

SOM CTU: Clinical Research Education Series Fall 2024

HIRE COMMITTEE: EXPOSED

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Human Investigations Involving Radiation Exposure (HIRE Ctte), Member

Department of Radiology and Medical Imaging

University of Virginia Health System

ACCREDITATION

The University of Virginia School of Medicine and School of Nursing awards **1.0 contact hour** for nurses who participate in this educational activity and complete the post activity evaluation.

The University of Virginia School of Medicine and School of Nursing awards **1.0 hour of participation** (consistent with the designated number of *AMA PRA Category 1 Credit(s)TM* or ANCC contact hours) to a participant who successfully completes this educational activity. The University of Virginia School of Medicine and School of Nursing maintains a record of participation for six (6) years.

DISCLOSURES

Full Disclosure Policy Affecting CME Activities: As a joint accredited provider, the University of Virginia Office of CME/CE requires attested and signed global disclosure of the existence of all financial interests or relationships with commercial interest from any individual in a position to control the content of a CME activity sponsored by OCME.

Disclosure Summary:

No one in a position to control the content of this educational activity has disclosed a relevant financial interest or relationship with any commercial interest

ACTIVITY CODE

Activity Code: **24762**

Instructions for claiming credits/contact hours can be found [here](#).

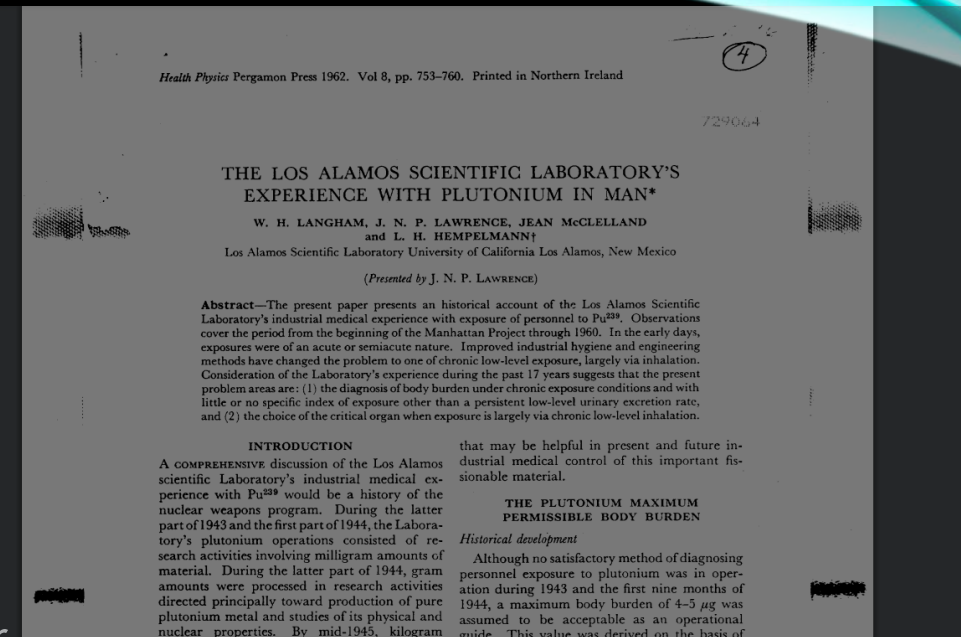
OBJECTIVES FOR TODAY

- Describe the purpose and function of the HIRE Committee
- Identify when medical imaging in your protocol is being performed for research purposes and when HIRE submission is required
- Explain what information is needed when submitting to the HIRE committee

OUR HISTORY...

Various human radiation experiments have been conducted in the United States, often funded by U.S. government agencies. Many of these occurred with vulnerable populations, without participant consent or knowledge, and with no benefit.

- Manhattan Project 1945-1947 , physicians injected hospitalized humans with plutonium, uranium, and polonium – secretly studying the effects on humans to help develop safety protocols for MP workers
- 1963-1973- Researchers irradiated the testicles of 232 prisoners to study the effects on testicular function. Some of the inmates left prison and had offspring born with birth defects
- US Atomic Energy Commission & Quaker Oats 1946-1953 - fed 73 disabled children radioactive calcium and other radioisotopes to track how nutrients were digested. The children were told by hospital staff and researchers that they were joining a science club.



CFR - Code of Federal Regulations Title 21

§ 50.25 Elements of informed consent.

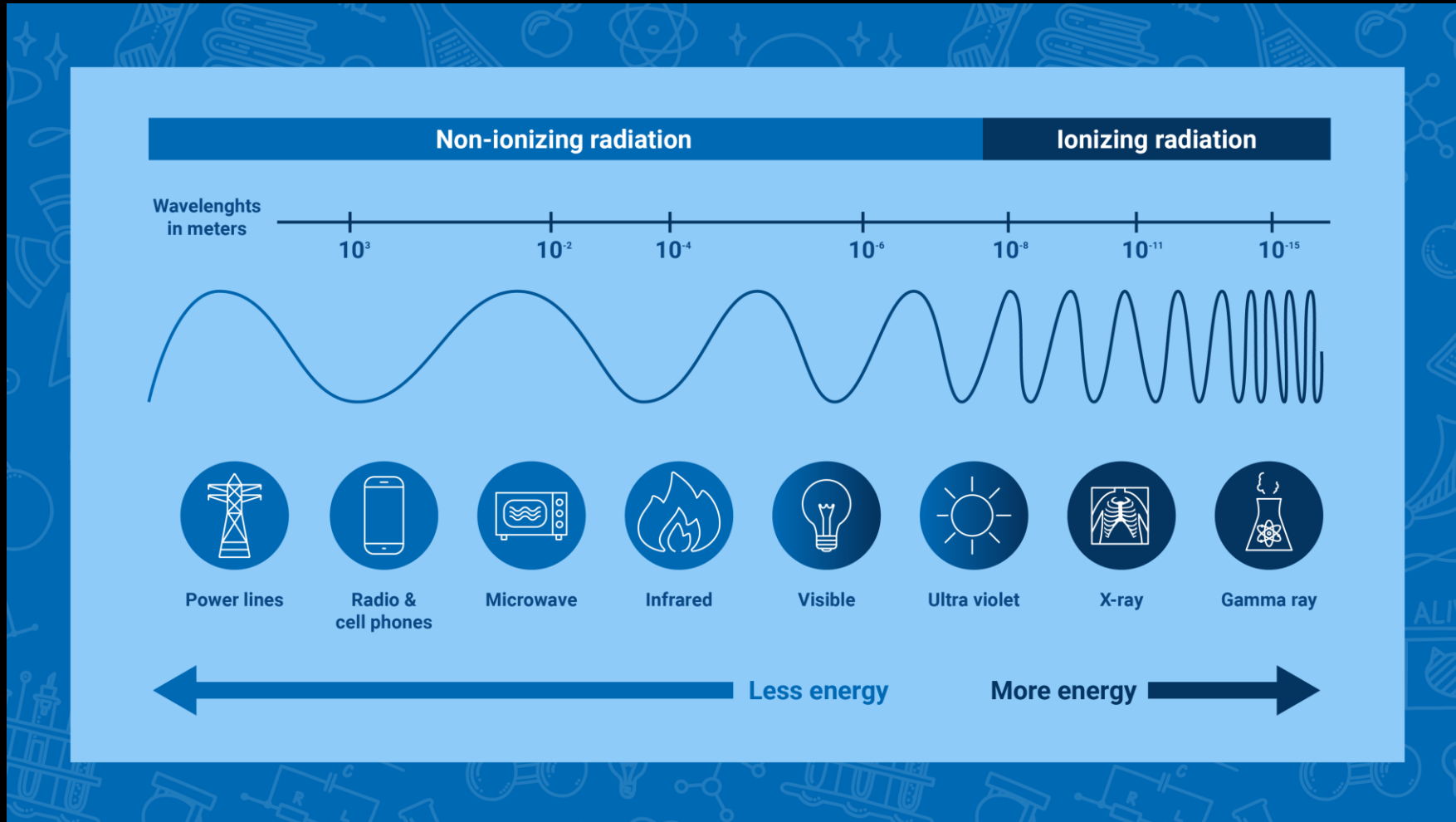
- (a) *Basic elements of informed consent.* In seeking informed consent, the following information shall be provided to each subject:
 - (1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.
 - (2) A description of any reasonably foreseeable risks or discomforts to the subject.
 - (3) A description of any benefits to the subject or to others which may reasonably be expected from the research.

benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

- (b) *Additional elements of informed consent.* When appropriate, one or more of the following elements of information shall also be provided to each subject:
 - (1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable.

WHAT IS RADIATION?

Radiation is energy that moves from one place to another in a form that can be described as waves or particles.



WHY HIRE?

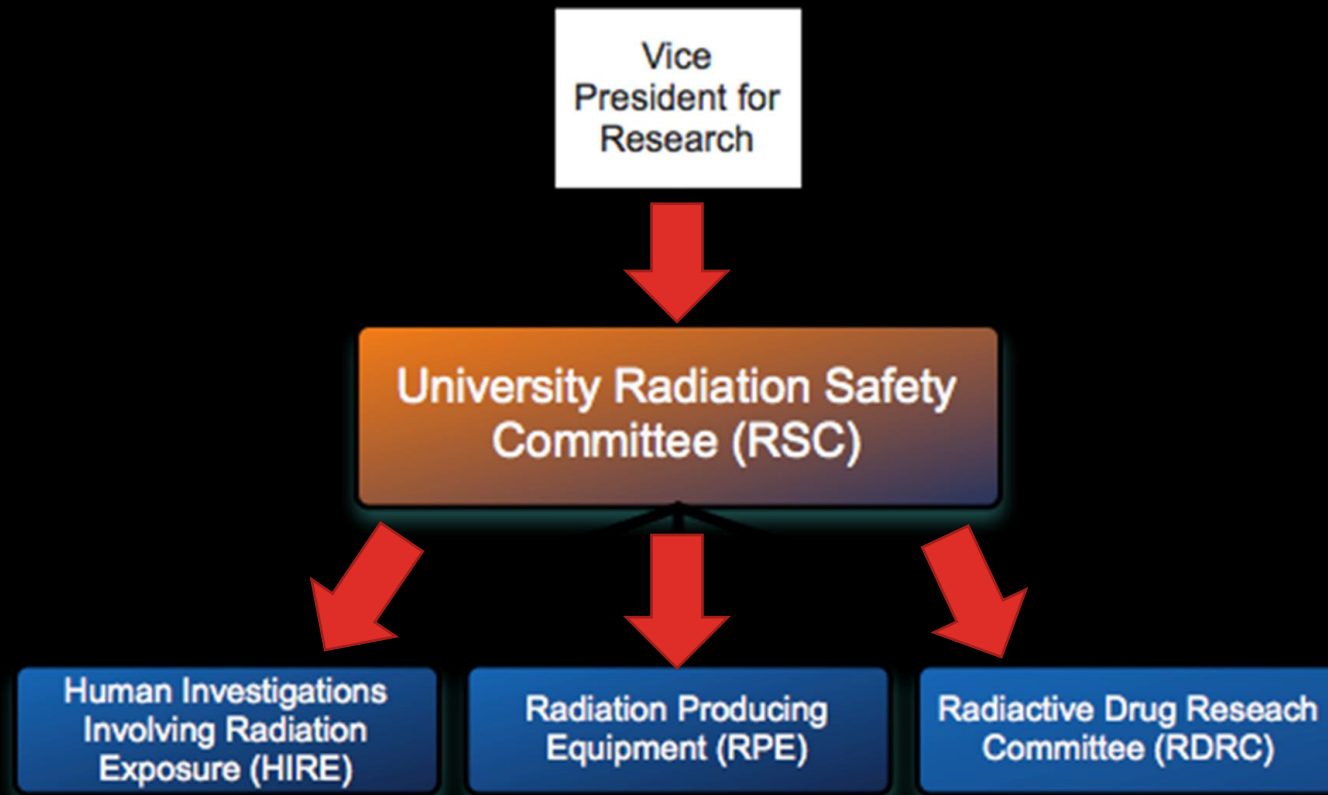
“Use of ionizing radiation in human research in any manner that does not directly benefit the patient/subject (i.e. beyond standard of care) must be approved by the RSC, specifically the Human Investigations Involving Radiation Exposure (HIRE) subcommittee or the Radioactive Drug Research Committee (RDRC).”

The main roles of the HIRE committee are:

1. Ensure the safe, effective use and proper design of research studies that involve the use of ionizing radiation
2. Provide estimates of radiation dose to subjects in those trials that convey the risk of participating in the trial or study, through proper consent language



HIRE COMMITTEE STRUCTURE



WHO IS THE HIRE COMMITTEE?



Allen Goode, MS, DABR Chief Diagnostic Medical Physicist, HIRE Chairman



Patricia Collins, PhD, DABR Diagnostic Medical Physicist



Andrew Polemi, PhD Diagnostic Medical Physicist

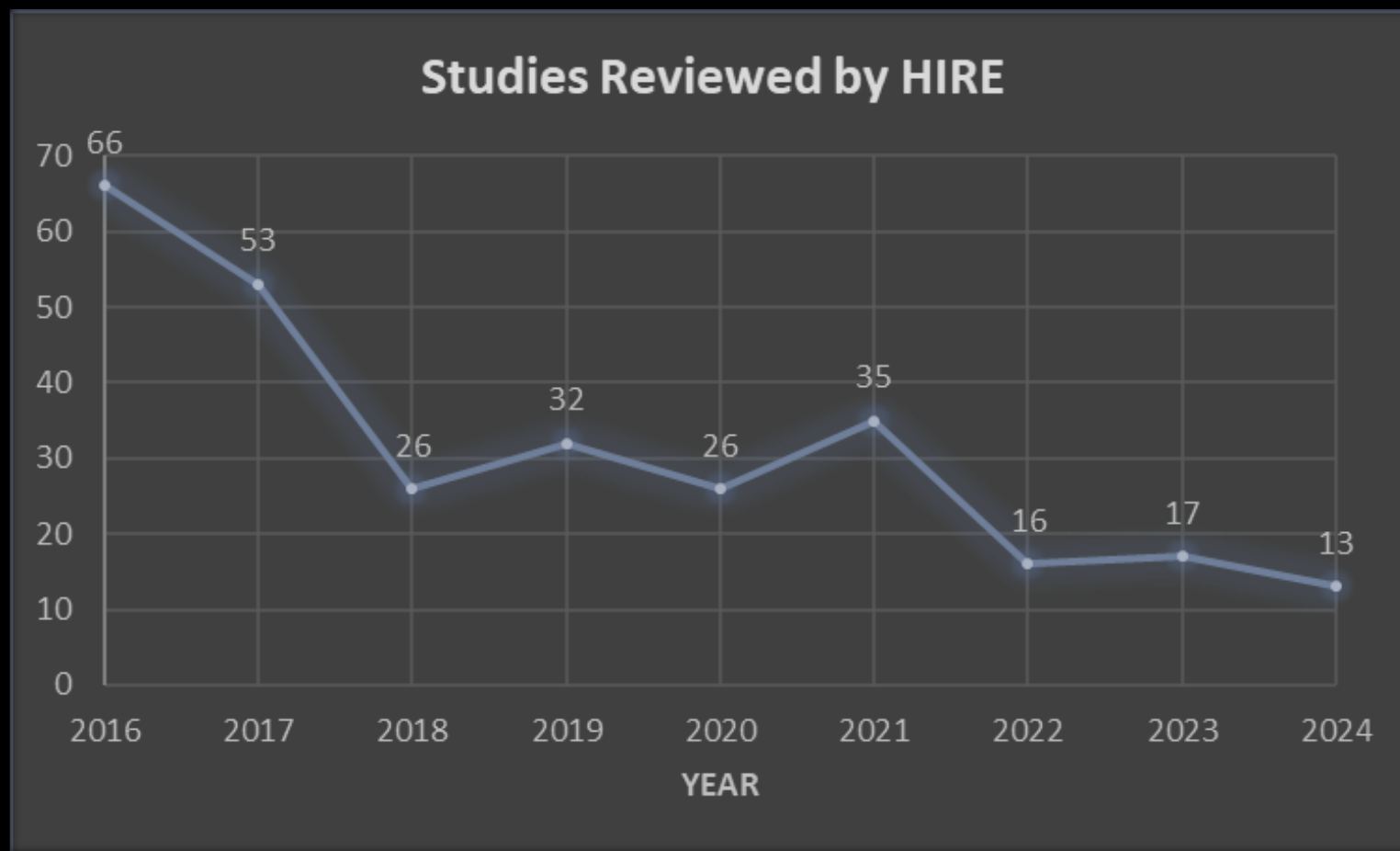
Mike Welling, MS Radiation Safety Officer (Health Physicist)

J. Fritz Angle, MD (Radiologist)

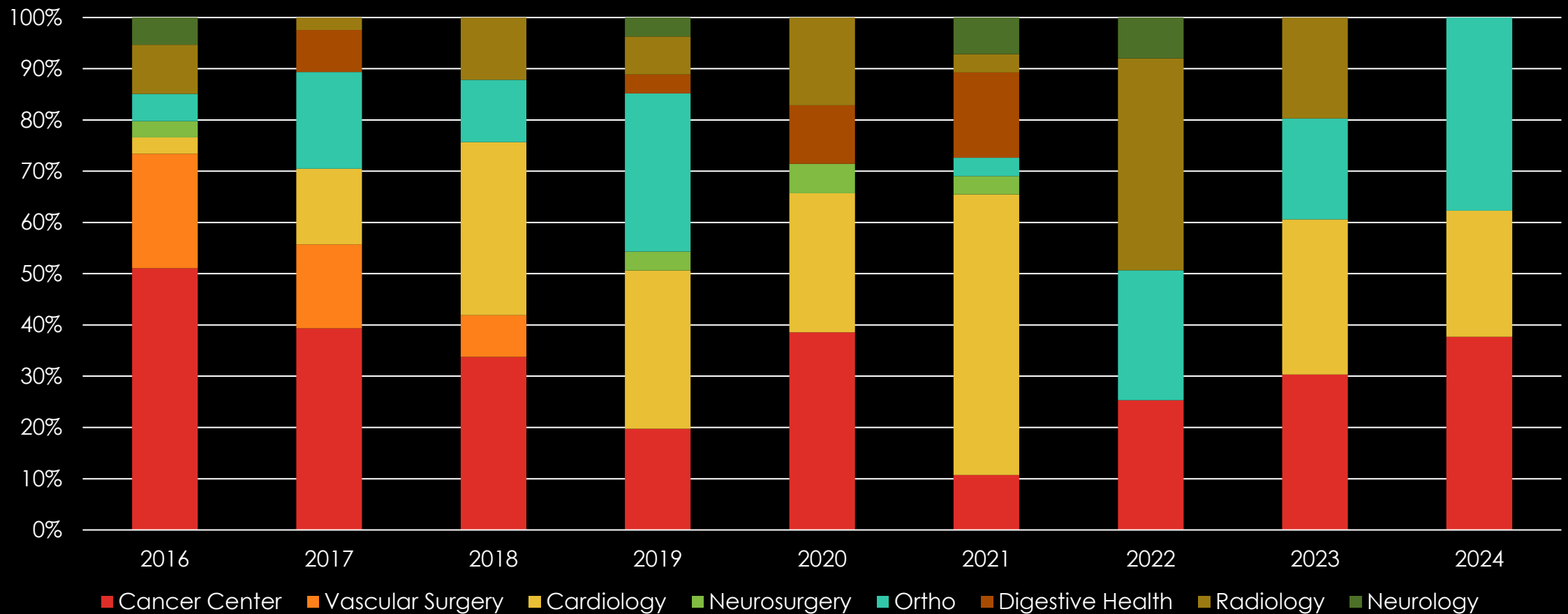
Klaus Hagspiel, MD (Radiologist)

Christopher M. McLaughlin, MD (Radiation Oncologist)

VOLUME OF STUDIES REVIEWED BY HIRE



WHAT TEAMS KEEP HIRE BUSY?



TWO SUBMISSION PATHWAYS

(NEW) Protocols that have not been approved by UVA IRB HSR

Protocol Builder

CRConnect

CRConnect2

OR

**(MOD) Protocols that have been previously approved by the UVA IRB HSR
that have been amended**

Use X-Ray imaging form from the HIRE web

HIRE SUBMISSION PROCESS

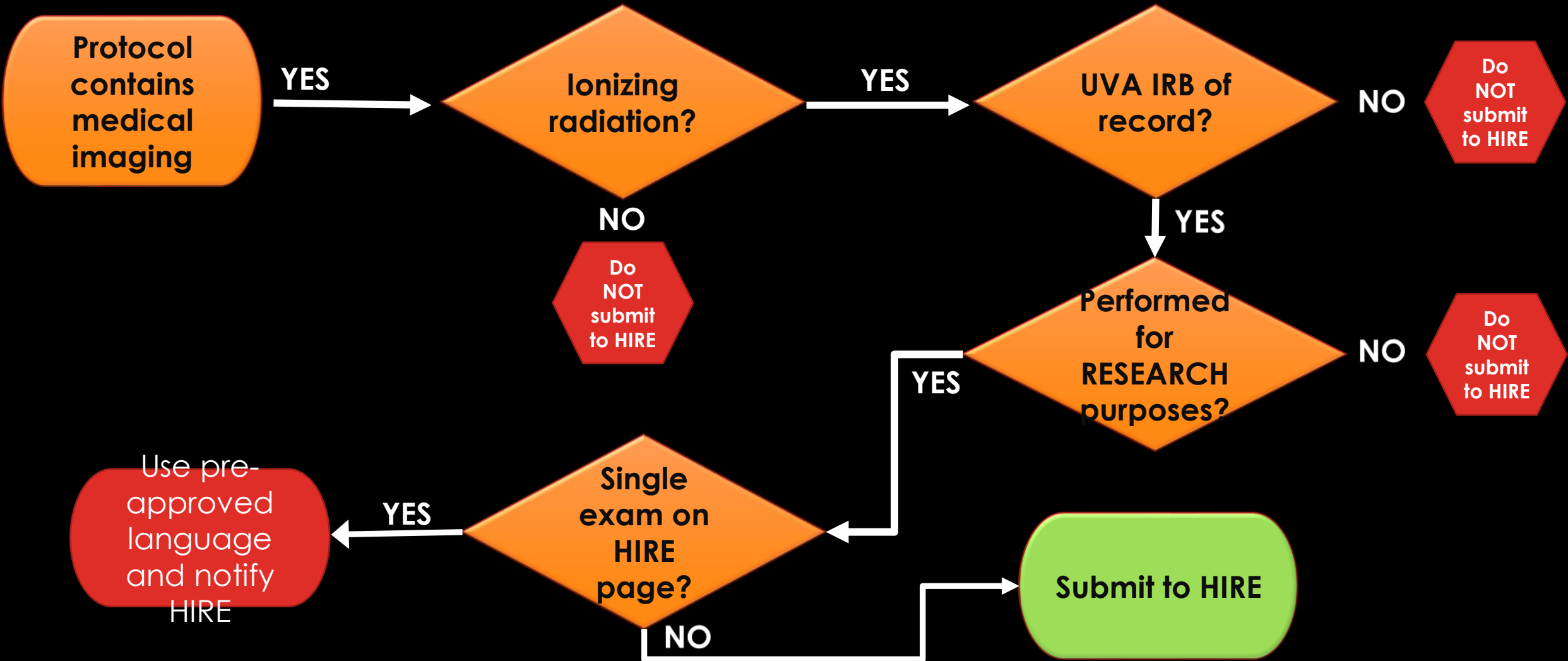
1. Read the protocol
2. Repeat step #1
3. Identify any medical imaging OR tests/procedures that utilize medical imaging.
4. Determine if it is ionizing or non-ionizing.
 1. X-rays
 2. CT scans
 3. Fluoroscopy
 4. Nuclear Medicine
 5. Interventional Procedures

Need help?

AskHIRE@virginia.edu

NOW FOR THE FUN STUFF.....

Do I need HIRE to provide risk language?



SUBMISSION DOS AND DON'TS



- Provide imaging manuals/acquisition guidelines if available
- Inform HIRE if your study enrolls minors/peds – which age groups
- Tell us if UVA is following the protocol differently than as written
- If your subjects will be using a specific scanner or location
- CALL US



- Avoid cutting and pasting lengthy unrelated details from the protocol
- Dismiss screening, end of study, or poor quality imaging exams.
- Guess at number of views or anatomy to be imaged
- Have an identity crisis - SOC vs research

WHERE DOES MY SUBMISSION GO?

3 Categories for Risk in Trials

	Effective Dose Range (mrem)	Dose + Risk	Annual background exposure 300 mrem
LEVEL A	0-300	Low Dose – most are listed on the HIRE web page	DEXA Whole Body < 1 Chest XR (2 view PA + LAT) 24 Head CT 200 Mammo 70-200
LEVEL B	300-5000	Medium Dose and Risk, majority of trials fall in this category	Chest CT 800 Angioplasty (cardiac) 750-5700 Coronary Angiogram 460-1580
LEVEL C	>5000 OR 5 Rem	High Dose, Higher Risk, trials in this category can be complex to review. <u>These require HIRE Committee review and voting.</u>	Annual Dose allowed for radiation workers 5000

I HAVE SUBMITTED TO HIRE....NOW WHAT?

Once your submission has been received by HIRE we generally send an email acknowledgement.

If we need more information we will contact you.

We strive for 2 weeks turnaround from the time we receive complete and accurate submission.

Check in with us if needed.

Thank you!

Questions?

AskHIRE@virginia.edu

bkelly@virginia.edu

<https://ahf.nuclearmuseum.org/ahf/history/human-radiation-experiments/>

<https://www.iaea.org/>

<https://www.xrayrisk.com/>

<https://www.epa.gov/radiation/calculate-your-radiation-dose>

<https://med.virginia.edu/radiology/resources/medical-physics-support/human-investigations-involving-radiology-exposure-hire-committee/>

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