

Acetyldihydrocodeine is an opiate derivative of low to moderate potency used as a cough suppressant and analgesic in various other countries. Acetyldihydrocodeine is not approved for medical use in the United States and is controlled under Schedule I of the CSA.

Codeine is an opioid drug closely related to morphine. Codeine can cause opioid tolerance, dependence, addiction, poisoning, and respiratory depression in high doses. It is an active ingredient in several approved narcotic analgesic and antitussive medicines in the United States. Codeine is approved for marketing in the United States and available as a single-ingredient product, or in combination with one or more nonnarcotic ingredients in recognized therapeutic amounts. Codeine is controlled in Schedule II of the CSA. Some codeine combination products are controlled in Schedule III and some in Schedule V, depending on the concentration or amount of codeine present in the approved product.

Dihydrocodeine is a semisynthetic narcotic related to codeine. Dihydrocodeine is an active ingredient in prescription-only oral tablet combination products approved for marketing in the United States for the treatment of moderate to moderately severe pain. Dihydrocodeine is controlled in Schedule II of the CSA. Some dihydrocodeine-containing combination products are controlled in Schedule III and some in Schedule V, depending on the concentration or amount of dihydrocodeine present in the approved product.

Ethylmorphine is a derivative of morphine with analgesic and antitussive effects. It is not approved for medical use in the United States but is approved for use in various other countries around the world. Ethylmorphine is controlled in Schedule II of the CSA. Some ethylmorphine containing combination products are controlled in Schedule III and some in Schedule V, depending on the concentration or amount of ethylmorphine present in the approved product.

Nicocodine (nicocodeine) and nicodicodine (nicodicodeine) are esters of codeine and dihydrocodeine, respectively. They are opioids with analgesic and cough suppressant effects. They are not approved for medical use in the United States. Nicocodeine is controlled in Schedule I of the CSA. As an ester of dihydrocodeine, nicodicodine is controlled in Schedule II of the CSA.

Pholcodine is an opiate with cough suppressant effects but little to no analgesic effects. It is an active

ingredient in cough lozenges in some countries but is not an ingredient in any products approved for medical use in the United States. Pholcodine is controlled in Schedule I of the CSA.

#### IV. Opportunity To Submit Domestic Information

As required by paragraph (d)(2)(A) of the CSA, FDA, on behalf of HHS, invites interested persons to submit comments regarding the 21 drug substances. Any comments received will be considered by HHS when it prepares a scientific and medical evaluation for drug substances that is responsive to the WHO Questionnaire for these drug substances. HHS will forward such evaluation of these drug substances to WHO, for WHO's consideration in deciding whether to recommend international control/decontrol of any of these drug substances. Such control could limit, among other things, the manufacture and distribution (import/export) of these drug substances and could impose certain recordkeeping requirements on them.

Although FDA is, through this notice, requesting comments from interested persons, which will be considered by HHS when it prepares an evaluation of these drug substances, HHS will not now make any recommendations to WHO regarding whether any of these drugs should be subjected to international controls. Instead, HHS will defer such consideration until WHO has made official recommendations to the Commission on Narcotic Drugs, which are expected to be made in late 2019. Any HHS position regarding international control of these drug substances will be preceded by another **Federal Register** notice soliciting public comments, as required by paragraph (d)(2)(B) of the CSA.

Dated: September 4, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

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#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Solicitation of Nominations for Membership on the Secretary's Advisory Committee on Human Research Protections

**AGENCY:** Office of the Assistant Secretary for Health, Office for Human Research Protections, Office of the Secretary, Department of Health and Human Services.

**ACTION:** Notice.

**SUMMARY:** The Office for Human Research Protections (OHRP), a program office in the Office of the Assistant Secretary for Health, Department of Health and Human Services (HHS), is seeking nominations of qualified candidates to be considered for appointment as members of the Secretary's Advisory Committee on Human Research Protections (SACHRP). SACHRP provides advice and recommendations to the Secretary, HHS (Secretary), through the Assistant Secretary for Health, on matters pertaining to the continuance and improvement of functions within the authority of HHS directed toward protections for human subjects in research. SACHRP was established by the Secretary on October 1, 2002. OHRP is seeking nominations of qualified candidates to fill three positions on the Committee membership that will be vacated during the 2020 and 2021 calendar years.

**DATES:** Nominations for membership on the Committee must be received no later than 45 days from the date of this publication.

**ADDRESSES:** Nominations may be emailed to [SACHRP@hhs.gov](mailto:SACHRP@hhs.gov). Nominations may also be mailed or delivered Julia Gorey, Executive Director, SACHRP, Office for Human Research Protections, Department of Health and Human Services, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852. Nominations will not be accepted by facsimile.

**FOR FURTHER INFORMATION CONTACT:** Julia Gorey, Executive Director, SACHRP, Office for Human Research Protections, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852, telephone: 240-453-8141. A copy of the Committee charter and list of the current members can be obtained by contacting Ms. Gorey, accessing the SACHRP website at [www.hhs.gov/ohrp/sachrp](http://www.hhs.gov/ohrp/sachrp), or requesting via email at [sachrp@hhs.gov](mailto:sachrp@hhs.gov).

**SUPPLEMENTARY INFORMATION:** The Committee provides advice on matters pertaining to the continuance and improvement of functions within the authority of HHS directed toward protections for human subjects in research. Specifically, the Committee provides advice relating to the responsible conduct of research involving human subjects with particular emphasis on special populations such as neonates and children, prisoners, the decisionally impaired, pregnant women, embryos and fetuses, individuals and populations in international studies, investigator conflicts of interest and populations in which there are

individually identifiable samples, data or information.

In addition, the Committee is responsible for reviewing selected ongoing work and planned activities of the OHRP and other offices/agencies within HHS responsible for human subjects protection. These evaluations may include, but are not limited to, a review of assurance systems, the application of minimal research risk standards, the granting of waivers, education programs sponsored by OHRP, and the ongoing monitoring and oversight of institutional review boards and the institutions that sponsor research.

**Nominations:** The OHRP is requesting nominations to fill three positions for voting members of SACHRP. Nominations of potential candidates for consideration are being sought from a wide array of fields, including, but not limited to: Public health and medicine, behavioral and social sciences, health administration, and biomedical ethics. To qualify for consideration of appointment to the Committee, an individual must possess demonstrated experience and expertise in any of the several disciplines and fields pertinent to human subjects protection and/or clinical research.

The individuals selected for appointment to the Committee can be invited to serve a term of up to four years. Committee members receive a stipend and reimbursement for per diem and any travel expenses incurred for attending Committee meetings and/or conducting other business in the interest of the Committee. Interested applicants may self-nominate.

Nominations should be typewritten. The following information should be included in the package of material submitted for each individual being nominated for consideration: (1) A letter of nomination that clearly states the name and affiliation of the nominee, the basis for the nomination (*i.e.*, specific attributes which qualify the nominee for service in this capacity), and a statement that the nominee is willing to serve as a member of the Committee; (2) the nominator's name, address, daytime telephone number, and the home and/or work address, telephone number, and email address of the individual being nominated; and (3) a current copy of the nominee's curriculum vitae. Federal employees should not be nominated for consideration of appointment to this Committee.

The Department makes every effort to ensure that the membership of HHS Federal advisory committees is fairly balanced in terms of points of view represented and the committee's

function. Every effort is made to ensure that individuals from a broad representation of geographic areas, women and men, ethnic and minority groups, and the disabled are given consideration for membership on HHS Federal advisory committees. Appointment to this Committee shall be made without discrimination on the basis of age, race, ethnicity, gender, sexual orientation, disability, and cultural, religious, or socioeconomic status.

Individuals who are selected to be considered for appointment will be required to provide detailed information regarding their financial holdings, consultancies, and research grants or contracts. Disclosure of this information is necessary in order to determine if the selected candidate is involved in any activity that may pose a potential conflict with the official duties to be performed as a member of SACHRP.

**Authority:** 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended. The Committee is governed by the provisions of Public Law 92-463, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

Dated: August 23, 2019.

**Julia Gorey,**

*Executive Director, Secretary's Advisory Committee on Human Research Protections, Office for Human Research Protections.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Cancer Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

**Name of Committee:** National Cancer Institute Special Emphasis Panel; SEP-4: Small Grants Program for Cancer Research (Omnibus R03).

**Date:** October 16, 2019.

**Time:** 8:00 a.m. to 5:00 p.m.

**Agenda:** To review and evaluate grant applications.

**Place:** Hyatt Regency Bethesda, 7400 Wisconsin Avenue, Bethesda, MD 20814.

**Contact Person:** Robert Stephen Coyne, Ph.D., Scientific Review Officer, National Cancer Institute, NIH, Division of Extramural Activities, Special Review Branch, 9609 Medical Center Drive, Room 7W236, Rockville, MD 20850, 240-276-5120, [coyners@mail.nih.gov](mailto:coyners@mail.nih.gov).

**Name of Committee:** National Cancer Institute Special Emphasis Panel; SEP-1: Small Grants Program for Cancer Research (Omnibus R03).

**Date:** October 30, 2019.

**Time:** 12:00 p.m. to 5:00 p.m.

**Agenda:** To review and evaluate grant applications.

**Place:** National Cancer Institute Shady Grove, 9609 Medical Center Drive, 7W242, Rockville, MD 20850 (Telephone Conference Call).

**Contact Person:** Zhiqiang Zou, Ph.D., Scientific Review Officer, Special Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, 7W242, Bethesda, MD 20892, 240-276-6372, [zouzhiq@mail.nih.gov](mailto:zouzhiq@mail.nih.gov).

**Name of Committee:** National Cancer Institute Special Emphasis Panel; Research Projects in Cancer Systems Biology.

**Date:** October 31, 2019.

**Time:** 12:00 p.m. to 4:00 p.m.

**Agenda:** To review and evaluate grant applications.

**Place:** National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W238, Rockville, MD 20850 (Telephone Conference Call).

**Contact Person:** Byeong-Chel Lee, Ph.D., Scientific Review Officer, Resources and Training Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W238, Rockville, MD 20850, 240-276-7755, [byeong-chel.lee@nih.gov](mailto:byeong-chel.lee@nih.gov).

**Name of Committee:** National Cancer Institute Special Emphasis Panel; PQ: Cancer with Underlying HIV Infection.

**Date:** November 13, 2019.

**Time:** 12:00 p.m. to 5:00 p.m.

**Agenda:** To review and evaluate grant applications.

**Place:** National Cancer Institute Shady Grove, 9609 Medical Center Drive, 7W242, Rockville, MD 20850 (Telephone Conference Call).

**Contact Person:** Zhiqiang Zou, Ph.D., Scientific Review Officer, Special Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, 7W242, Bethesda, MD 20892, 240-276-6372, [zouzhiq@mail.nih.gov](mailto:zouzhiq@mail.nih.gov).

**Name of Committee:** National Cancer Institute Initial Review Group; Subcommittee A—Cancer Centers.

**Date:** November 21, 2019.

**Time:** 8:00 a.m. to 2:00 p.m.

**Agenda:** To review and evaluate grant applications.

**Place:** Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Bethesda, MD 20852.