Instructions: This review is for all Radiology services being requested during a research protocol, regardless of who is paying for the procedure. This form should be completed even if the procedure will be billed to insurance. Email the completed Word Document to India Taliaferro ([india.taliaferro@choa.org](mailto:india.taliaferro@choa.org)) along with the protocol and imaging manuals (if applicable).

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| Short Title: | | | Date form completed by study team: |
| Study Title: | | | Protocol version (include version date): |
| Funding Source: | Internal  Federal  Foundation  Non-industry | | |
| Industry Unfunded  Other: | | |
| PI Name (Last, First): | | PI Department: | |
| PI Phone Number: | | PI Email Address: | |
| Study Coordinator: | | Research Administrator: | |
| Phone Number: | | Phone Number: | |
| Email Address: | | Email Address: | |

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| **General** | | |
| 1 | At which CHOA locations will the radiology procedures be performed? | EG  SR  WB  TC |
| 2 | What is the target enrollment number for the CHOA site? |  |
| 3 | Provide an age range of your target population. |  |
| 4 | Is a CHOA Radiologist a co-investigator on this study? | YES  NO |
| 4a | If yes, provide the name(s) of the radiologist(s). |  |
| 5 | Does the Sponsor supply an Imaging Manual or a document with imaging instructions that exists separate from the protocol?  Note: Please confirm with Sponsor. Provide a copy with this completed form. If a manual is supplied AFTER the review, a new review will be required and may change the outcome of the first review. | YES  NO |
| 6 | Does the sponsor require or suggest Radiology complete training specific to your protocol?  Note: Please confirm with Sponsor. If yes, please ask Sponsor to email an outline of the training requirements to the radiology coordinator. | YES  NO |
| 7 | Does your Sponsor require any Phantom or QA scans performed at the initiation or during the duration of the study?  Note: Please confirm with Sponsor. | YES  NO |
| 8 | Will sedation be used on all or some of the patients enrolled in this study?  Note: This includes sedation ordered for research or as clinically indicated. | Yes, as clinically indicated  Yes, IRB approved/pending  No sedation |
| 9 | What modalities will be used during the research study? **For each modality marked, complete the corresponding sections below.**  MRI: MRI, MRA/MRV, Cardiac MRI  Nuclear Medicine: PET/CT, PET, MIBD, DXA, Bone Scan, Liver SPECT  Interventional Radiology: Liver Biopsy, Fluoroscopy  If you require tumor imaging and specific scans are unknown at the start of the study, select each modality that may be used. | X-Ray  MRI  CT  Nuclear Medicine  Ultrasound  Interventional Rad. |
| 10 | How will data be transferred from Radiology to Sponsor?  Ex. de-identified disk, sFTP, online upload, Rad report printed from EPIC, etc. |  |
| 11 | Will you need a waiver of a clinical read on any scans performed in this study? | YES  NO |
| 11a | If yes, list which scans should not be read by CHOA Radiology. | MRI |
| 11b | If yes, is there a Central Reviewer who will be reading the images? | YES  NO |
| 11c | If yes, when will the Central Reviewers read the images (i.e., 2 days, 2 years)? |  |
| 11d | If yes, will the Central Reviewers let CHOA know if there are any incidental findings? | YES  NO |

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| **X-Rays** | | |
| 1 | What pages in the protocol discuss x-rays? |  |
| 2 | What x-ray procedures are requested?  List out individual orders.  X-Ray Ankle 2v bilateral  X-Ray Femur 2v lateral (right leg)  X-Ray Bone Age  If you require Tumor Imaging and specific scans are unknown at study start-up. Please enter “Tumor Imaging.” |  |
| 3 | How many times are the patients scanned throughout the study?  Provide minimum number of individual scans required for a single patient.  If maximum number of scans varies from patient to patient depending on cycles, subgroups, etc., mark as such. | Min:  Max:  Varies from patient to patient |
| 4 | Do you require Radiology to complete Data Transfer Forms (DTF) or Research Forms for each patient scan? | YESM  NO |
| 5 | Does the protocol request the reading Radiologist to provide certain measurements or information in the radiology report?  If no, Radiology assumes we will perform our SOC reading protocols. | YESM  NO  Waiver Requested |
| 5a | If yes, describe reading requirements. |  |
| 7 | Any additional comments concerning scan(s)? |  |
| **Radiology Use Only** | | |
| 1 | Is there an imaging manual for x-ray? | YES  NO |
| 2 | Does the Sponsor require Phantom/QC Scans? | YES  NO |
| 2a | If yes, at what interval? | Initial  QuarterlyM  MonthlyM  AnnuallyM  Other: |
| 3 | Will Radiology perform a clinical read? | YES  NO |
| 3a | If no, who approved the waiver? | Slkjslkjfhdsikfol |
| 4 | Will the study team need a de-identified disk or data transfer? | YESM  NO |
| 5 | Is a specific scanner required? | YES  NO |
| 5a | If yes, which one? |  |
| 6 | Do the requested procedures match our SOC imaging protocols? | YES  NO |
| 6a | EG Radiology Review: kHV | |
| 6b | SR Radiology Review: | |
| 7 | Will radiology perform specific reading requirements? | YESM  NO |
| 7a | EG Radiology Review: | |
| 7b | SR Radiology Review: | |
| 8 | Additional comments: | |

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| **Magnetic Resonance Imaging (MRI)** | | |
| 1 | What pages in the protocol discuss MRI? |  |
| 2 | What MRI procedures are requested?  List out individual orders.  MRI Brain without contrast  MRI spine with and without contrast  MR Spectroscopy of extremity  If you require Tumor Imaging and specific scans are unknown at study start-up, enter “Tumor Imaging.” |  |
| 3 | How many times are the patients scanned throughout the study?  Provide minimum number of individual scans required for a single patient.  If maximum number of scans varies from patient to patient depending on cycles, subgroups, etc., mark as such. | Min:  Max:  Varies from patient to patient |
| 4 | Does the study *require* a morning or early afternoon scan? | YES  NO |
| 4a | If yes, explain why it is required. |  |
| 5 | Is an MRI required at the screening visit (or first visit of the study)?  Note: The wait list for an MRI is two-three weeks. Please be sure to allow enough time between patient enrollment and screening visit to accommodate the busy MRI schedule. | YES  NO |
| 6 | Do you require Radiology to complete Data Transfer Forms (DTF) or Research Forms for each patient scan? | YESM  NO |
| 7 | Does the protocol request the reading Radiologist to provide certain measurements or information in the radiology report?  If no, Radiology assumes we will perform our SOC reading protocols. | YESM  NO  Waiver Requested |
| 7a | If yes, describe reading requirements. |  |
| 8 | Any additional comments concerning scan(s)? |  |
| **Radiology Use Only** | | |
| 1 | Is there an imaging manual for MRI? | YES  NO |
| 2 | Does the Sponsor require Phantom/QC Scans? | YES  NO |
| 2a | If yes, at what interval? | Initial  QuarterlyM  MonthlyM  AnnuallyM  Other: |
| 3 | Will Radiology perform a clinical read? | YES  NO |
| 3a | If no, who approved the waiver? |  |
| 4 | Will the study team need a de-identified disk or data transfer? | YESM  NO |
| 5 | Is a specific scanner required? | YES  NO |
| 5a | If yes, which one? |  |
| 6 | Do the requested procedures match our SOC imaging protocols? | YES  NO |
| 6a | EG Radiology Review: | |
| 6b | SR Radiology Review: | |
| 7 | Will radiology perform specific reading requirements? | YESM  NO |
| 7a | EG Radiology Review: | |
| 7b | SR Radiology Review: | |
| 8 | Additional comments: | |

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| **Computed Tomography (CT)** | | |
| 1 | What pages in the protocol discuss CT? |  |
| 2 | What CT procedures are requested?  List out individual orders.  CT neck without contrast  CT chest with and without contrast  CTA Abdomen  If you require Tumor Imaging and specific scans are unknown at study start-up, enter “Tumor Imaging.” |  |
| 3 | How many times are the patients scanned throughout the study?  Provide minimum number of individual scans required for a single patient.  If maximum number of scans varies from patient to patient depending on cycles, subgroups, etc., mark as such. | Min:  Max:  Varies from patient to patient |
| 4 | Does the study *require* a morning scan? | YES  NO |
| 4a | If yes, explain why it is required? |  |
| 5 | Do you require Radiology to complete Data Transfer Forms (DTF) or Research Forms for each patient scan? | YESM  NO |
| 6 | Does the protocol request the reading Radiologist to provide certain measurements or information in the radiology report?  If no, Radiology assumes we will perform our SOC reading protocols. | YESM  NO  Waiver Requested |
| 6a | If yes, describe reading requirements. |  |
| 7 | Any additional comments concerning scan(s)? |  |
| **Radiology Use Only** | | |
| 1 | Is there an imaging manual for CT? | YES  NO |
| 2 | Does the Sponsor require Phantom/QC Scans? | YES  NO |
| 2a | If yes, at what interval? | Initial  QuarterlyM  MonthlyM  AnnuallyM  Other: |
| 3 | Will Radiology perform a clinical read? | YES  NO |
| 3a | If no, who approved the waiver? |  |
| 4 | Will the study team need a de-identified disk or data transfer? | YESM  NO |
| 5 | Is a specific scanner required? | YES  NO |
| 5a | If yes, which one? |  |
| 6 | Do the requested procedures match our SOC imaging protocols? | YES  NO |
| 6a | EG Radiology Review: | |
| 6b | SR Radiology Review: | |
| 7 | Will radiology perform specific reading requirements? | YESM  NO |
| 7a | EG Radiology Review: | |
| 7b | SR Radiology Review: | |
| 8 | Additional comments: | |

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| **Nuclear Medicine (NM)** | | |
| 1 | What pages in the protocol discuss NM? |  |
| 2 | What NM procedures are requested?  List out individual orders.  FDG-PET  Bone Scan  DEXA  If you require Tumor Imaging and specific scans are unknown at study start-up, enter “Tumor Imaging.” |  |
| 3 | How many times are the patients scanned throughout the study?  Provide minimum number of individual scans required for a single patient.  If maximum number of scans varies from patient to patient depending on cycles, subgroups, etc., mark as such. | Min:  Max:  Varies from patient to patient |
| 4 | Does the study *require* a morning scan? | YES  NO |
| 4a | If yes, explain why it is required? |  |
| 5 | Do you require Radiology to complete Data Transfer Forms (DTF) or Research Forms for each patient scan? | YESM  NO |
| 6 | Does the protocol request the reading Radiologist to provide certain measurements or information in the radiology report?  If no, Radiology assumes we will perform our SOC reading protocols. | YESM  NO  Waiver Requested |
| 6a | If yes, describe reading requirements. |  |
| 7 | Any additional comments concerning scan(s)? |  |
| **Radiology Use Only** | | |
| 1 | Is there an imaging manual for NM? | YES  NO |
| 2 | Does the Sponsor require Phantom/QC Scans? | YES  NO |
| 2a | If yes, at what interval? | Initial  QuarterlyM  MonthlyM  AnnuallyM  Other: |
| 3 | Will Radiology perform a clinical read? | YES  NO |
| 3a | If no, who approved the waiver? |  |
| 4 | Will the study team need a de-identified disk or data transfer? | YESM  NO |
| 5 | Is a specific scanner required? | YES  NO |
| 5a | If yes, which one? |  |
| 6 | Do the requested procedures match our SOC imaging protocols? | YES  NO |
| 6a | EG Radiology Review: | |
| 6b | SR Radiology Review: | |
| 7 | Will radiology perform specific reading requirements? | YESM  NO |
| 7a | EG Radiology Review: | |
| 7b | SR Radiology Review: | |
| 8 | Additional comments: | |

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| **Ultrasound (US)** | | |
| 1 | What pages in the protocol discuss ultrasound? |  |
| 2 | What ultrasound procedures are requested?  List out individual orders.  Transcranial Doppler  Abdominal limited  Duplex venous upper extremity bilateral  If you require Tumor Imaging and specific scans are unknown at study start-up, enter “Tumor Imaging.” |  |
| 3 | How many times are the patients scanned throughout the study?  Provide minimum number of individual scans required for a single patient.  If maximum number of scans varies from patient to patient depending on cycles, subgroups, etc., mark as such. | Min:  Max:  Varies from patient to patient |
| 4 | Do the ultrasound scans need to be de-identified?  Note: De-identifying US requires action by the sonographer prior to the scan. It is imperative that we are aware the scan is for research and needs to be de-identified prior to the scan. | YESM  NO |
| 5 | Do you require Radiology to complete Data Transfer Forms (DTF) or Research Forms for each patient scan? | YESM  NO |
| 6 | Does the protocol request the reading Radiologist to provide specific measurements or information in the radiology report?  If no, Radiology assumes we will perform our SOC reading protocols. | YESM  NO  Waiver Requested |
| 6a | If yes, describe reading requirements. |  |
| 7 | Any additional comments concerning scan(s)? |  |
| **Radiology Use Only** | | |
| 1 | Is there an imaging manual for ultrasound? | YES  NO |
| 2 | Does the Sponsor require Phantom/QC Scans? | YES  NO |
| 2a | If yes, at what interval? | Initial  QuarterlyM  MonthlyM  AnnuallyM  Other: |
| 3 | Will Radiology perform a clinical read? | YES  NO |
| 3a | If no, who approved the waiver? |  |
| 4 | Will the study team need a de-identified disk or data transfer? | YESM  NO |
| 5 | Is a specific scanner required? | YES  NO |
| 5a | If yes, which one? |  |
| 6 | Do the requested procedures match our SOC imaging protocols? | YES  NO |
| 6a | EG Radiology Review: | |
| 6b | SR Radiology Review: | |
| 7 | Will radiology perform specific reading requirements? | YESM  NO |
| 7a | EG Radiology Review: | |
| 7b | SR Radiology Review: | |
| 8 | Additional comments: | |

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| **Interventional Radiology (IR)** | | |
| 1 | What pages in the protocol discuss IR? |  |
| 2 | What Interventional Radiology procedures are requested?  List out individual orders.  Liver Biopsy  Fluoroscopy (Cardiology reviews all Fluoro that occurs in Cath Lab)  Venogram renal unilateral  If you require Tumor Imaging and specific scans are unknown at study start-up, enter “Tumor Imaging.” |  |
| 3 | How many times are the patients scanned throughout the study?  Provide minimum number of individual scans required for a single patient.  If maximum number of scans varies from patient to patient depending on cycles, subgroups, etc., mark as such. | Min:  Max:  Varies from patient to patient |
| 4 | Does the study *require* a morning scan? | YES  NO |
| 4a | If yes, explain why it is required? |  |
| 5 | Do you require Radiology to complete Data Transfer Forms (DTF) or Research Forms for each patient scan?  If yes, send forms to radiology coordinator. | YESM  NO |
| 6 | Does the protocol request the reading Radiologist to provide certain measurements or information in the radiology report?  If no, Radiology assumes we will perform our SOC reading protocols. | YESM  NO  Waiver Requested |
| 6a | If yes, describe reading requirements. |  |
| 7 | Any additional comments concerning scan(s)? |  |
| **Radiology Use Only** | | |
| 1 | Is there an imaging manual for IR? | YES  NO |
| 2 | Does the Sponsor require Phantom/QC Scans? | YES  NO |
| 2a | If yes, at what interval? | Initial  QuarterlyM  MonthlyM  AnnuallyM  Other: |
| 3 | Will Radiology perform a clinical read? | YES  NO |
| 3a | If no, who approved the waiver? |  |
| 4 | Will the study team need a de-identified disk or data transfer? | YESM  NO |
| 5 | Is a specific scanner required? | YES  NO |
| 5a | If yes, which one? |  |
| 6 | Do the requested procedures match our SOC imaging protocols? | YES  NO |
| 6a | EG Radiology Review | |
| 6b | SR Radiology Review: | |
| 7 | Will radiology perform specific reading requirements? | YESM  NO |
| 7a | EG Radiology Review: | |
| 7b | SR Radiology Review: | |
| 8 | Additional comments: | |

**This page is to be completed by Radiology**

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| **Conclusion** | |
| Initiation Fee | 750.00  Waived |
| Maintenance Fee | 50.00/month  No  Waived |
| Imaging manuals | Yes  No |
| Training required | Yes  No |
| Phantom/QC scans required | Yes  No |
| Non-SOC scans | Yes  No |

Below is the information that should be inserted by the ordering physician(s) when the order is placed. Information goes into the comments section of the order form. This information allows radiology to know this is a research scan and what procedures to perform. It also allows radiology to prepare properly thus limiting any disruptions in our clinical workflow.

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| **Radiology Order Form Comments Section** | |
| X-Ray |  |
| MRI |  |
| CT |  |
| Nuclear Medicine |  |
| Ultrasound |  |
| Interventional Rad. |  |

Be sure to send a Department Approval Form to India Taliaferro to incorporate initiation fees, maintenance fees, and any technical/professional fees into your budget.

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Signature of Radiology Research Coordinator Date

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Print Name