

Review/IRB Recordkeeping/Informed Consent/Consent Documentation, OMB No. 0990–0260.

Information reported to the Federal departments and agencies under the Common Rule with respect to a satisfactory assurance is used to ensure that an institution engaged in non-exempt research involving human subjects conducted or supported by a

Common Rule department or agency has (1) established adequate administrative policies and procedures for protecting the rights and welfare of human subjects in research, and (2) accepts that responsibility. Other reporting requirements are used to: Assess whether the institution is following the established procedures; ensure that Federal funds are not expended for

unapproved human subjects research; and, determine if the approved status of an awarded grant, contract, or cooperative agreement should be reviewed, with the ultimate goal of maintaining or increasing human subject protections.

Likely Respondents: Institutions, institutional review boards and investigators.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

Common rule provision	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
.103(b)(5), .113 [Pre-2018 Requirements]/.108(a)(4), .113 [2018 Requirements]—Incident Reporting, Suspension or Termination of IRB approval Reporting	5,200	1	5,200	1	5,200
Total			5,200		5,200

TABLE 2—ESTIMATED ANNUAL IRB RECORDKEEPING BURDEN

Common rule provision	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
.115 [Pre-2018 and 2018 Requirement]—Preparation and documentation of IRB activities	6,000	16	96,000	12	1,152,000
Total	6,000		96,000		1,152,000

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN

Common rule provision	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
.109(d) [Pre-2018 and 2018 Requirements]—Written notification of IRB approval or disapproval of research	6,000	25	150,000	0.5	75,000
.46.116(a) and (b) (Pre-2018 Requirements)/.46.116 (b), (c) and (d) [2018 Requirements]—Elements of informed consent and broad consent	6,000	25	150,000	0.5	75,000
.46.116(h)—[2018 Requirements]—Posting clinical trial consent form	100	3	300	0.5	150
.117(a) [Pre-2018 and 2018 Requirements]—Documentation of informed consent	6,000	25	150,000	0.5	75,000
.117(c)(2) [Pre-2018 and 2018 Requirements]—Written statement about the research when informed consent documentation is waived	6,000	10	60,000	1	60,000
Total			510,300		285,150

Sherrette A. Funn,

Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.

[FR Doc. 2021–13211 Filed 6–23–21; 8:45 am]

BILLING CODE 4150–36–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Committee on Vital and Health Statistics: Notice of Meeting and Request for Public Comment

Pursuant to the Federal Advisory Committee Act, the Department of

Health and Human Services (HHS) announces the following advisory committee meeting.

Name: National Committee on Vital and Health Statistics (NCVHS), Hearing of the Subcommittee on Privacy, Confidentiality and Security

DATES: Wednesday July 14, 2021: 9:30 a.m.–5:30 p.m. EST.

ADDRESSES: Virtual open meeting.

FOR FURTHER INFORMATION CONTACT:

Substantive program information may be obtained from Rebecca Hines, MHS, Executive Secretary, NCVHS, National Center for Health Statistics, Centers for

Disease Control and Prevention, 3311 Toledo Road, Hyattsville, Maryland 20782, or via electronic mail to vgh4@cdc.gov; or by telephone (301) 458–4715. Summaries of meetings and a roster of Committee members are available on the home page of the NCVHS website, <https://ncvhs.hhs.gov/>, where further information including an agenda and instructions to access the broadcast of the meeting will also be posted.

Should you require reasonable accommodation, please contact the CDC Office of Equal Employment

Opportunity on (770) 488–3210 as soon as possible.

SUPPLEMENTARY INFORMATION: On July 14, 2021, the National Committee on Vital and Health Statistics (NCVHS), Subcommittee on Privacy, Confidentiality, and Security, will seek input from experts to examine solutions for improving the security posture of the healthcare industry. At the hearing, the Subcommittee will hear from invited experts on the range of security challenges affecting the health care industry and business partners. The Subcommittee will also hear about the range of policy options that may be available to the Department of Health and Human Services (HHS) and data stewards to improve the security posture of those organizations holding individually identifiable information (III), including federal, state, local, and tribal organizations.

The Committee will use this input to identify and describe the changing security landscape and risks to the privacy and security of III held by the health care industry and highlight promising policies, practices, and technologies. The Committee will lay out integrative models for how best to secure individually identifiable information while enabling beneficial uses, services, and technologies. The Committee will formulate recommendations for the Secretary on actions that HHS might take and prepare a report for the Secretary.

The Committee requests comments from the public in advance of the hearing to inform its deliberations and will consider them together with the input of subject matter experts at the hearing. Please submit comments to NCVHSmial@cdc.gov by close of business Tuesday, July 13, 2021. There also will be a public comment period at the meeting. The meeting times and topics are subject to change. Please refer to the NCVHS website for information and agenda updates.

Sharon Arnold,

Associate Deputy Assistant Secretary for Planning and Evaluation, Science and Data Policy, Office of the Assistant Secretary for Planning and Evaluation.

[FR Doc. 2021–13329 Filed 6–23–21; 8:45 am]

BILLING CODE 4150–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Delivery of a Corrective Glucose-6-Phosphatase-Alpha Gene to Treat Glycogen Storage Disease Type 1a (GSD-1a) in Humans

AGENCY: National Institutes of Health, DHHS.

ACTION: Notice.

SUMMARY: The National Institute of Child Health and Human Development, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the U.S. and foreign Patents and Patent Applications listed in the Supplementary Information section of this notice to Panacea Opportunity, Ltd.

DATES: Only written comments and/or applications for a license which are received by the National Institute of Child Health and Human Development c/o National Cancer Institute's Technology Transfer Center on or before July 9, 2021 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated Exclusive Patent License should be directed to: Alan Hubbs, Ph.D., Senior Technology Transfer Manager at Telephone: (240)–276–5530 or Email: hubbsa@mail.nih.gov.

SUPPLEMENTARY INFORMATION: The following represents the intellectual property to be licensed under the prospective agreement:

Intellectual Property

1. Priority Application, U.S.P.T.O. No. 62/096,400, filed December 23, 2014 [HHS Reference No. E–039–2015/0–US–01];
2. PCT Patent Application No. PCT/US2015/067338, filed December 22, 2015 [HHS Reference No. E–039–2015–0–PCT–02];
3. Pending Canadian Patent Application No. 2972038, filed on December 22, 2015, [HHS Reference No. E–039–2015–0–CA–03];
4. Issued China Patent No. ZL201580076462.4, filed on December 22, 2015, Issued December 11, 2020 [HHS Reference No. E–039–2015–0–CN–04];
5. Issued European Patent No. 2182936, filed December 22, 2015, Issued July 22, 2020 [HHS Reference No. E–039–2015–0–EP–05];
6. Issued Israeli Patent No. 253103, filed on December 22, 2015, Issued

April 1, 2020 [HHS Reference No. E–039–2015–0–IL–06];

7. Issued Japan Patent No. 6824169, filed June 22, 2017, Issued January 14, 2021 [HHS Reference No. E–039–2015–0–JP–07];

8. Issued United States Patent No. 10,415,044, filed September 17, 2019, Issued September 17, 2019 [HHS Reference No. E–039–2015–0–US–08]

9. Pending United States Patent Application No. 16/526,327, filed July 30, 2019, [HHS Reference No. E–039–2015–0–US–08]

With respect to persons who have an obligation to assign their right, title and interest to the Government of the United States of America, the patent rights in these inventions have been assigned to the Government of the United States of America. The prospective exclusive license territory may be world-wide, and the field of use may be limited to the use of Licensed Patent Rights for the following: “Delivery of a corrective glucose-6-phosphatase-alpha gene to treat glycogen storage disease type 1a (GSD-1a) in humans.”

This technology discloses a gene therapy to treat glycogen storage disease type 1a (GSD-1a) in humans using adeno-associated virus mediated delivery of a corrective glucose-6-phosphatase-alpha (G6Pase- α) gene nucleic acid sequence that codes for a protein having an amino acid sequence that differs from the wildtype human amino acid sequence at amino acid position 293.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the National Institute of Child Health and Human Development receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404. In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially, and may be made publicly available.

License applications submitted in response to this Notice will be presumed to contain business confidential information and any release of information in these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 U.S.C. 552.