

APA RESOLUTION on Support for the Expansion of Mature Minors' Ability to Participate in Research

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The promotion of health and prevention of disease are dependent on psychological research findings that are generalizable across samples and populations as well as specific to at-risk groups. Adolescent minors are at risk for a variety of sensitive health issues, such as human immunodeficiency virus and other sexually transmitted infections (HIV/STI) (Centers for Disease Control & Prevention [CDC], 2015a, 2016b) and substance abuse (CDC, 2016c). Furthermore, being part of stigmatized groups, including gender and sexual minorities (e.g., adolescent males who engage in same-sex sexual behavior; gay, lesbian, bisexual, and transgender youth) makes these young individuals more vulnerable to such health risks (CDC, 2015b, 2016a). Research that includes at- or high-risk minors is imperative to the design of effective prevention and intervention programs. The American Psychological Association (APA) recognizes and affirms the principle of autonomy, including the rights of parents to choose whether or not their children participate in research. However, studies examining stigmatized issues face participation barriers when obtaining parental permission may put the minor at risk of harm (American College of Obstetricians and Gynecologists [ACOG], 2016; Duncan, Drew, Hodgson, & Sawyer, 2009; Fisher, 2015; Fisher, Arbeit, Dumont, Macapagal, & Mustanski, 2016; Fisher & Mustanski, 2014; Moore, Paul, McGuire, & Majumder, 2016; Mustanski & Fisher, 2016). Even though current federal regulations allow for the waiver of parental permission in certain instances, institutional review boards (IRBs) have been inconsistent in their application of the relevant regulations (Mustanski & Fisher, 2016).

WHEREAS requiring parental permission for mature minors' participation in some research may undermine (a) the quality of the science, (b) the availability or application of evidence-based interventions for adolescent minors, and (c) addressing serious health concerns (e.g., HIV/STI among adolescents) (Culp & Caucci, 2013; Duncan et al., 2009; Fisher, 2015; Fisher & Mustanski, 2014; Fisher et al., 2016; Moore et al., 2016; Mustanski, 2011; Mustanski & Fisher, 2016; Society for Adolescent Medicine [SAM], 2003; Toner & Schwartz, 2003); and

WHEREAS minors who are willing to participate in sensitive research that requires parental permission and therefore knowledge of participation in at-risk behavior or membership in a stigmatized group may not be representative of the "true" population (Bruce, Berg, & McGuire, 2009; Culp & Cauci, 2013; Fisher & Mustanski, 2014; Fisher et al., 2013, 2016; Moore et al.,

2016; Mustanski, 2011; Mustanski & Fisher, 2016; Rojas, Sherrit, Harris, & Knight, 2008); and

WHEREAS critical progress may be unintentionally hindered by IRBs through lack of (a) recognizing and applying federal regulations allowing mature minors to participate in research without parental permission, (b) extension of mature minor laws from health care to research, and (c) clarity on parental rights and minor decision-making capacity (ACOG, 2016; Coleman & Rosoff, 2013; Fisher, 2015; Fisher & Mustanski, 2014; Fisher et al., 2013, 2016; Moore et al., 2016; Mustanski, 2011; Mustanski & Fisher, 2016; Ruiz-Canela et al., 2013); and

WHEREAS guardian permission is intended to protect the minor, parental rights may be misunderstood to supersede those of the mature adolescent minor in cases when physical, psychological, or social harms may result for children if parents are informed about the study focus (Chenneville, Sibille, & Bendell-Estroff, 2010; Duncan et al., 2009; Flicker & Guta, 2008; Moore et al., 2016; Mustanski, 2011; Office for Human Research Protections, n.d.; Pasternak, Geller, Parrish, & Cheng, 2006; Rojas et al., 2008; Ruiz-Canela et al., 2013; SAM, 2004); and

WHEREAS research supports that children as young as 14 years old can provide valid informed consent similarly to adults when information is presented at developmentally appropriate levels and the consent process is conducted under minimal stress (Berkowitz, 2006; Fisher et al., 2013, 2016; Moore et al., 2016; Mustanski & Fisher, 2016; Ruiz-Canela et al., 2013; SAM, 2003; Steinberg, 2013; Toner & Schwartz, 2003);

THEREFORE BE IT RESOLVED that APA reaffirms the federal regulations for the protection of research participants promulgated by Office for Human Research Protections (n.d.) and the Food and Drug Administration (Roth-Cline, Gerson, Bright, Lee, & Nelson, in press) that classify minors as "adults" if they have attained their state-determined age to consent to treatment or to study-related procedures.

FURTHER BE IT RESOLVED that APA supports the extension of mature minor laws from health care to research when participation in the study does not pose more than a minor increase in minimal risk of harm to the participant.

FURTHER BE IT RESOLVED that APA encourages IRBs to be knowledgeable about, and require research protocols to include, current and contextually appropriate data on the ability of youth to independently consent (Dunn, Nowrangi, Palmer, Jeste, & Saks, 2006), how to tailor consent procedures to the decision-making abilities needs of mature minors, and use of participant advocates when appropriate.

FURTHER BE IT RESOLVED, in accordance with current regulations, that APA asks IRBs to waive the parental permission requirement when it could potentially harm the mature minor and when alternative and appropriate research protections are in place.

FURTHER BE IT RESOLVED that APA urges IRBs to allow minors fair access to research critical to identifying developmentally appropriate evidence-based interventions.

REFERENCES

- American College of Obstetricians and Gynecologists. (2016). Guidelines for adolescent health research. *Obstetrics and Gynecology*, 127, e183-e186.
- Berkowitz, C. D. (2006). The need for a developmental approach to adolescent decision-making. *American Journal of Bioethics*, 5(5), 77-78.
- Bruce, C. R., Berg, S. L., & McGuire, A. L. (2009). Please don't call my mom: Pediatric consent and confidentiality. *Clinical Pediatrics*, 48(30), 243-246.
- Centers for Disease Control and Prevention. (2015a). *HIV surveillance report, 2015* (Vol. 27). Retrieved from <http://www.cdc.gov/hiv/library/reports/hiv-surveillance.html>
- Centers for Disease Control and Prevention. (2015b). *Youth risk behavior surveillance*. Retrieved from <https://www.cdc.gov/healthyyouth/data/yrbs/index.htm>
- Centers for Disease Control and Prevention. (2016a). Sexual identity, sex of sexual contacts, and health-related behaviors among students in grades 9-12. *MMWR Surveillance Summary*, 65(9), 1-201.
- Centers for Disease Control and Prevention. (2016b). *Sexual risk behaviors: HIV, STD, & teen pregnancy prevention*. Retrieved from <https://www.cdc.gov/healthyyouth/sexualbehaviors/>
- Centers for Disease Control and Prevention. (2016c). *Trends in the prevalence of marijuana, cocaine, and other illegal drug use. Youth Risk Behavior Survey: 1991-2015*. Retrieved from https://www.cdc.gov/healthyyouth/data/yrbs/pdf/trends/2015_us_drug_trend_yrbs.pdf
- Chenneville, T., Sibille, K., & Bendell-Estroff, D. (2010). Decisional capacity among minors with HIV: A model for balancing autonomy rights with the need for protection. *Ethics & Behavior*, 20(2), 83-94.
- Coleman, D. L., & Rosoff, P. M. (2013). The legal authority of mature minors to consent to general medical treatment. *Pediatrics*, 131, 786-793.
- Culp, L., & Caucci, L. (2013). State adolescent consent laws and implications for HIV pre-exposure prophylaxis. *American Journal of Preventive Medicine*, 44(1, Suppl. 2), S119-S124.
- Duncan, R. E., Drew, S. E., Hodgson, J., & Sawyer, S. M. (2009). Is my mum going to hear this? Methodological and ethical challenges in qualitative health research with young people. *Social Science and Medicine*, 69, 1691-1699.
- Dunn, L. B., Nowrangi, M. A., Palmer, B. W., Jeste, D. V., & Saks, E. R. (2006). Assessing decisional capacity for clinical research or treatment: A review of instruments. *American Journal of Psychiatry*, 163, 1323-1334.
- Fisher, C. B. (2015). Enhancing the responsible conduct of sexual health prevention research across global and local contexts: Training for evidence-based research ethics. *Ethics & Behavior*, 25(2), 87-96.
- Fisher, C. B., Arbeit, M. R., Dumont, M. S., Macapagal, K., & Mustanski, B. (2016). Self-consent for HIV prevention research involving sexual and gender minority youth: Reducing barriers through evidence-based ethics. *Journal of Empirical Research on Human Research Ethics*, 11(1), 3-14.
- Fisher, C. B., Brunnuquell, D. J., Hughes, D. L., Liben, L. S., Maholmes, V., Plattner, S., . . . Susman, E. J. (2013). Preserving and enhancing the responsible conduct of research involving children and youth: A response to proposed changes in federal regulations. *Sharing Child and Youth Development Knowledge*, 27(1), 1-10.
- Fisher, C. B., & Mustanski, B. (2014). Reducing health disparities and enhancing the responsible conduct of research involving LGBT youth. *Hastings Center Report*, 44(s4), S28-S31.
- Flicker, S., & Guta, A. (2008). Ethical approaches to adolescent participation in sexual health research. *Journal of Adolescent Health*, 42, 3-10.
- Moore, Q. L., Paul, M. E., McGuire, A. L., & Majumder, M. A. (2016). Legal barriers to adolescent participation in research about HIV and other sexually transmitted infections. *American Journal of Bioethics*, 106(1), 40-44.
- Mustanski, B. (2011). Ethical and regulatory issues with conducting sexuality research with LGBT adolescents. *Archives of Sexual Behavior*, 40, 673-686.
- Mustanski, B., & Fisher, C. B. (2016). HIV rates are increasing in gay/bisexual teens: IRB barriers to research must be resolved to bend the curve. *American Journal of Preventive Medicine*, 51(2), 249-252.
- Office for Human Research Protections. (n.d.). *Guidance: Informed consent FAQs*. Retrieved from <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent/index.html>
- Pasternak, R. H., Geller, G., Parrish, C., & Cheng, T. L. (2006). Adolescent and parent perceptions on youth participation in risk behavior research. *Archives of Pediatric and Adolescent Medicine*, 160, 1159-1166.
- Rojas, N. L., Sheritt, L., Harris, S., & Knight, J. R. (2008). The role of parental consent in adolescent substance use research. *Journal of Adolescent Health*, 42, 192-197.
- Roth-Cline, M. D., Gerson, J., Bright, P., Lee, C. S., & Nelson, R. M. (in press). Ethical considerations in conducting pediatric research. In H. Seyberth, A. Rane, & M. Schwab (Eds.), *Pediatric clinical pharmacology* (1st ed.). Springer.
- Ruiz-Canela, M., Lopez-del Burgo, C., Carlos, S., Calatrava, M., Beltramo, C., Osorio, A., & de Irala, J. (2013). Observational research with adolescents: A framework for the management of the parental permission. *BMC Medical Ethics*, 14(2), 1-9.
- Society for Adolescent Medicine. (2003). Guidelines for adolescent health research. *Journal of Adolescent Health*, 33, 396-409.
- Society for Adolescent Medicine. (2004). Confidential health care for adolescents. *Journal of Adolescent Health*, 35(1), 1-8.
- Steinberg, L. (2013). Does recent research on adolescent brain development inform the mature minor doctrine? *Journal of Medicine and Philosophy*, 38, 256-267.
- Toner, K., & Schwartz, R. (2003). Why a teenager over age 14 should be able to consent, rather than merely assent, to participation as a human subject of research. *American Journal of Bioethics*, 3(4), 38-40.