Clinical Research:

REPORT FROM CLINICAL RESEARCH

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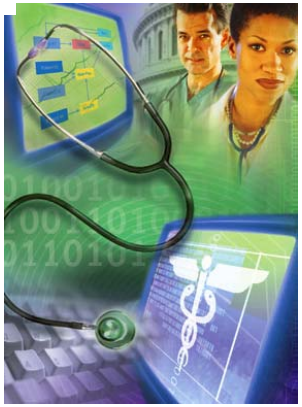
Clinical Research: *Preamble*

We the people . . . .

hereby recommend that the NHII ensure that clinical and translational research needs are interwoven through the foundational NHII strategic plan, in order to form a more perfect Union between clinical care and research endeavors.

Be it known that we also urge our nation's government to articulate the long-term vision and mission for research within the NHII, in addition to the articles set forth herein, enunciating our short-term actionable articles of faith.

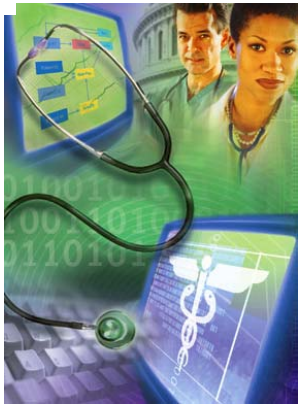


Clinical Research: *Preamble*

The NHII should be concerned with all facets of research related to human health and well-being, including but not limited to:

clinical research, basic science, population research, environmental sciences, bioengineering, and informatics.

. . . . We hold these truths to be self-evident.

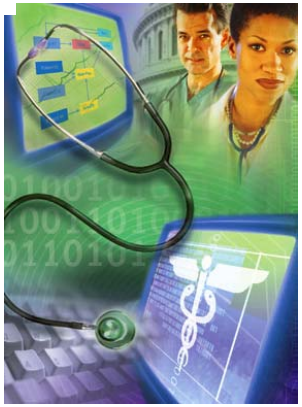


Clinical Research:

KEY RECOMMENDATIONS

The U.S. Department of Health and Human Services (DHHS) should develop NHII in a manner that encourages the reuse of clinical care data for research.

In lieu of a singular master ID, DHHS should create a Task Force to define and disseminate best practices for identifying and linking unique individuals across multiple relevant databases.



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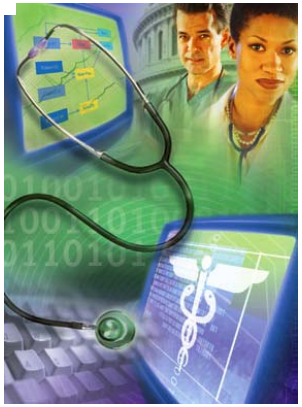
KEY RECOMMENDATIONS

OPHR should create a national IRB standard.

NCVHS should ensure that HIPAA rules are reviewed and amended to take into account evolving demands that emerge because of universal access to electronic health data.



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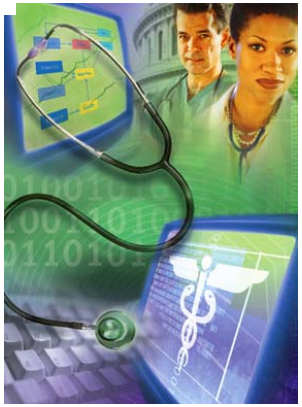
In collaboration with the healthcare and research communities, DHHS and the Department of Commerce should evaluate the capacity of existing controlled research vocabulary resources (including animal, vector, environmental and other nonhuman data related to human health) to support the integration of clinical practice and research data.

DHHS should maintain these standard terminologies in the public domain, in a non-proprietary fashion.



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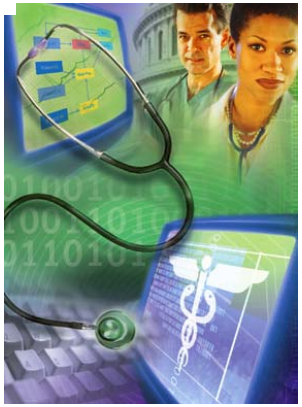
Funding agencies should promote, and investigators should conduct, informatics research that assists in the further development and implementation of the NHII architecture, in a manner conducive to supporting research as well as patient care.



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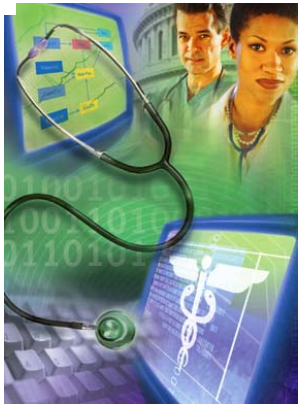
DHHS should support the creation of managed open source requirements for interoperable tools, applications, and infrastructure for end- to- end clinical research life cycle (e.g.,community, private practice).

DHHS should ensure that emerging research work flow processes, information models, protocol representation and data representation standards being developed by CDISC via HL7 RCRIM and the Clinical Genomics Special Interest Group are used as metadata standards in PHIN and NHII.



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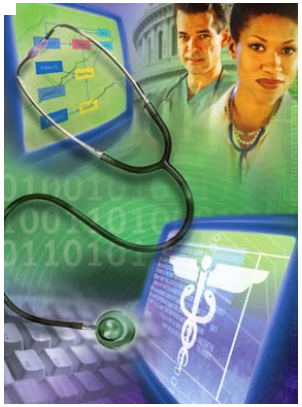
KEY RECOMMENDATIONS

DHHS should fund demonstration projects of connectivity between existing clinical care networks and existing research networks.

CMS should implement new interoperable and universally accessible technologies to provide Medicare claims-data compression and export (e.g. via XML and ASCII format) to researchers.



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KEY RECOMMENDATIONS

NHII should establish a communication vehicle for the timely, appropriate data exchange among researchers, including computable research results, and the dissemination of summarized research results and publicly accessible databases for consumers and healthcare providers.