

See below for two different announcements for funding opportunities, each with two mechanisms (R01 and R21) – four links total.

### **Ethical Issues in Research on HIV/AIDS and Its Co-Morbidities.**

National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health is issuing a program announcement for grants on **Ethical Issues in Research on HIV/AIDS and Its Co-Morbidities**. This Funding Opportunity Announcement (FOA) invites applications addressing ethical issues in research relevant to populations with HIV and associated co-morbidities, and populations at high risk of HIV acquisition. This is a reissue of PARs 12-244 and 12-243, previous announcements that expired this year.

The program announcement invites proposals involving conceptual or empirical bioethics work or a combination of the two. Projects involving empirical methods may use qualitative or quantitative methods or both. Applications from foreign and domestic institutions are accepted. A detailed list of topics of interest is included in the program announcement; other topics not listed that fall within the scope of the FOA are also allowed.

All applicants are strongly encouraged to contact one of the program officers (scientific contacts) listed on the program announcement when considering submitting an application. As always, questions can be directed to program officers at any time.

<http://grants.nih.gov/grants/guide/pa-files/PAR-15-275.html>  
<http://grants.nih.gov/grants/guide/pa-files/PAR-15-274.html>

### **Ethical, Legal and Policy Issues in HIV Research on Key Populations**

National Institute of Allergy and Infectious Diseases (NIAID) and National Institute for Mental Health (NIMH), National Institutes of Health are issuing a **new** program announcement for grants on **Ethical, Legal and Policy Issues in HIV Research on Key Populations, PAR 15-328 and PAR 15-327:**

<http://grants.nih.gov/grants/guide/pa-files/PAR-15-328.html>  
<http://grants.nih.gov/grants/guide/pa-files/PAR-15-327.html>.

This new program announcement seeks applications to addresses ethical, legal, and policy challenges in HIV-related research and program implementation among key populations. The term “key populations” describes populations that experience high risk of HIV acquisition due to certain behaviors and risk exposures. [2014 WHO Guidance](#) states: “Key populations are defined groups who, due to specific higher-risk behaviors, are at increased risk of HIV irrespective of the epidemic type or local context. Also, they often have legal and social issues related to their behaviors that increase

their vulnerability to HIV The 2014 WHO guidance addresses five key populations: (1) men who have sex with men; (2) people who inject drugs; (3) people in prisons and other closed settings; (4) sex workers and (5) transgender people. This FOA calls for research related to those five groups and also includes research related to adolescent girls and young women at high risk of HIV acquisition or living with HIV.

The program announcement invites proposals involving conceptual or empirical work or a combination of the two. Projects involving empirical methods may use qualitative or quantitative methods or both. Applications from foreign and domestic institutions are accepted. A detailed list of topics of interest is included in the program announcement; other topics not listed that fall within the scope of the FOA are also allowed.

All applicants are strongly encouraged to contact one of the program officers (scientific contacts) listed on the program announcement when considering submitting an application. As always, questions can be directed to program officers at any time.

**The first application due date for these PARs is January 7th, 2016.**

Please forward this on to anyone who may be interested.

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[Here is a description of the work on adolescents, from the PARs on Ethical Issues in Research on HIV/AIDS and its Co-Morbidities](#)

### **Ethics of Research Involving Adolescents and Young Adults**

Research with adolescents is urgently needed to meet the needs of HIV prevention, care and treatment for this age group. Clinical research studies are urgently needed to inform biomedical and behavioral interventions as well as mechanisms to strengthen health care systems to serve these youth. A vast proportion of biomedical interventions and therapies used in adolescents are implemented in the absence of specific data to support indications for their use, and are often justified by extrapolation from studies in much older adult populations. Substantial biomedical and psychosocial data suggest that adolescents differ from adults in critical ways. There is an urgent need for primary and secondary prevention among youth populations at high risk of acquisition or transmission of HIV, both globally and domestically. Important milestones have been achieved in HIV prevention and treatment in adult populations, but various scientific, implementation and regulatory concerns are barriers to their expansion to adolescents. Lack of appropriate research is detrimental to developing effective prevention and treatment for serious conditions such as HIV and related co-morbidities.

Investigators frequently encounter a variety of difficulties in working with youth, which create a disincentive to carry out research in these populations. Barriers include individual factors such as non-adherence, risk behaviors and other psychosocial challenges; and structural barriers such as ethical, legal and regulatory problems. An adolescent's evolving autonomy, cognitive

development and decisional capacity all provide a legal and ethical basis for a right to independence and self-determination in accessing health care and research. However, ethical, cultural, legal and regulatory considerations complicate the research picture.

Projects to address issues related to adolescents in research could include, but are not limited to, the following:

- Conceptual and empirical work on issues of evolving adolescent autonomy, decisional capacity, consent, assent and parental permission, particularly in regard to youth at risk for HIV infection and other Sexual Transmitted Infections (STIs) in the US and in other countries;
- Analysis of legal provisions for protection of confidentiality of minors and for rights to self-determination and decision-making by adolescents about participation in research; analysis of these legal and ethical issues in various research settings relevant to research on HIV risk, HIV prevention and HIV care and treatment;
- Research on ethical, legal and/or cultural aspects of waivers of parental permission for research in specific contexts;
- Research on ethical challenges of studies with sexually active adolescents, including issues of reporting requirements for underage sexual activity in various countries; concerns about confidentiality of the research participants and their contacts; social harms; parental and family concerns, and other legal and ethical issues;
- Research on ethical challenges in research with adolescents in settings where sensitive information is involved, such as mood disorders research, sexual behaviors, and substance use, as well as other potential risk determinants for HIV acquisition, such as homelessness, incarceration, truancy, and other circumstances and conditions;
- Projects to gather and analyze biomedical, behavioral and other psychosocial data related to adolescents and young adults to better characterize risks and benefits of research with youth;
- Legal and ethical analysis of different levels of risks in research with adolescents, including minimal risk, minor increase over minimal risk, and greater than minimal risk as defined in human subjects regulations; analysis of when and how risk thresholds should be applied and what ethical implications these risks have for adolescent research participation;
- Development of a conceptual ethical framework for enrollment of adolescents in clinical trials; such a framework should be supported by ethical analysis, data, and stakeholder engagement.
- Gathering and analyzing information from stakeholders (patients, clinicians, researchers, ethics committees/IRBs, regulators) about cultural, ethical, legal or regulatory challenges in research with adolescents.
- Ethical issues in determining best HIV prevention communication and messaging for adolescents, given that HIV risk involves sensitive or stigmatized behaviors, and HIV risk communication may raise cultural, political or parental concerns.

- See more at: <http://grants.nih.gov/grants/guide/pa-files/PA-15-275.html#sthash.uqgS9Bt2.dpuf>