

available variant data, see: <http://www.nhgeneticvariant.com/>.

A minority of resulting data from DNA specimens are not restricted. In these cases, the resulting data will undergo disclosure review by the NCHS Confidentiality Officer and NCHS Disclosure Review Board or designee before the linked data are sent to the investigators for quality control review. Once approved by disclosure review and after the investigators have signed the Data Sharing Agreement, the linked data file will be sent to the investigators for use pursuant to the terms of the relevant agreement. The quality control review must take place within 60 days or a negotiated length of time, and the return of the data to NCHS within the next 30 days so these data may be released to the public.

Disposition of Specimens

The provided DNA specimens cannot be used for any purpose other than the

specifically requested purpose outlined in the proposal and approved through the Scientific and Institutional Review. No DNA specimens can be shared with others, including other investigators, unless specified in the proposal and so approved. Specimens must be returned upon completion of the approved project or destroyed. Both options require written approval from the NHANES Project Officer.

Cost Schedule for Providing NHANES DNA Specimens

There is a nominal processing fee of \$17.17 for each DNA specimen received from an NHANES DNA Repository. The costs include collecting, processing, storing, and retrieving the DNA specimens, reviewing proposals, and preparing the data files. The costs listed are for the recurring laboratory materials to dispense and prepare the DNA specimens during collection and shipping. The NHANES DNA Specimen

repository costs include long-term storage (including inventory management and materials and equipment) and accessioning of specimens and specimen retrieval for shipment to the investigator. Labor costs are based on a proposal administrator to manage the proposal process and computer programmers at NCHS who prepare the data files for the release of the data along with documentation on the NHANES web page. If the investigators request to use the DNA specimens for another proposed project after the completion of the initial project, the additional cost will be 5 percent of the specimen set cost to handle the processing of the data and management of the subsequent proposal process. A new proposal must be submitted and go through the approval process before any additional use of the DNA specimens.

COST SCHEDULE FOR NHANES DNA SPECIMENS

Total costs	1999–2002, 2007–2008, 2009–2010, 2011–2012 complete sets	1999–2002, 2007–2008, 2009–2010, 2011–2012 partial set	NHANES III complete set
Materials and equipment—contractor: plates, reagents, assays, aliquoting and packaging specimens; use of equipment	\$1.72	\$5.15	\$0.85
Labor—contractor: processing, handling, and shipping; NCHS: data quality control	5.66	28.31	2.83
Proposal review and administrative expenses—contractor: inventory management and reporting; NCHS: management of proposal process non-NCHS: technical panel fees ...	3.43	6.87	1.72
Space—contractor: freezer use and maintenance	6.36	6.36	3.17
Cost per specimen	17.17	46.69	8.58
Cost per new proposal:			
1999–2002	134,430.92	*	
2007–2008	79,181.82	*	
2009–2010	84,006.11	*	
2011–2012	71,181.89	*	
III			61,454.85
Cost per additional proposal:**			
1999–2002	6,721.94	***	
2007–2008	4,130.72	***	
2009–2010	4,200.08	***	
2011–2012	3,559.95	***	
III			3,072.17

* Cost calculated upon request.

** Additional research using DNA specimens already obtained from previous solicitations.

*** This charge will be 5 percent of the original cost.

Note: Applicable CDC overhead and NCHS management and oversight charges will be added to these rates for proposals coming from federal agencies.

Angela K. Oliver,
Executive Secretary, Centers for Disease Control and Prevention.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Solicitation of Nominations for Appointment to the Board of Scientific Counselors, National Center for Injury Prevention and Control (BSC, NCIPC)

ACTION: Notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC) is seeking nominations for membership on the BSC, NCIPC. The BSC, NCIPC consists of 18 experts in fields associated with surveillance; basic epidemiologic research; intervention research; and implementation, dissemination, and evaluation of promising and evidence-based strategies for the prevention of injury, violence, and drug abuse. Nominations are being sought for

individuals who have expertise and qualifications necessary to contribute to the accomplishments of the Committee's objectives. Nominees will be selected based on expertise in the fields of pertinent disciplines involved in injury, violence, and drug overdose prevention, including, but not limited to, epidemiology, statistics, trauma surgery, rehabilitation medicine, behavioral science/psychology, health economics, program evaluation, political science, law, criminology, informatics, and other aspects of injury management. Federal employees will not be considered for membership. Members may be invited to serve for up to four-year terms. Selection of members is based on candidates' qualifications to contribute to the accomplishment of BSC, NCIPC objectives (<https://www.cdc.gov/injury/bsc/>).

DATES: Nominations for membership on the BSC, NCIPC must be received no later than September 1, 2022. Packages received after this time will not be considered for the current membership cycle.

ADDRESSES: All nominations should be emailed to ncipcbosc@cdc.gov.

FOR FURTHER INFORMATION CONTACT: Arlene Greenspan, DrPH, MPH, PT, Associate Director for Science, NCIPC, CDC, 4770 Buford Highway NE, Mailstop S-1069, Atlanta, Georgia 30341; Telephone: (770) 488-1279; Email: ncipcbosc@cdc.gov.

SUPPLEMENTARY INFORMATION: The U.S. Department of Health and Human Services policy stipulates that committee membership be balanced in terms of points of view represented and the Committee's function.

Appointments shall be made without discrimination on the basis of age, race, ethnicity, gender, sexual orientation, gender identity, HIV status, disability, and cultural, religious, or socioeconomic status. Nominees must be U.S. citizens and cannot be full-time employees of the U.S. Government. Current participation on federal workgroups or prior experience serving on a federal advisory committee does not disqualify a candidate; however, HHS policy is to avoid excessive individual service on advisory committees and multiple committee memberships. Committee members are Special Government Employees, requiring the filing of financial disclosure reports at the beginning and annually during their terms. CDC reviews potential candidates for BSC, NCIPC membership each year and provides a slate of nominees for consideration to the Secretary of HHS for final selection. HHS notifies selected

candidates of their appointment near the start of the term in September, or as soon as the HHS selection process is completed. Note that the need for different expertise varies from year to year and a candidate who is not selected in one year may be reconsidered in a subsequent year. Candidates should submit the following items:

- Cover letter stating area of expertise.
- Current curriculum vitae, including complete contact information (telephone numbers, mailing address, email address).

- At least one letter of recommendation from person(s) not employed by the U.S. Department of Health and Human Services. Candidates may submit letter(s) from current HHS employees if they wish, but at least one letter must be submitted by a person not employed by an HHS agency (*i.e.*, CDC, NIH, FDA, SAMHSA, etc.).

Nominations may be submitted by the candidate himself or herself or by the person/organization recommending the candidate.

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2020-E-2120 and FDA-2020-E-2121]

Determination of Regulatory Review Period for Purposes of Patent Extension; TABRECTA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for TABRECTA and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the

Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by September 9, 2022. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by January 9, 2023. See "Petitions" in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before September 9, 2022. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 9, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").