sleic-safety-comm-background–2013–10–18.md

1. Incidental findings pathway
    - Give images or not?
        - **We give only by request**.
        - UC Santa Barbara says: "Current IRB policy holds that no research-related images can be provided for diagnostic purposes."
    - Review no scans, those flagged by MR Tech or Investigator, or all?
        - **We review only those flagged**.
        - George Mason says: "As a service to research participants, George Mason University sends structural scans to a consulting neuroradiologist for review, and relays any findings to the research participants…Image data is sent to the neuroradiologist monthly, unless atypicality is observed, in which case the images are sent immediately for urgent review."
    - Notify individual or health care professional?
        - **We notify individual only if consulting radiologist suggests that we do so**.
        - Staff or PI notifies.
    - Add additional clinically useful scan, such as T2?
        - **We do not do so currently**.
        - George Mason says: "A 2-minute T2 weighted structural scan is run by the MRI Technologist at least once per year for each research participant, and is forwarded to the consulting neuroradiologist along with the T1 structural scans."
2. Pregnancy screen
    - Test or self-report?
        - **We solicit self-report**.
        - UC Berkeley says: "It is the policy of the CPHS that for all studies involving MRI, fMRI, or MRS, women of childbearing potential must undergo pregnancy testing, and must be excluded from the study if the pregnancy test is positive. The Committee recommends that such potential subjects be asked to conduct a self-administered pregnancy test immediately prior to scanning, and adult women be instructed to exclude themselves from the study if the test is positive (i.e., indicates pregnancy). Post-menopausal female subjects and those who have not yet begun menstruating need not have a pregnancy test."
        - UC Santa Barbara says: "Females that self-report pregnancy will be excluded from participation unless the protocol specifically has pregnancy as an inclusion criterion….Pregnant women are not permitted in the magnet room during scanner operation, except in cases where IRB approval to include pregnant women in experimental procedures has been sought and approved or for clinical diagnostic purposes."
        - George Mason: "For female participants, pregnancy tests must be completed the same day as the scan."

- UC Davis: “Individuals who are or may be pregnant are not allowed to remain in the MR scanner room while the RF and gradients are operating. Pregnant individuals may remain in the control room and enter the magnet room between scans, during the study. This includes staff or individuals accompanying the research participant. Female research participants that are pregnant are not eligible to participate in an MRI scan. If a research participant suspects pregnancy, the MRI scan will be postponed until the research participant is able to confirm that she is not pregnant.”
- NIMH Council Workgroup 2005 report says: "A variety of approaches are used across centers to screen for and/or exclude pregnant or possibly pregnant participants. Some sites simply note, during the consent/assent process, that the individual should not participate if there is a possibility she may be pregnant. Other sites use questions that include the date of the last menstrual period and/or whether there is any chance the potential participant might be pregnant. Still others test for pregnancy in all females who have begun menstruation unless they are post- menopausal or have undergone surgical procedures after which pregnancy is not a possibility. The approach which will be used to screen for pregnancy should be described in the protocol in order for the IRB to assess the risks and benefits of the protocol.

Pregnancy testing has the benefit of providing new information in cases where a female may not yet realize she has conceived. Without such testing, a female may be scanned while unknowingly pregnant. At the same time, pregnancy testing holds implications for the disclosure of such results. For example, having a parent first learn of a child’s sexual activity and/or pregnancy during the consent/assent or screening process may be harmful for the adolescent female and her family; sensitivity to cultural influences is warranted here. Caution is warranted to avoid accidental disclosures of pregnancy to individuals who might be accompanying the participant.

If disclosing a pregnancy can have potential negative consequences/risks under certain circumstances, IRBs will want to consider this issue. Investigators should consider, in advance, how an “incidental finding” of pregnancy will be managed, i.e., whether appropriate staff are available to provide counseling and how such findings will be reported and participants counseled. Thus, it is important that this information be provided to the IRB so that it may carefully balance the risks and benefits pertaining to the specific population, research procedures, and methods used to screen for pregnancy when reviewing protocols and consent/assent procedures."

- What about minors?
  - **We have no specific policy**.
  - UC Berkeley says: “Pregnancy Testing with Minors: When a minor is to be screened for pregnancy (i.e., a female under the age of 18* who has had her first menstrual period), special provisions should be made and discussed in the protocol. In order to minimize the risk of placing subjects, parents, and investigators in a difficult situation as a result of an unexpected

positive pregnancy test result, it should be explicitly stated during the recruitment process and in recruitment materials that pregnancy screening will be required. Investigators should consider in advance, and address in the protocol, how an "incidental finding" of pregnancy with a minor will be managed. Special care should be taken to protect the subject's privacy in such a situation; researchers should maintain this information as confidential and should not report the results directly to parents unless permitted or requested by the minor (e.g., they may inform the parents that the subject cannot be included in the study but should not specify the reason for exclusion). In addition, research staff should have a word in private with the minor before dispensing the pregnancy test, confirming that she is comfortable with it. To prevent any confusion regarding results, a member of the research staff should read and confirm the results of the pregnancy test."

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    - Staff?
        - **We have no specific policy**.
        - Martinos Center says: "However, given the scarcity of data on the subject and the high susceptibility of the developing fetus to damage in general, we believe it is not worth the risk for pregnant women to participate as subjects in MR research studies. Most clinical units allow pregnant employees to enter the scan room, but not to remain in the room while the RF and gradient fields are applied during image acquisition. Pregnant researchers at the Center will regulate their own exposure to the magnets."
    - Could we move to risk statement alone?