<td>Recommended</td>
</tr>
<tr>
<td>Focal Spot</td>
<td>Small</td>
<td>Required</td>
</tr>
<tr>
<td>Densitometer</td>
<td>1 to 1.2</td>
<td>Recommended</td>
</tr>
<tr>
<td>Beam Centering</td>
<td>Joint line</td>
<td>Required</td>
</tr>
<tr>
<td>Beam Angulation</td>
<td>Horizontal</td>
<td>Required</td>
</tr>
<tr>
<td>Other</td>
<td>Use Right/Left Lead Markers</td>
<td>Required</td>
</tr>
</tbody>
</table>

Examination Procedure

**Positioning the Participant**

- The single-ball spherical phantom (provided by Synarc) is secured laterally to the knee of interest lateral to the knee at the level of the head of the fibula (secured with gauze, paper tape, or Velcro straps).
- The double-ball rectangular phantom is taped to the cassette in a vertical orientation lateral to the knee in a location where it will not obscure the anatomy.
- Ask the participant to stand upright facing the table on the footboard with the medial border of the foot and heel of the knee of interest parallel to the tape marker on the footboard that indicates 10° of external rotation. Lower the cassette holder so that the center of the film/receptor is at the level of the participant’s tibiofemoral joint line.
- Ask the participant to slowly flex both knees until they touch the anterior wall. Then press both thighs against the table.
- Body weight is distributed equally between the two legs.
• The participant’s gonads are shielded with a half apron.

*Positioning the X-ray Tube and Film Comments*

• The horizontal x-ray beam is centered on the back of the knee at the level of the joint line, defined by the horizontal skin crease of the popliteal fossa.

• Starting with the knees extended, the participant slowly flexes both knees during fluoroscopy until the midpoint of anterior and posterior rims of the medial tibial plateau are superimposed (see Fig. 3.7.1 below). Participant holds this position without further movement.

• Radiograph the knee when the anterior and posterior rims are superimposed. In contrast to the non-fluoro technique, each knee is imaged separately with the fluoro technique.

• Fluoroscopic exposure per knee should be in the 5-10 second range.

• Collimate to the size of the film.

• Use small lead Right/Left markers and place them on the cassette close to the knee but where they will not obscure the knees or the location for study label.

• Repeat process for the other knee.

*Special Remarks*

• To assist with participant confidentiality, the biographical information flashed onto the films should include participant study information, not the participant’s name. The flash region may be covered with the self-adhesive study label, but do not apply multiple layers of labels. Please refer to Appendix II for further detail on film labeling.

• If a participant was difficult to position or had a special consideration, please relay that information to Synarc, Inc. in the “comments” section of the Transmittal Form. Synarc, Inc. may decline to request a repeat if the participant’s knee posed a difficult positioning situation that would most likely not be corrected with another attempt.
Figure 3.7.2— The single-ball metal-ball spherical phantom is strapped to the knee of interest over the head of the fibula. The double-ball rectangular phantom is taped to the cassette in a vertical orientation lateral to the knee in a location where it will not obscure the anatomy. The feet are fixed in external rotation by aligning them with the tape on the footplate. Body weight is distributed equally between the two legs. The horizontal x-ray beam is centered on the femorotibial joint line of the knee of interest. Both knees are flexed during fluoroscopy until the anterior and posterior rims of the medial tibial plateau superimpose. The radiograph is acquired with this knee flexion.
3.7.2 Criteria for Assessing Quality of Semi-Flexed Fluoro Guided Knee Radiographs

- Each knee is exposed on a separate film.
- Each knee must be centered on the film.
- The medial tibia plateau should be flat; the vertical distance between the anterior and posterior tibial margins at the center of the medial tibial plateau should not be greater than approximately 1 mm (see Fig. 3.7.3).
- Optimum exposure to visualize the delineation of the articular cortex of the medial femoral condyles, tibial plateaus and the soft tissue should be clearly visible without the use of a high intensity light.
- The entire joint, including the femoral and tibial metaphyses and the head of the fibula, must appear on the film.
- The single-ball phantom over the head of the fibula must be visible on the film.
- The double-ball phantom should be visible on the film superior to the single-ball phantom.
- Right or left side markers are present on both films.

Figure 3.7.3— a closer look at a good quality depiction of the medial joint space: The distance between the anterior and posterior tibial margins at the center of the medial tibial plateau (distance between arrows) should be less than 1 mm, and the cortex of the tibial plateau floor should be sharply delineated.
3.7.3 Examples of Semi-Flexed Fluoro Guided Knee Projection

For examples of acceptable and unacceptable quality semi-flexed fluoro guided knee radiographs, see the following pages.

Semi-Flexed Fluoro Guided Knee – Acceptable

This is a good quality image because the anterior and posterior rims of the medial tibial plateaus are superimposed. The single ball phantom has been attached to the knee (can determine this by its magnification and blurred contours) and the double ball phantom has been secured to cassette in correct orientation.
Semi-Flexed Fluoro Guided Knee – Unacceptable

The anterior and posterior rims of the medial tibial plateau are not superimposed. There is no delineation of the tibial floor. The double ball phantom should not obscure the anatomy and the single ball phantom should be visualized at the level of the head of the fibula.
Semi-Flexed Fluoro Guided Knee – Unacceptable

This image is underexposed and the single and double ball phantoms are not present.
3.8 Lateral Knee Radiograph for Normal Controls

For the OAI study, separate radiographs of the right and left knees will be acquired in the normal control subcohort at Enrollment, 24 Months and 48 Months. For all radiographs, please concentrate on image quality and optimum positioning of the participant since follow-up radiographs will be compared to baseline radiographs to evaluate development of new disease.

3.8.1 Lateral Knee Radiographic Technique

This protocol requires a weight-bearing, semi-flexed position.

Exposure Technique

<table>
<thead>
<tr>
<th>Imaging System</th>
<th>Bucky</th>
<th>Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>FFD</td>
<td>72”</td>
<td>Required</td>
</tr>
<tr>
<td>Film Size</td>
<td>10” x 12”</td>
<td>Required</td>
</tr>
<tr>
<td>mAs</td>
<td>Dependent on Film/Screen System</td>
<td></td>
</tr>
<tr>
<td>kVp Range</td>
<td>65-72 kVp</td>
<td>Recommended</td>
</tr>
<tr>
<td>Beam Centering</td>
<td>Knee joint</td>
<td>Required</td>
</tr>
<tr>
<td>Beam Angulation</td>
<td>0</td>
<td>Required</td>
</tr>
<tr>
<td>Focal Spot</td>
<td>Small</td>
<td>Required</td>
</tr>
<tr>
<td>Lead Markers</td>
<td>Use Right/Left Lead Markers</td>
<td>Required</td>
</tr>
</tbody>
</table>

Examination Procedure

Examination Preparation

- Instruct the participant to remove their shoes.

Positioning the Participant

- The participant is standing upright lateral position to the plane of the bucky with the leg and knee to be x-rayed nearer and parallel to the bucky, positioned as close as possible.
- Place the ball of the foot (first MTP joint) on the same side as the knee to be x-rayed in the middle of the horizontal dimensions of the cassette. This will be helpful in centering of the knee to the cassette.
- The foot of the leg not being x-rayed should be in normal stance and just posterior to the foot of the leg being x-rayed (see Fig. 3.8.1). Weight is distributed evenly between the feet.
- Have the participant flex the knee to be x-rayed to about 30 degrees by aligning the front of the patella vertically with the tip of the great toe.
• Adjust the participant’s hips and/or the forefoot until the knee is in a true lateral position where the anterior rims of the femoral condyles are superimposed and the plane of the patella is perpendicular to the cassette. This will ensure that the x-ray beam will pass through joint space opening beneath the patella and the anterior femoral condyles will appear superimposed on the film.

• Shield the participant’s gonads.

![Diagram](image)

**Figure 3.8.1**—Positioning the participant for the lateral knee x-ray.

**Positioning the X-ray Tube and Film**

• Place a small ink mark on the surface of the skin of each knee over the bony projections of the medial and lateral epicondyles. These points should be approximately on the same level anterior in the middle of the patellofemoral joint. These landmarks will be used to center the x-ray beam.

• The angle of the x-ray tube is 0°, with the central ray perpendicular to the cassette.

• Center the x-ray beam over the medial epicondyle.

• Collimate to the size of the film.

• Use small lead Right/Left markers and place them on the cassette where they will not obscure the knees or the location for the study label.

• Each knee is x-rayed separately.

**Special Remarks**
• The arm closest to the bucky can be moved out of the way by extending it forward and holding on a stable IV pole or resting on the top of the bucky for support to help the participant stand close to the bucky.

• If a participant was difficult to position or had a special consideration, please relay that information to Synarc, Inc. in the “comments” section of the Transmittal Form. Synarc, Inc. may decline to request a repeat if the participant’s knee posed a difficult positioning situation that would most likely not be corrected with another attempt.

3.8.2 Criteria for Assessing Quality of Lateral Knee Radiographs

The primary quality goals for this view are superimposition of the anterior margins of the femoral condyles and a clear and open projection of the joint space between the femur and patella (see examples on following pages).

Criteria of good quality lateral knee radiographs

The following quality criteria should be evaluated for each examination:

• Both knees are exposed on a separate film.
• Each knee must appear in the center of the film.
• Optimum exposure to visualize the delineation of the articular cortex of the medial femoral condyles and the patella, and the soft tissue should be clearly visible without the use of a high intensity light.
• Complete depiction of the knee joint including the fibular head, tibial tubercle, and patella.
• Knee in true lateral position: The anterior rims of the femoral condyles should be superimposed and their anterior articular surfaces sharply delineated. The patellofemoral joint space should be open.
• Complete depiction of the knee joint including the fibular head, tibial tubercle, and patella.
• Right or left side markers are present on both films.
3.8.3 Examples of Lateral Knee Projection

For examples of acceptable and unacceptable quality lateral knee radiographs, see the following pages.

A closer look at the patellofemoral compartment. This is a good quality mediolateral radiograph because the anterior surfaces of the femoral condyles are superimposed and the patellofemoral joint space is open (identified by arrows).
This is an acceptable lateral knee radiograph of a participant because the anterior rims of the femoral condyles have been superimposed. An accurate measurement can be made of the patellofemoral joint space from the posterior elements of the patella to the intercondylar fossa because the knee was positioned in a true lateral position.
Poor positioning of the knee leading to an oblique view. Femoral condyles not superimposed, and patellofemoral joint space is not clearly delineated.
3.9 Full Limb Radiograph for Progression Subcohort.

Radiographs of both entire lower extremities will be acquired using this protocol in all participants in the Progression Cohorts at 12 months. For all radiographs, optimal image quality and positioning is critical because precise measurement will be made from these images.

3.9.1 AP Full Limb Radiographic Technique

Exposure Technique

<table>
<thead>
<tr>
<th>Site</th>
<th>Imaging System</th>
<th>Focus-Film Distance (FFD)</th>
<th>Film Size</th>
<th>mAs</th>
<th>KVp Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pittsburgh</td>
<td>GE Compax 40E</td>
<td>80”</td>
<td>14” x 51”</td>
<td>100-300</td>
<td>80-90 kVp</td>
</tr>
<tr>
<td>Ohio State</td>
<td>Continental TM 80-2</td>
<td>84”</td>
<td>3 14” x 17” cassettes</td>
<td>100-300</td>
<td>80-90 kVp</td>
</tr>
<tr>
<td>Univ of Maryland</td>
<td>GE MVP 60</td>
<td>80”</td>
<td>3 14” x 17” cassettes</td>
<td>100-300</td>
<td>80-90 kVp</td>
</tr>
<tr>
<td>Johns Hopkins</td>
<td>Siemens Multix</td>
<td>80”</td>
<td>14” x 51”</td>
<td>100-300</td>
<td>80-90 kVp</td>
</tr>
<tr>
<td>Rhode Island</td>
<td>GE</td>
<td>120”</td>
<td>3 14” x 17” cassettes</td>
<td>100-300</td>
<td>80-90 kVp</td>
</tr>
</tbody>
</table>
Examination Objective

Radiographs of the entire lower extremities are taken together in an upright weight-bearing position. This image includes complete visualization of the femoral head and the talus of the foot. The objective of this examination is to measure knee alignment. The measurement is made by drawing a line from the femoral head to the knee and from the knee to the ankle surface using specific landmarks. Alignment is characterized as neutral (hip/knee/ankle angle is 0 degrees), varus (alignment is > 0 degrees contributing to a bow-legged appearance) and valgus (alignment is < 0 degrees contributing to a knock-knee appearance).

**Figure 3.9.1**-Full limb image of neutral alignment.
Figure 3.9.2-Full limb image of varus and valgus alignment.
Examination Preparation

- Remove clothing, shoes, and metal material from lower limb area.
- Position the radiopaque ruler vertically to the center of the cassette with the numbers increasing upwards toward the pelvis.

Positioning the Participant

- Place the participant in an upright AP position with their back toward the bucky. Center both lower limbs to the film.
- Position the participant’s feet 6 inches apart. Permanent markings can be made on the step stool 6 inches apart. Position the great toes on these markings for consistency.
- Ask the participant to place the toes perpendicular to the film and help adjust the leg to position the femoral epicondyles parallel to the cassette.
- Instruct the participant to stand straight with knees fully extended and distribute weight evenly.
- Shield the participant’s gonads without obscuring the hip joint.

Positioning the X-ray Tube and Central Ray

- Secure the wedge filter on the collimator. For wedge shaped filters place the thicker end inferior to the thinner end. The thicker end will attenuate the x-ray beam nearer the ankle joint to avoid overexposure from the higher technique needed to expose the hips. Ensure that the filter covers the entire light field for uniform exposure of the lower limbs.
- Direct the central ray horizontal and center it midway between the knees at the level of the knee joint. (If the participant is over 6 feet, center at a point midway between the knees at the level of the top of the patella).
- Angle the tube at zero degrees perpendicular to the film
- Place a right and left marker on the film
- Instruct the participant to hold still.
- Image both lower extremities on one film.

Special Remarks

- For participants with extreme cases of “bowed legs”, it will be necessary to image each lower limb separately in order to get adequate coverage.
  - When imaging each lower limb separately, center the limb on the film and center the beam on the knee joint space.
• Position the radiopaque ruler on the lateral side of each limb and include on the image.

• The use of a grid is advised to reduce secondary and scatter radiation to increase the quality of these images. This will require an increase of the exposure technique.

**Electronic Stitching for Digital Images**

After the image has been acquired and processed, stitch the images together using the procedure steps in your software operating manual. Make certain that these steps are accurately repeated with each full limb image acquired.

**Transmittal of image for conventional film**

Please submit the entire full limb image intact to Synarc, Inc. Do not separate the trifold film at any time.

### 3.9.2 Criteria for Assessing Quality of Full Limb Radiographs

**Common Mistakes**

• Incomplete visualization of the femoral heads or the ankle joints due:
  
  o Underexposure of the hips due to insufficient exposure techniques and/or exposing the image without a grid.
  
  o The stitch line covering the anatomical landmarks for measurement. If the stitch line obscures any of these landmarks, reposition the cassette(s) and/or participant and repeat the exam.
  
  o Not covering the entire light field with the filter.

• No markers are present on the film. Please remark the film before submitting the image to Synarc.

**Criteria of good quality full limb radiographs**

Ideally, radiographs of insufficient quality should be identified by the radiology technologist at the time of acquisition and repeated immediately. If the film does not demonstrate good quality in the following criteria, please repeat the exam:

• The lower limbs are centered on the film.

• Optimum exposure to visualize the articular cortex of the measurement landmarks (center of the femoral head, tibial spines, center of talar surface) without the use of a high intensity light.

• Accurate alignment of the radiopaque ruler on the stitched image.

• Right or left side markers are present on both films.
3.9.3 Examples of Full Limb view

For examples of acceptable and unacceptable quality full limb radiographs, see the following pages.

![Full Limb – Acceptable](image)

This is an example of an acceptable full limb image. The participant has been centered and all three joints (hip, knee, and ankle) are visualized.
This is an example of an acceptable full limb exam performed on a larger participant. Although the participant is centered, his uneven stance causes the right trochanter to be clipped. This is acceptable as long as the proximal femoral shaft is visualized on the image.
Full Limb – Unacceptable

This image is unacceptable due to underexposure of the hip joints and there are no lead markers visualized. Always remember to shield the participant’s gonads.
This image is unacceptable because it has been digitally “stitched” incorrectly causing the pelvis to be missing from the image. Furthermore, the feet are positioned too close together.
A closer look at the previous unacceptable image that has been digitally “stitched” incorrectly. Note that the numbers on the ruler “jump” from 77 to 105.
This image was taken without the grid and an insufficient exposure technique leading to loss of contrast and overall underexposure of the image.

This image was taken with the grid and optimum exposure was achieved allowing visualization of the measurement landmarks.
4.0 DATA HANDLING PROCEDURES

Radiographs should be sent to Synarc, Inc. according to the procedures described in this section.

4.1 Supplies

Synarc, Inc. will be providing the following supplies to the Clinical Sites:
- Radiographic Procedure Manual
- Quick Reference Guides
- Radiograph Jackets (if conventional film x-ray equipment will be used)
- X-ray padded mailers (if conventional film x-ray equipment will be used)
- CDs for digital data submission (if digital x-ray equipment will be used)
- Jewel cases for CDs (if digital x-ray equipment will be used)
- Labels for radiographs, electronic media, and jackets
- Pre-printed air waybills
- Hand Positioning Aid (2)
- SynaFlexer Positioning Frame (2)

To request more of the study supplies, please photocopy the Supply Order Form (Appendix V), fill it out clearly, and fax it to Synarc, Inc. using the fax number on the form.

The shipping material is available through the local FedEx office; however, if you need additional pre-printed air waybills, use the Supply Order Form (Appendix V). Call the courier if you need additional shipping supplies (1-800-GOFEDEX).

4.2 Data Preparation

All knee, hand, pelvic, lateral knee and full limb radiographs for participants screened for the study will be sent to Synarc. If your site is using conventional equipment, send original radiographs only. If your site is using digital equipment, copy the images onto a CD and send the CD to Synarc. Make sure the electronic images and/or their corresponding folders and the CD are clearly labeled with participant identifiers.

Complete the X-ray Transmittal Form, keeping a copy for your site records and sending the original to Synarc, Inc. (see Appendix I for instructions) with the participant radiograph.

If you are sending Screening visit knee radiographs, include a copy of the Screening Knee X-ray Reading Form (included in the Screening Visit Workbook) in the shipment to Synarc.

When archiving digital data, please make sure the digital image does not have the participant ID or acrostic embedded in the image itself.
radiographs, electronic media, and radiograph jackets should be labeled using the pre-printed adhesive labels provided by Synarc, Inc. (see Appendix II for instructions).

Place the X-ray Transmittal Form and labeled radiographs (or CDs) for each participant in the respective radiograph jacket.

If an x-ray exam has been repeated, please include the following in the radiograph jacket:

- Both the repeat radiograph(s) and the original radiographs (which Synarc, Inc. will have sent back for review, if hardcopy film)
- A new X-ray Transmittal Form for the repeat radiograph (Synarc, Inc. will still have the X-ray Transmittal Form for the initial exam). Please make sure when filling out the new transmittal form that the repeat bubble on the upper right hand corner of the transmittal form is filled in.
- Please also include in the package the “Repeat Request” letter that was received via email by your site.

4.3 Data Shipping

FedEx is the designated courier for this study.

Complete the pre-printed air waybill, keeping a copy for tracking purposes in case a package is lost or delayed.

Call your local FedEx office to schedule your package pick-up, taking into account the latest call and pick-up time.

Collect and ship radiographs to Synarc. All radiographs should be sent as soon as possible to Synarc, to allow for repeats of poor quality radiographs within 2 weeks of the scheduled visit. Radiographs should be sent twice per week at the beginning of the study; ultimately, we will change to shipping once per week. Synarc, Inc. will inform you when the shipment schedule changes.

We suggest that you ship radiographs on Tuesdays and Fridays; however, schedules at your site may require slight deviations from this schedule.

Important: If you are submitting digital x-rays to Synarc, your site must keep a permanent archive copy of the x-rays for the duration of the study.
Ship radiographs to Synarc, Inc. using the pre-printed air waybills. If the air waybills are not available, please complete a blank air waybill with the following information:

Andrey Semyonov  
OAI  
Synarc, Inc.  
575 Market Street, 15th Floor  
San Francisco, CA 94105 USA  

Telephone: 415-817-8987  
Fax: 415-817-8999  

Your Internal Billing Reference: 36239SYNFX (This MUST be included.)

Use Standard Overnight service.

FedEx Third Party Account Number: 252620729
APPENDIX I  Instructions for Completing the X-ray Transmittal Form

To properly complete the X-ray Transmittal Form, follow the guidelines below.

<table>
<thead>
<tr>
<th>Participant Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Record the participant demographic information including the 7-digit OAI Participant ID and 4-letter Acrostic.</td>
</tr>
<tr>
<td>• Check the box for the appropriate visit.</td>
</tr>
<tr>
<td>• Check repeat box in upper right hand corner of form to indicate if exam is a repeat requested by Synarc.</td>
</tr>
<tr>
<td>• Record the 4-digit Screening X-ray Reader ID# (if screening visit).</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Radiograph Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Complete date of radiographic exam. Enter the dates using the date format: MM/DD/YYYY (e.g., 02/27/2003 for February 27, 2003).</td>
</tr>
<tr>
<td>• For each exam type, indicate format of data being submitted: digital or film.</td>
</tr>
<tr>
<td>• If sending digital data on CDs number each CD in the package and indicate the appropriate CD number on each Transmittal Form.</td>
</tr>
<tr>
<td>• Complete the OAI X-ray Tech ID # of the x-ray technologist who acquired the data.</td>
</tr>
<tr>
<td>• Document any relevant comments (these may include, but are not limited to, positioning or scheduling issues).</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Data Shipment to Synarc</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Document the air waybill number &amp; number of films sent to Synarc, Inc. for the participant visit.</td>
</tr>
<tr>
<td>• Enter Staff ID # after checking for completeness and correctness.</td>
</tr>
<tr>
<td>• Keep copy of the transmittal form at site for your records.</td>
</tr>
</tbody>
</table>

- Please always include a transmittal form with every submission of participant x-rays.

- In cases where these instructions are not followed or there is an error in the information provided, a Data Clarification Form will be submitted to the site. These forms should be completed, signed and faxed.
REMINDERS

- Print CLEARLY – all writing needs to be legible.
  - Use black ink. Avoid making stray marks. Completely darken the bubbles.
  - Print in capital letters. Print only one letter or number per box. Keep the letter or number completely inside the box.
  - Do not use white-out. Cross out the wrong answer with a single line. Record the correct answer and the reason for correction. Initial and date the correct answer.

- The original, properly completed X-ray Transmittal Form must be sent with the original radiographs to Synarc.

- Fill in the repeat bubble on the upper right hand corner of the transmittal form if exam was a repeat requested by Synarc.

- Include the “Repeat Request” letter from Synarc, Inc. that was received by your site with the repeat scans shipment.

- Retain a copy of each form for your files along with a copy of the courier’s air waybill when the radiographs are shipped.

- The Clinic Coordinator will receive a fax confirmation (Participant Status Report) from Synarc, acknowledging receipt of the films and providing feedback on the film quality within 5 business days of receipt of data at Synarc. If you have not received this report when you expect to (allowing for transit time from site to Synarc), please contact Synarc:

  Contact: Andrey Semyonov  
  Tel. 415-817-8987  Fax 415-817-8999  
  Email: andrey.semyonov@synarc.com
APPENDIX II Instructions for Completing Radiograph Labels

1. **OAI X-ray**

2. **OAI Participant ID:** Enter 7 digit participant ID

3. **Acrostic:** Enter 4 character acrostic (first letter of participant’s first name and first three letters of participant’s last name) and **CD#:** (if making a label for electronic media)

4. **X-ray Exam Date:** Enter the x-ray date using the format **MM/DD/YYYY** (example: 02/27/2003 for February 27, 2003).

5. **Visit:** Check the box indicating the visit name.

**Note:** These adhesive labels should be used for all radiographs, electronic media, and radiograph jackets. If using a label for electronic media, be sure to complete the CD #. The label should be applied directly to the films, the radiograph jackets and the CD itself. If you plan on submitting a CD with several participants archived on the CD, please make sure to print or write with soft indelible marker all of the participants that are archived on the CD (this may limit the number of patients on one CD). Include patient ID, acrostic, exam date and visit. Indicate if image is a repeat or resubmission.

1. Pre-printed header identifies the study and modality.
2. **OAI Participant ID:** Enter 7 digit participant ID
3. **Acrostic:** Enter 4 character acrostic (first letter of participant’s first name and first three letters of participant’s last name) and **CD#:** (if making a label for electronic media)
4. **X-ray Exam Date:** Enter the x-ray date using the format **MM/DD/YYYY** (example: 02/27/2003 for February 27, 2003).
5. **Visit:** Check the box indicating the visit name.

**Please Remember:** OAI Participant ID and Acrostic will be provided by the Clinic Coordinator.
Radiograph Labeling

- One label must be affixed to the bottom or top right corner (when radiograph is in portrait orientation) on the front of each radiograph submitted. Be sure you do not obscure any anatomy when attaching the label.

- The flash region may be covered by the study label, but do not apply multiple layers of labels or labels on the back of the film. If there is any confidential information in the flash region, please use the study label to cover it up.

- Do not wrap label around the edge of the film (this hinders digitization of the film at Synarc).

- Do not attach other labels to the film.

- Do not mark the film with grease or wax pens.

- All knee, hand, pelvic, full limb and lateral knee radiographs should be placed in the same radiograph jacket. The radiograph jacket should be labeled with the same adhesive label used for the radiographs. Complete this label with the same information as on the radiographs.
# APPENDIX III X-ray Transmittal Form

**OAI X-ray Transmittal Form**

<table>
<thead>
<tr>
<th>Participant Information</th>
<th>To be completed by Study Site</th>
</tr>
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<tbody>
<tr>
<td>OAI Participant ID</td>
<td></td>
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<tr>
<td>Address</td>
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</tr>
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</table>

<table>
<thead>
<tr>
<th>Exam Information</th>
<th>To be completed by Study Site</th>
</tr>
</thead>
<tbody>
<tr>
<td>X-ray Exam</td>
<td>X-ray Exam Date</td>
</tr>
<tr>
<td>Bilateral PA Fixed Flexion Knee</td>
<td>2000</td>
</tr>
<tr>
<td>PA Dominant or Bilateral Hand</td>
<td>2000</td>
</tr>
<tr>
<td>AP Pelvis</td>
<td>2000</td>
</tr>
<tr>
<td>Fluor-guided Right Knee</td>
<td>2000</td>
</tr>
<tr>
<td>Fluor-guided Left Knee</td>
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</tr>
<tr>
<td>Lateral Right Knee</td>
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<tr>
<td>Lateral Left Knee</td>
<td>2000</td>
</tr>
<tr>
<td>Full Limb</td>
<td>2000</td>
</tr>
</tbody>
</table>

**Comments:**

---

**Date Shipment to Synarc:**

Staff ID# of the person responsible for completing the information on the above portion of this Transmittal Form: [ ]

OAI X-ray Tech ID# [ ]

Total number of films [ ]

---

**Date Receipt:**

SYNARC

---

**Package Complete?**

- Yes
- No

- X-ray
- Initial X-ray if repeat
- X-ray Label
- Other Specify:

**Package Correct?**

- Yes
- No

- Transmittal Form
- Other Specify:

**Comments:**

---

**Processing**

SYNARC

---

**Synarc Tracking Number:** 0163 09 2004 0810 00001

---

**Synarc**

Ver 2.1 23-Aug-2006

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### Appendix IV OAI X-ray Parameter Log

#### Screening

<table>
<thead>
<tr>
<th>Exam</th>
<th>kVp</th>
<th>mAs</th>
<th>FFD</th>
<th>Tech. ID #</th>
<th>Comments</th>
<th>X-ray Date</th>
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</thead>
<tbody>
<tr>
<td>Bilateral Knees</td>
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#### Enrollment

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#### 12 Month

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This Parameter Log should be photocopied or printed from the OAI website (under the Documents and Forms link) and completed for each study participant. It should then be filed in the participant’s chart and referenced at subsequent participant visits (the form will need to travel with the participant to the x-ray facility to be completed by the technologist and then back to the clinic for filing). Do NOT send this form to Synergy.

Page 1, March 6, 2006
### OAI X-ray Parameter Log (page 2)

**24 Month**

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**36 Month**

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March 6, 2006
APPENDIX V Supply Order Form

Please fill out a copy of this form and keep the blank original in the manual.

<table>
<thead>
<tr>
<th>OAI</th>
<th>Radiographic Supply Order Form</th>
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Please indicate quantity of each radiograph supply needed and fax this form to:
Andrey Semyonov
Fax: 415-817-8999
Attention: OAI Project Team

Supplies will be sent to the following location:
Please update contact name and address information as needed.

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<table>
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