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Dear IRB Committee Members,

Effective January 14, 2020, following a periodic review of MRI safety and related policies, the Brain Mapping Center has modified its default policy regarding MRI research subjects who have tattoos. The purpose of this letter is to clarify the basis for this policy change, which may cause some researchers who utilize the center to request modifications to their IRB and consent documents and/or to reference this default policy in new IRB submissions.

It has been known for many years that rare patients undergoing MRI scanning can experience first or even second degree burns related to tattoos (Kreidstein *et al.*, *Plastic Reconstructive Surgery*, 1997;99; 1717-1720; Vahlensieck, *European Radiology*, 2000; 10:197; Wagle and Smith, *American Journal Roentgenology*, 2000; 174:1795; Franiel, Schmidt and Klingebiel, *American Journal of Roentgenology*, 2006; 187:W556; Ross and Matava, *Sports Health*, 2011;3(5):431-434). In clinical settings, current recommendations are therefore to screen all patients for the presence of tattoos, to inform patients who have tattoos of the risk of burns at the time of the procedure, and to closely monitor patients with tattoos during scanning, discontinuing scanning if any discomfort develops (Shellock, http://www.mrisafety.com/SafetyInformation_view.php?editid1=228). Application of cold compresses to the tattoo is recommended for extensive or dark tattoos (Kanal *et al*, *Journal of Magnetic Resonance Imaging* 2013;37:501-530). Tattoos are generally not considered a contraindication to clinical MRI scanning, with the risk of tattoo related burns small compared to the benefits diagnostic clinical information, though Shellock notes that some radiologists (inappropriately in his opinion, based on evidence discussed below) have refused to perform MRI procedures on certain subjects with cosmetic tattoos.

In the research setting, there is often no expectation of personal medical benefit associated with MR scanning. Prior to the above-mentioned review, Brain Mapping Center policy had been to follow the clinical recommendation above, requiring pre-scan screening for tattoos and proceeding with scanning only if subjects were informed of the potential risk of burns and carefully monitored during scanning. However, the Center had previously left it entirely to the discretion of the PI (presumably in consultation with the IRB) whether to describe the risk of tattoo-related burns in IRB or consent materials and had not prohibited scanning of subjects with tattoos in the absence of such descriptions. To my knowledge, no human subject has ever experienced an MRI related burn in the Brain Mapping Center, but under the prior policy, were a tattoo-related burn to occur, it is possible that there would be no formal written documentation that the subject had been advised of the risk.

A recent prospective study of tattoo safety during MRI published in the *New England Journal of Medicine* has informed the Center's revised policy. The study was published as a letter by Callaghan, *et al.*, (*New England Journal of Medicine* 2019; 380:495-496) and excluded subjects with tattoos of the head, neck or genitals, tattoos greater than 20 cm in length, and persons with more than 5% of the body tattooed. Subjects were scanned using any of five different 3 Tesla scanners (the same field strength used in the Brain Mapping Center), without any preventative use of cold compresses. Of 330 subjects, collectively having 932 tattoos, one participant reported a tingling during scanning not felt to be a tattoo related event, and one other participant experienced warmth and tightness at a tattoo site that was classified as a mild tattoo-related event (though not termed a "burn" by the authors), leading to discontinuation of the MRI study with complete resolution of symptoms within 24 hours without medical intervention.

The Callaghan *et al.* study provides important quantitative evidence of the general safety of MRI scanning of subjects with tattoos that meet the described entry criteria. However, the entry criteria also suggest an implicit standard, raising the concern that tattoos not meeting the entry criteria due to size or location might constitute a higher risk. With regard to tattoo size, there is a clear presumption that larger tattoos do indeed pose a larger risk. However, Callaghan *et al.*, did not provide a rationale for their exclusion of tattoos of the face, neck and genitals. For the neck and genitals, this may simply reflect an abundance of caution in areas more likely to cause greater pain or distress if a burn were to occur. For facial tattoos, an additional consideration may have factored into the exclusion criteria. Facial tattoos are more likely to be cosmetic in nature (e.g., tattooed eyeliner) and by intent may seek to achieve deeper coloration with a higher concentration of pigments prone to MR heating. Of note, one brief case report in the literature described a woman with narrow permanent tattooing of her upper eyelids who suffered a first degree burn despite prompt discontinuation of MRI scanning upon her reporting of discomfort (Franiel, Schmidt and Klingebiel, *American Journal of Roentgenology*, 2006; 187:W556). This may underlie the past reluctance of some radiologists to perform MRI scanning in subjects with cosmetic tattoos. Tope and Shellock (*Journal of Magnetic Resonance Imaging* 2002; 15:180-184) have demonstrated in a retrospective survey of 135 subjects with cosmetic tattoos that burns are not common, with just one subject reporting a slight burning sensation (not necessarily involving tissue injury) and other reporting tingling at the tattoo site. The 2013 American College of Radiology Guidance Document on MR Safe Practices recommends the use of cold compresses over dark tattoos including tattooed eyeliner but does not consider such tattoos to be contraindications to MR scanning (Kanal *et al*, *Journal of Magnetic Resonance Imaging* 2013;37:501-530). A 2019 update to the guidelines is in process but not yet available (<https://www.acr.org/Clinical-Resources/Radiology-Safety/MR-Safety>); from a summary of the impending updated guidelines, no changes in the 2013 recommendations regarding tattoos is anticipated (Greenburg, *et al.*, *Journal of Magnetic Resonance in Imaging* 2020;51:331-338).

It should be noted that in most (though not all) MRI procedures, energy is deposited into the body using a large body coil even when a specialized receiver coil is used to increase sensitivity over a particular body part. In the case of brain imaging, the receiver coil is designed to conform closely to the contours of the head and may prevent effective use of cold compresses over tattoos of the face, scalp or neck. While it is both feasible and appropriate to use a cold compress over the tattooed eyelids of a subject having an MRI scan of their abdomen, it is often not feasible to do so during scans of the brain. In addition, brain imaging often involves having subjects perform functional task that require an unobstructed view of images displayed in the scanner, preventing the use of cold compresses that would cover the eyes.

In discussing tattoos and risks with our Center faculty, staff and users, it is neither practical nor desirable to simply exclude all subjects with tattoos, or even to only exclude subjects with tattoos not meeting the Callaghan inclusion criteria from MRI research studies. Tattoos are particularly common in certain clinical populations and among certain demographic groups, and excluding potential subjects due to a small but non-zero incremental risk compared to non-tattooed subjects would not be fair or scientifically appropriate. The risks of tattoo related burns are small and do not exceed risks regularly approved by IRB boards when offset by benefits of well-designed research.

The Brain Mapping Center's revised default policy with respect to tattoos appended below applies only to IRB approved studies where the risk of tattoo related burns was not explicitly considered by the IRB, as evidenced by the absence of valid discussion of tattoo-related risks in both the approved consent form(s) and in the IRB submission. Where the PI and IRB have considered the risk of tattoo-related burns, the IRB approved policy supersedes the Brain Mapping Center default policy. It is anticipated that the IRB may commonly approve less restrictive policies based on due consideration of the potential study risks and benefits.

Brain Mapping Center policies continue to mandate that all subjects be provided with an emergency squeeze ball to alert staff of any problems and that scanning should be discontinued immediately for any discomfort reported at a tattooed site, regardless of size or location. Scanning can only be resumed if a cold compress was not already in place and has subsequently been applied. Scanning of tattooed subjects unable to promptly and reliably report discomfort during scanning is prohibited. It should be noted that no Brain Mapping Center studies currently involve sedated subjects, but scanning of sedated subjects with tattoos is prohibited under the default policy as a placeholder in case the use of sedation is approved by the IRB at some point in the future.

Brain Mapping Center default tattoo policy for human research subjects

The following categories of subjects with tattoos are excluded from MRI scanning by the default policy:

- Subjects who are unable to promptly and reliably report discomfort at a tattoo site during scanning due to cognitive impairment, sedation, young age, or other factors
- Subjects who have previously suffered any tattoo related burn during MR scanning
- Subjects who have previously had MRI scans discontinued before completion due to tattoo related discomfort
- Subjects with facial (including tattooed permanent makeup/microblading), scalp, or genital tattoos other than small tattooed dots applied medically to mark radiation treatment portals
- Subjects with neck tattoos that cannot be covered with a cold compress during MRI scanning due to coil or task constraints
- Subjects with large tattoos (> 20 cm length) that cannot be covered with a cold compress during MRI due to physical or task constraints

The following categories of subjects with tattoos must always have a cold compress applied to the tattoo(s) during MRI scanning under the default policy:

- Subjects who have previously experienced tattoo related discomfort during MRI procedures but who do not meet the exclusion criteria above
- Subjects who have experienced tattoo related discomfort during the current MRI procedure but who do not meet the exclusion criteria above
- Subjects with neck tattoos
- Subjects with large tattoos (> 20 cm length)

The goal of the default policy is to set guardrails such that MRI scanning can continue to be considered a minimal risk procedure for tattooed subjects who meet the default criteria and who are managed as specified. The Center welcomes feedback from the IRBs if it is felt that any modification of the default guidelines would better achieve this goal.

Sincerely,



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