THE UNIVERSITY OF IOWA

Human Subjects Office/
Institutional Review Board (IRB)
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For all Principal Investigator or research team contact on an IRB-01 or IRB-03 study:

This notice is intended to target researchers who may be using or plan to use a gadolinium based contrast agent with MRI imaging done for research purposes. Please note the new FDA guidance that was released on 9/9/10 by following the below link. In particular note the warnings and the screening requirements for possible reduced kidney function.

http://www.fda.gov/Drugs/DrugSafety/ucm223966.htm?sms_ss=email

Question V.2 in the HawkIRB application asks if "contrast agents of any kind are used for any purpose in this study." This question requires a "Yes" response if a gadolinium based contract agent(s) is used for *any* reason during the conduct of a study. A subsequent question V.3 will appear as a field requiring additional information be provided to describe what agent(s) will be used and how it will be administered. A common misperception of this question could be that it is looking for only the iodinated contrast used in X-ray/CT scanning. This is incorrect.

If a gadolinium based contrast agent is used, additional precautionary safety measures will be required to be incorporated into the research study by the IRB. These measures can be incorporated into the research protocol, informed consent document, and Section VII (Risks) of the HawkIRB application. In line with the FDA guidelines, the IRB minimum recommendations are, but are not limited to,

- Screening patients prior to administration of gadolinium-based contrast agents to identify those with acute kidney injury or chronic, severe, kidney disease. If an MRI with gadolinium is performed solely for research purposes, the IRB is likely to require that renal function be specially tested (e.g. serum creatinine) prior to the MRI, as many patients with reduced kidney function will be asymptomatic and not aware of their level of kidney function.

- Using the clinical history to screen patients for features of acute kidney injury or risk factors for chronically reduced kidney function.

- Avoiding the use of gadolinium-based contrast agents in patients suspected or known to have impaired drug elimination unless the need for the diagnostic information is essential and not available with non-contrasted MRI or other alternative imaging modalities.

- Monitoring for signs and symptoms of Nephrogenic Systemic Fibrosis after gadolinium-based contrast agents are administered to a patient suspected or known to have impaired elimination of the drug.

- Do not repeat administration of any gadolinium-based contrast agents during a single imaging session.

- Advising patients/subjects with kidney disease to contact a healthcare professional if any of the following symptoms occurs after receiving a gadolinium-based contrast agents: burning, itching, swelling, scaling, hardening and tightening of the skin; red or dark patches on the skin; stiffness in joints with trouble moving, bending or straightening the arms, hands, legs or feet; pain in the hip bones or ribs; or muscle weakness.

- Record the specific gadolinium-based contrast agents and the dose administered to a patient.

- When administering gadolinium-based contrast agents, do not exceed the recommended dose. Prior to any re-administration, allow sufficient time for elimination of the gadolinium-based contrast agents from the body.

- Report any adverse events with gadolinium-based contrast agents to FDA's MedWatch program &/or to the UI IRB under the REF tab found on the Project Summary page in HawkIRB. For additional reporting requirements for adverse events, please review Chapter 7, Section C of the UI Guide for Human Subjects Research (or Investigator's Guide) on the Human Subjects Office website found here. (https://research.uiowa.edu/hso/index.php?get=about)

Thank you for your attention to this information. If you have any questions regarding how to incorporate these changes into your HawkIRB application, please contact the Human Subjects Office at (319) 335-6564 or irb@uiowa.edu.

If you have a question regarding the use of a gadolinium based contrast agent in research, please contact Dr. Bertolatus or one of the other IRB chairs. Their contact information can be found on the Contact Us page on the HSO website found here. (http://research.uiowa.edu/hso/index.php?get=contact)