AAHRPP Site Visit Countdown

The AAHRPP (Accreditation of Human Research Protection Programs) will be conducting a “site visit” as part of the accreditation process for the Harvard University Human Research Protection Program (HRPP) on Monday, September 28th and Tuesday, September 29th.

The Harvard University IRB began the process of accreditation for our HRPP in November 2019. We have made it through two separate evaluations of our written materials (standard operating procedures, forms, processes) and the site visit is the last step prior to being accredited. Because of the COVID pandemic, the entirety of the site visit will occur remotely, via Zoom.

The site visit is an opportunity for us to share the awesomeness of our HRPP with AAHRPP. There will be various meetings with institutional and IRB office representatives, IRB members, key stakeholders from across the university, as well as a few researchers.

We know that being part of this process may feel overwhelming, especially given the times that we are living in. The IRB office has developed materials to prepare all that are involved in this process and to make the site visit as stress-free as possible. We will be sharing these
materials with you shortly. We are also available to answer questions at any time and provide you with as much information as possible prior to the scheduled visit.

Viva Accreditation!

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**Lapsed IRB Approvals and Administrative Closure – Do not Let this Happen to You!**

Although the revised federal regulations removed the requirement to provide the IRB with a ‘progress report’ of the past year’s activities (otherwise known as a continuing review) for most studies, there are several older studies that are still required to do so.

So, what happens if you forget to do this before the expiration of your study? Well, this is called a lapse in IRB approval. A lapse in IRB approval occurs whenever a researcher does not provide continuing review information to the IRB prior to the expiration date of IRB approval. In such circumstances, all research activities involving human subjects must stop, unless the IRB determines that it is in the best interests of already-enrolled subjects to continue taking part in the research. When a study has a lapse in IRB approval, new participants may not be enrolled, and continuing participation of already-enrolled subjects may be appropriate only when the research interventions hold out the prospect of direct benefit to the participants or when withholding those interventions poses increased risk to them.

The IRB office administratively closes studies when the study has been lapsed in approval for over 30 days. ESTR, our IRB online submission system, will send a reminder to submit a continuing review request at specific time points following the first day of the lapse of IRB
approval. At the 30-day mark, IRB staff will leave a comment in the ESTR study submission space that if a continuing review request is not submitted in 10 business days, the study will be administratively closed. This comment is also sent to the study team.

If you have a study that requires a yearly continuing review, do not let this happen to you! Submit your continuing review request at least six weeks before your study expires!!!
minimal risk, with no prospect of direct benefit, but likely to yield generalizable knowledge about the underlying condition or disorder.

The permission of one parent is sufficient for the first two categories. For research that is greater than minimal risk, with no prospect of direct benefit, but likely to yield generalizable knowledge about the underlying condition or disorder, permission must be obtained from both parents unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

**Can Parent Permission be waived?**

Remember, like consent, obtaining parent permission is the default. If there is no parent permission, then the IRB must document why. If a waiver of parent permission is being sought, the IRB requires researchers to make a compelling and persuasive argument for why parental permission is not a necessary condition for proceeding with the research.

*There are several ways that parent permission may be waived:*

- The IRB may waive the requirement for parental permission if the IRB determines that such permission is not a reasonable requirement to protect the child participants (for example, neglected or abused children) and the waiver is not inconsistent with applicable laws (e.g., the IRB may not waive the permission requirement for a procedure for which parental consent is required under state law).

Research on neglected or abused children is one example for a possible waiver, however this waiver may also be applicable to adolescents (yes, still considered “children” according to the regulations) who are in situations where they may be outside of parental influence or control (though not legally able to consent for themselves).

Under this type of waiver, the regulations require the substitution of another mechanism to protect the child participants. The choice of a proper mechanism will depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.
• If the study involves no more than minimal risk, the IRB may also waive the requirement for parent permission in accord with the “standard” waiver of consent criteria:

The research involves no more than minimal risk to the subjects;

• The research could not practicably be carried out without the requested waiver or alteration;
• If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
• The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
• Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

*Note that FDA regulations differ on parent permission and generally do not allow such a waiver.*

We could go on about parent permission but realize we only have so much room in this monthly newsletter. If you are interested in learning more, our federal regulators have some great FAQ's about the involvement of children in research and parent permission. You can check that out [here](#).

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**From all of us at the HUA IRB, Be Well and Stay Healthy!**

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