



Children and Minors in Research

The Human Research Protection Program has posted revised [guidelines](#), an [application supplement](#), and a [chart summarizing the applicable federal regulations](#) for involving children and minors in research. The major changes are the following:

- Circumstances in which people under 18 can consent for themselves are explained more clearly. The federal regulations requiring parental permission and special protections for children do not have to be applied to these minors. The revised application supplement allows researchers to treat them separately.
- One or two parents' signature: The CHR now must formally decide whether one or two parents' signature is needed. The revised application supplement asks the researcher to address this issue. In most studies, one parent's signature will continue to be sufficient.
- The documents refer to "children" rather than "minors" and to parental "permission" rather than parental "consent" in most places, to conform with federal regulations.
- The documents refer to FDA regulations as well as the DHHS regulations.