IRB Survey Results

Thanks to all of you who completed our IRB User Survey last spring. We have compiled the results and responded in detail to the questions and comments. There were a number of great suggestions that we are working to implement, and some we've already put into place. Click here to see the full IRB survey results (pdf).

Parental Consent Waivers / "Opt-out" consent

The Belmont Report, Nuremberg Code (pdf), and Common Rule all place special emphasis on the importance of informed consent. In the case of minors, this means obtaining written permission from the parent or guardian ("parental consent"). The IRB's default stance is that parental consent should always be obtained when children are research subjects. Exceptions to this are made only on a case-by-case basis, and are not routinely or easily granted.

"Opt-out" procedures are treated the same way as a full waiver of parental consent, as there is no way to guarantee that parents received the information.

To grant a waiver of parental consent, each of the following needs to be justified in your application:

1. Research is minimal risk.
2. The research could not practicably be carried out without the waiver.
    - This is **not** the same as saying it would be difficult to enroll, or that a lot of people wouldn't return the signed consent. "Impracticable" is a much higher bar than merely "difficult". It means that the research *couldn't* be done, or that the results would be so biased as to be unusable if parental consent were required.
3. The waiver will not adversely affect the participants' (or parents') rights or welfare.
4. Whenever appropriate, the participants (and parents) will be provided with information about the research.

In certain sensitive research where these criteria are not met, a waiver can be granted if obtaining parental consent is not in the best interest of the child and could put them at risk. An example is studies involving gay or transgender youth, where requiring consent would "out" them to their parents and could result in some type of harm. In those cases, the IRB would still ask that parental consent be obtained when it is safe to do so, and when not, that another appropriate mechanism is substituted to ensure the children's rights and welfare are protected.

Rule of thumb: If your research involves children, you should get parental consent.

Collecting gender demographics

Many research studies collect gender demographics, but the traditional binary of "Male / Female" is not adequate for many reasons. Keep the following in mind as you design your studies:

- Use "man", "woman", and "another gender identity" for collecting information about gender. Depending on your research, it may or may not matter what that other gender identity is. If it is important to know, you can include a blank allowing participants to specify.
- Use "male", "female", and "intersex" for collecting information about biological sex. However, you should only ask this question if it is truly necessary to your research aims, as it can feel intrusive to transgender and non-binary individuals. Most studies we see don't need to ask about sex assigned at birth. If you do need to ask this, include a question about gender identity as well.

For more detailed information and examples, please see the LGBTQ+ guidance on our website.