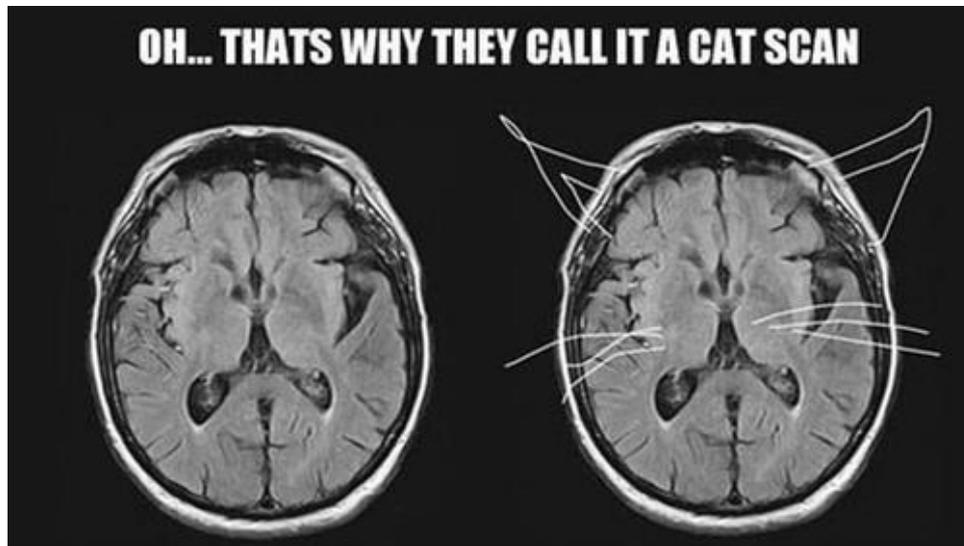


# Conducting Research Involving Medical Imaging



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# Objectives

- Summarize the risks of medical imaging involving ionizing radiation
- Summarize requirements for studies involving imaging at UNC, including SOPs and the IRBIS application
- Summarize the facilities and resources available at the UNC Biomedical Research Imaging Center



# Benefits of Medical Imaging

- Early detection/treatment
- Treatment response assessment



# *What are some uses of medical imaging for research?*

- Improve medical imaging techniques
- Oncology screening
- Assess response to medical treatment (lesion tracking, bone density changes, etc)



# Key topics to consider

- Incidental Findings: A finding that is outside the original intended purpose of the test
- Radiation considerations
- Pregnancy testing considerations
- Patient assumption that images are reviewed



# Risks of Medical Imaging

## – *Economic*

- *getting insurance or a job*
- *cost of additional diagnostics/treatment*

## – *Psychological*

- *anxiety or stress from diagnoses*
- *Claustrophobia*

## – *Medical*

- *false-positives/false-negatives*
- *additional treatment*
- *research images may not be diagnostic quality*
- *risk to fetus*
- *radiation risk*
- *discomfort*
- *contrast considerations (rash, fever, IV, etc)*



# Radiation Exposure

<b>Procedure</b>	<b>Average effective dose (mSv)</b>
Bone density test+	0.001
X-ray, arm or leg	0.001
X-ray, panoramic dental	0.01
X-ray, chest	0.1
X-ray, abdominal	0.7
Mammogram	0.4
X-ray, lumbar spine	1.5
CT, head	2
CT, cardiac for calcium scoring	3
Nuclear imaging, bone scan	6.3
CT, spine	6
CT, pelvis	6
CT, chest	7
CT, abdomen	8
CT, colonoscopy	10
CT, angiogram	16
CT, whole body	variable
Nuclear imaging, cardiac stress test	40.7

Source: Mettler FA, et al. "Effective Doses in Radiology and Diagnostic Nuclear Medicine: A Catalog," *Radiology* (July 2008), Vol. 248, pp. 254–63.



# UNC IRB SOPs

Where do I start with a study involving imaging at UNC?

Link to UNC IRB SOPs:

<https://research.unc.edu/human-research-ethics/>



# Does my study need to be reviewed by the Radiation Safety Subcommittee?

- Does your study imaging involve ionizing radiation (ie, x-ray, CT, fluoroscopy, PET imaging)?
- Is the radiation dose greater than that of 5 chest x-rays?

If the answer is yes to both of the above, your study must be reviewed by the RSS.



Does my study need pregnancy testing?



# UNC IRB Pregnancy Testing Requirements

*All females who are of child-bearing potential (CBP) being considered for participation in a research study, in which there is a real or reasonably inferred known harm to a fetus from the study interventions, must have a negative pregnancy test before undergoing any study-related activities.*



# Childbearing Potential

- Childbearing Potential (CBP):
  - are anatomically and physiologically capable of becoming pregnant
    - Currently menstruating
- Past or not of CBP:
  - 60 years old or greater, or
  - Age 50 and has not menstruated for 12 months or has a follicle stimulating hormone level  $> 40$  mIU/L
  - hysterectomy or a bilateral oophorectomy



# Pregnancy testing outside of UNCHC

- Tests must be:
  - U.S. Food and Drug Administration (FDA) approved
  - used prior to the date of expiration
  - read by an appropriately trained member of the research team



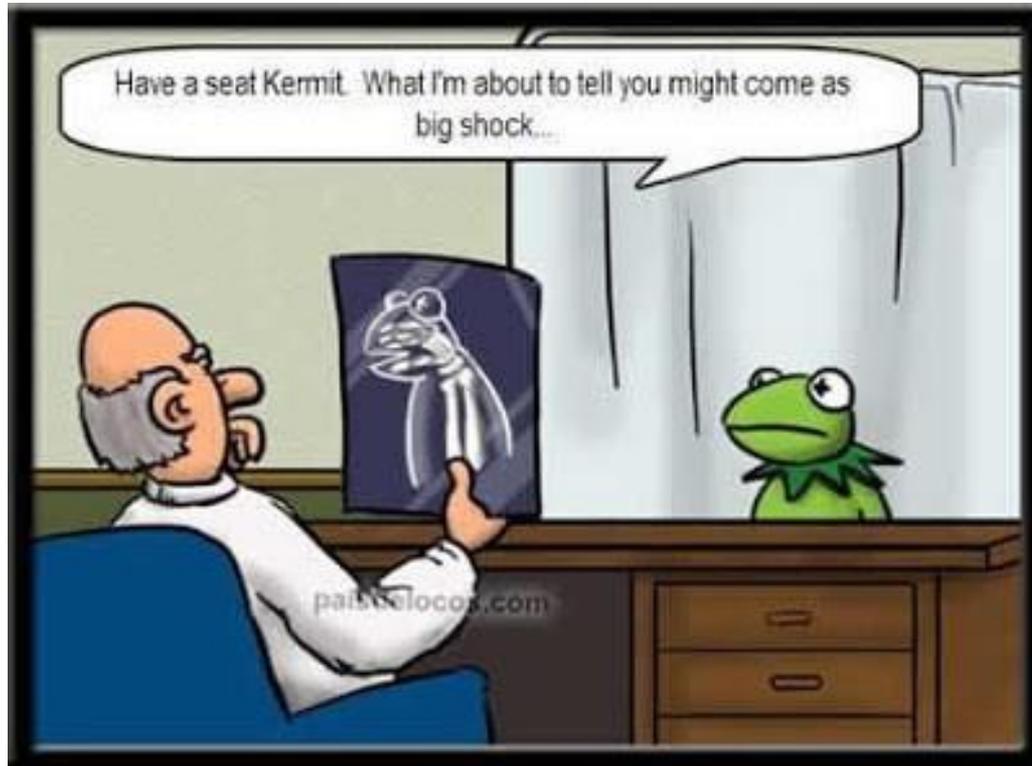
# MRI- Pregnancy Testing

- No pregnancy testing (verbal confirmation only)
  - FDA approved Magnetic Resonance Imaging (MRI) machines without contrast\*
  - Non-FDA approved receive-only MRI coils used
- Pregnancy testing required (within 36 hours prior)
  - Non FDA-approved MRI machines with or without contrast.
  - Non- FDA approved transmit-receive MRI coils used

\*If the patient suspects that she is pregnant, a pregnancy test must be done.



# How should incidental findings be reviewed at UNC?



# Overview of Major Categories of Incidental Findings

- The PI and IRB feel it is unlikely that clinically significant abnormalities will be present
- The PI and IRB feel that the incidence of clinically significant incidental findings is higher than in the general population
- If the imaging findings will be used as exclusion criteria or primary study endpoints
- If a central reading facility is used, such as in a multisite trial



Unlikely that clinically significant abnormalities will be present

- No requirement for radiologist or other qualified reviewer
- If IF is seen, then contact radiologist to review before notifying subject
- Consultation pathway should be outlined in the IRB application
- Subject notification should be outlined in the application



Incidence of clinically significant incidental findings is higher than in the general population

- All images should be reviewed by a radiologist credentialed by UNC Health Care or other qualified reviewer
- Consultation pathway should be outlined in the IRB application



# Imaging findings will be used as exclusion criteria or primary study endpoints

- Radiologist or other qualified reviewer should be included as an investigator on the study



# A central reading facility is used

- Include a description of the process
- Consent should outline information about review of images and whether IFs disclosed



# IRBIS Changes in Section A.4.A

Any form of medical imaging (ultrasound, MRI, CT, X-ray, PET-CT, PET-MRI)

As your study involves the use of medical imaging, which has potential to identify incidental findings. Please indicate which of the following best applies to your study.

1. It is unlikely that clinical abnormalities will be present in the research imaging. (This option includes studies with healthy volunteers or where the potential for incidental findings is similar to the general population.) **OR**
2. The incidence of incidental findings from research imaging is higher than the general population.

Please select all that apply.

- The imaging findings from this study will be used as exclusion criteria or primary study endpoints .
- A central site will be used to read all research images.

Describe the image review process, including who will review these images and the steps that will be taken to communicate any findings that have been identified and confirmed by a qualified reviewer.

Describe the risk/benefit ratio of disclosing incidental findings.



# Additional ICF Language

## **What will happen if you take part in the study?**

*Whenever imaging [MRI, CT, X-ray, etc.] is done, there is the chance of finding something unexpected. Unexpected findings can have clinical significance, or no clinical significance. Clinically significant means that the [MRI, CT, X-ray, etc.] shows a problem that may or require further follow up or treatment. The imaging studies in this study will be reviewed by a qualified radiologist. You will be informed of any findings of clinical significance that may be discovered during the imaging procedure.*

*There may be benefits to learning such results (such as early detection and treatment of a medical condition), but there are risks as well (such as problems with getting insurance or a job, or feeling worried about a finding for which no treatment is required or appropriate). The [MRI, CT, X-ray, etc.] we are using in this research study is not the same quality as a [MRI, CT, X-ray, etc.] that you may have as part of your health care. If you believe you are having symptoms that may require clinical imaging, you should contact your primary care physician.*

*If a central site will be used to read research images your [MRI, CT, X-ray, etc.] will be conducted here at UNC no UNC physician will review the [MRI, CT, X-ray, etc.]. Rather, your images will be reviewed by a “central reader,” a physician designated by the sponsor of this trial to review all of the images. We will inform you of any findings of clinical significance that the central reader tells us about.*



# Radiology Core Services

- Imaging Reads Outside of Standard Clinical Reads Or Imaging Requirements Not Considered Standard of Care For This Institution
- Image de-identification

[rad\\_core@med.unc.edu](mailto:rad_core@med.unc.edu)



# Core Rates

- Special Reads ..... \$53.00
- Anonymization (disc/upload) ..... \$46.00
- Hourly Rates\* ..... \$50.00



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