burden reduction and administrative
by NCVHS for recommendation to HHS
development that should be considered
use cases available or under
these improvements?
between patients, providers, payers,
Session.
Subcommittee-August-Listening-
Request-for-Public-Comment-Standards-
https://ncvhs.hhs.gov/
developed specific questions to ensure
interoperability across the health care
system.
In conjunction with the August 25th
listening session, the Subcommittee is
including in this notice a Request for
Public Comment to obtain written input
from any interested stakeholders
including: Trading partners and
consumers; payers; providers; patients;
standards organizations; advocacy
groups; data exchanges; health
information technology developers; and
other data producers and data
consumers including long term and
post-acute care providers; public health
agencies; population health registries;
and operators of public and private
sector claims and encounter data
reporting systems. The Committee has
developed specific questions to ensure
comments address key issues under
consideration by the Committee. Those
questions are outlined here and
available at: https://ncvhs.hhs.gov/
Request-for-Public-Comment-Standards-
Subcommittee-August-Listening-
Session.
(1) How can data sharing be improved
between patients, providers, payers,
public health system, and other actors
in health care? What are the barriers to
these improvements?
(2) Are there any new standards or
use cases available or under
development that should be considered
by NCVHS for recommendation to HHS
for adoption to support interoperability,
burden reduction and administrative
simplification? Some examples might
include new information sharing in
health care, such as data or semantics
for social determinants of health, public
health case reporting, or All Payor
Claims Databases. Please do not limit
responses to these examples.
(3) How have other industries
effectively implemented, tested, and
certified standards for data and their
exchange that could be considered for
health care?
(4) What short term, mid-term and
long-term opportunities or solutions do
you believe should be priorities for
HHS?
Please submit comments to
NCVHSmail@cdc.gov by close of
business Friday, July 30, 2021.
The Subcommittee will consider
information from the invited panelists
as well as all timely submitted written
comments from the public in its
development of a landscape assessment
and potential recommendations.
There will be a public comment
period. The meeting times and topics
are subject to change. Please refer to the
NCVHS website posted agenda for any
updates.
Contact Person for More Information:
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, telephone (301) 458–4715, email
NCVHSmail@cdc.gov. Summaries of
meetings and a roster of Committee
members are available on the home page
of the NCVHS website https://
ncvhs.hhs.gov/. Further information,
including an agenda and instructions to
access the broadcast of the meeting, will
be posted as soon as the information is
available.
Should you require reasonable
accommodation, please contact the CDC
Office of Equal Employment
Opportunity on (770) 488–3210 as soon
as possible.
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. 2021–13334 Filed 6–23–21; 8:45 am]
BILLING CODE 4150–05–P
SUPPLEMENTARY INFORMATION:
Interested persons are invited to send comments
regarding this burden estimate or any
other aspect of this collection of
information, including any of the
following subjects: (1) The necessity and
utility of the proposed information
collection for the proper performance of
the agency’s functions; (2) the accuracy
of the estimated burden; (3) ways to
enhance the quality, utility, and clarity
of the information to be collected; and
(4) the use of automated collection
techniques or other forms of information
technology to minimize the information
collection burden.
Title of the Collection: Protection of
Human Subjects: Assurance of
Compliance with Federal Policy/IRB
Review/IRB Recordkeeping/Informed
Consent/Consent Documentation.
Type of Collection: Extension with
change.
OMB No. 0990–0260 Office of the
Assistant Secretary for Health, Office for
Human Research Protections.
Abstract: The Office of the Assistant
Secretary for Health, Office for Human
Research Protections is requesting a
three-year extension of the Protection of
Human Subjects: Assurance of
Compliance with Federal Policy/IRB
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**

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

**TABLE 2—ESTIMATED ANNUAL IRB RECORDKEEPING BURDEN**

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

**TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN**

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

**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.