



**Human Subjects Office/
Institutional Review Board (IRB)**

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To: IRB-01 & IRB-03 Researcher Community
From: IRB Chairs

RE: Use of Gadolinium in Research

The U.S. Food and Drug Administration (FDA) is investigating the risk of brain deposits of gadolinium following repeated use of gadolinium-based contrast agents for magnetic resonance imaging (MRI). Recent publications in the medical literature have reported that deposits of gadolinium-based contrast agents remain in the brains of some patients who undergo four or more contrast MRI scans, long after the last administration. It is unknown whether these gadolinium deposits are harmful or can lead to adverse health effects. To reduce the potential for gadolinium accumulation, health care professionals should consider limiting gadolinium-based contrast agent use to clinical circumstances in which the additional information provided by the contrast is necessary. Health care professionals are also urged to reassess the necessity of repeated gadolinium-based MRIs in established imaging protocols.

In response to this new information, the IRB is requiring the following actions on the part of researchers:

1. For all existing research study(ies) using MRI with contrast, researchers are required to state in HawkIRB if gadolinium will or will not be the contrast agent used in question V.2. If any proposed scans will involve gadolinium based contrast, the researcher must also clearly indicate the purpose of the scan, indicating for research purposes only, for clinical purposes only, or if the scan is for safety assessment associated with a research procedure. This information may be added to HawkIRB question V.3..
2. For any newly proposed research or ongoing research that is still in an intervention phase and will use gadolinium based contrast in research related (non-clinically required) MRI scans, the following statement is required in the consent document: "Recent publications in the medical literature have reported that deposits of gadolinium-based contrast agents remain in the brains of some patients who undergo four or more contrast MRI scans, long after the scan was completed. It is unknown if these deposits are harmful or if they may lead to harmful health effects."
3. All subjects currently enrolled in studies involving gadolinium based contrast scans for non-clinical purposes must sign an updated consent with the risk information noted in #2 above, prior to receiving additional gadolinium based contrast scans.

At this time the IRB finds that the safety information available does not justify restricting use of gadolinium based contrast scans on protocols where there is a clinical, or safety justification for these scans. The IRB will consider on a case by case basis what information should be included in consent documents for gadolinium based contrast scans that have a clinical or safety assessment component.

For studies that employ gadolinium based contrast strictly for a research (non-clinical) purpose, the IRB will expect that the researcher present a clear justification for the use of gadolinium in the research imaging.