**Radiology Research Study Workflow**

1. Meet with Radiology Research Team
	1. Discuss your research proposal. Determine if you will need a Radiology Consultant (i.e. Co-investigator) or solely Radiology Services.
2. Complete IRB Protocol Submission (see Appendix A)
	1. Full IRB Committee convenes the first 3 Tuesdays of every month for approval.
	\*IN ORDER FOR YOUR STUDY PROTOCOL TO BE REVIEWED AT THIS MEETING,\*
		1. All Study Team COIs need to be completed;
		2. Study must be past the Pre-Submission ***AND*** Pre-Review stage in ClickIRB at least 10 days prior to this meeting.
	2. Full IRB Committee Review can take anywhere from 3-8 weeks from the time you submit your protocol for review. Be sure you are submitting the correct protocol template from ClickIRB Library (I.e. Prospective study, Chart Review, Expedited, Exempt). Be sure to discuss this with your Research Coordinator. This will ensure your submission is approved in as timely a manner as possible.
3. Human Imaging Research Core PI Questionnaire needs to be completed.
	1. Completion and receipt of this document at radiologyresearch@salud.unm.edu will generate HIRC MOU that PI must sign.
	2. ***SIGNED MOU MUST CONTAIN*** ***Study Index Number AND Departmental Alternate Index Number***. If these numbers are not listed on the MOU, study imaging with HIRC will not occur.
4. ***IF DATA NEEDS TO BE TRANSFERRED OUTSIDE OF UNM*:**
	1. PI/Research Coordinator of requesting study needs to complete DTA/DUA
		1. <https://hsc.unm.edu/financialservices/preaward/ancillary-agreements/data-agreements/index.html>
		2. Research teams have no control over the timeline for DTA approval, and the process for approval can take anywhere from several weeks to several months. Please be aware that submitting this request does not guarantee DTA/DUA approval.
	2. CTSC Data Warehouse Request must be completed.
		1. <https://ctsc.health.unm.edu/apps/data-request-landing/>
		2. Data Warehouse Committee meets 2nd and 4th Tuesday of every month. Data Requests should be in by preceding Friday to ensure your request is on the docket.
		3. Anonymized data can take a few weeks once Honest Broker has received CTSC Approval for the Data Pull depending on amount of data requested.

**Appendix A: New Study Submission Checklist**

Verify the correct template forms at this address: <https://hsc.unm.edu/research/hrpo/downloads/submission.html>.
Typically, the following are required documents for new studies.

**Required for ALL New Study Applications**

* New Study Submission (Click Smartform)
* Protocol (HRP Template OR Sponsor protocol and the Local Protocol Addendum
* Departmental Scientific Review Form
* IRB Fees Determination Form
* Grant Form (if applicable)

**Required for PI of record and ALL Study Team Members**

* CV (PI and Co PIs)
* HRPO Staff confirmation of all CITI training and FCOI training
	+ ***DON’T CLICK “SUBMIT” FOR IRB PRE-REVIEW UNTIL ALL COI DISCLOSURES ARE COMPLETE, IT WILL BE SENT BACK TO PRE-SUBMISSION.***

***If Applicable***

* Consent form
* HIPPA Addendum
* Recruitment Materials
* Drug/Device Information
* COI Screening form for non-UNM Investigators
* Certificate of Confidentiality.doc
* Radiation Safety Attachment
* Drug Attachment
* IND/HDE Info, approvals
* Biological Specimens Attachment
* Disclosure statement for MRN Employees
* CTSC Attachment
* Other IRB Approvals
* Investigator Brochure
* Letter of Support from sponsors
* Assent Forms

***Other Study Documents***

* Participant Material
* Data Collection tools
* Interview Script/Questions
* Case Report Forms
* Questionnaires
* Surveys

**\*\*\*ALL DOCUMENTS MUST BE ATTACHED IN THE IRB SMART FORM\*\*\***