

Pre-Decisional Draft. Do Not Distribute.

NHIN Coordinating Committee Operating Policy and Procedure

SUBJECT: PARTICIPATION – REVIEW AND DISPOSITION OF APPLICATIONS FOR PARTICIPATION AND DEFINITIVE PLANS		
STATUS: APPROVED by NHI NCC	POLICY #: NHIN-CC: 1	
Date: 02/18/2010	Version:2.0	Page 1 of 7

I. Purpose

The NHIN Coordinating Committee (NHINCC) is responsible for developing, implementing and operating the NHIN on an interim basis. The fulfillment of these responsibilities involves acceptance of new Participants for participation in the Nationwide Health Information Network and new Members for participation on the NHIN Coordinating Committee.

This policy outlines a framework for assessing the readiness of valid legal entities and governmental entities to become Participants in the NHIN or Members of the NHIN Coordinating Committee under a Definitive Plan.

II. Policy

Only entities that meet the eligibility requirements and are accepted by the NHIN Coordinating Committee may be Participants in the NHIN or Members of the NHIN Coordinating Committee.

III. Procedure

A. Eligibility Requirements

To be eligible to be a Participant in the NHIN or a Member of the NHIN Coordinating Committee under a Definitive Plan, the Applicant must:

- Be either (i) a valid legal entity, either public or private, that is a contractor, grantee or party to a cooperative agreement with a Federal government agency that addresses participation in the NHIN or (ii) a Federal agency;
- Be transacting health information electronically in production, on a routine and on-going basis using sufficient data to support priorities as defined by the NHIN Technical Committee;
- Facilitate and govern the exchange of health data among groups of persons or organizations (Participant Users) that wish to request and/or receive health data from other Participants in the NHIN such that the Applicant has the authority to enter into the DURSA, agree to the terms and conditions contained therein, and obligate its Participant Users to uphold those requirements;
- Intend to exchange (to request and/or receive) information with other Participants in the NHIN for a permitted purpose that is consistent with the priorities set by the NHIN Technical Committee and the NHIN Performance and Service Specifications;
- Have sufficient financial, technical and operational resources to support the testing and operation of information exchange via the NHIN; and
- Submit a completed Application for Participation or Definitive Plans.

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To be accepted as a Member of the NHIN Coordinating Committee through a Definitive Plan, the Applicant must attest that it:

- Intends to become a signatory to the DURSA by signing the DURSA or a Joinder Agreement;
- Has written privacy and security policies as required by Section 7.01 of the DURSA;
- Meets all of the eligibility requirements set forth in this policy;
- Has a timeline for implementation of the exchange of data, which has significant milestones leading up to the live exchange of data via the NHIN before December 31, 2010; and
- Agrees to hold all information disclosed to it as a Member of the NHIN Coordinating Committee in confidence in accordance with Policy #NHIN-CC: 6 – Information Handling.

To be accepted as a Participant in the NHIN, the Applicant must also:

- Execute the DURSA Joinder Agreement;
- Successfully complete the required technical testing in accordance with the NHIN Validation Plan;
- Be able to begin exchanging data with other NHIN Participants in production through the Participant’s successfully tested production system.

While an Applicant that applies to participate in the NHIN must submit a signed copy of the DURSA or Joinder Agreement with its application for participation, such signature does not make the Applicant a party to the DURSA. The Applicant does not become a party to the DURSA until the NHIN Coordinating Committee accepts the Applicant as a Participant and duly executes the Applicant’s Joinder Agreement following the Applicant’s production release of a validated system. The Coordinating Committee reserves the right to decline an Applicant admission even if such Applicant signs the DURSA.

B. Receipt of Applications

Applicants should forward a completed application as provided in Exhibit A to NeHC.

NeHC is requested to catalog all applications upon receipt. The record shall contain the date of receipt, the name of the Applicant, whether the application is for participation in the NHIN or on the Coordinating Committee through a Definitive Plan, and a brief description of the proposed exchange activities.

NeHC is requested to verify that an Applicant has responded to each element of the application. If an Applicant has failed to respond to any applicable items on the application, NeHC is requested to return the application for completion.

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C. Evaluation of Applications

The NHIN Coordinating Committee shall consider, at a regularly scheduled meeting, all applications which are received by NeHC at least two (2) weeks prior to the NHIN Coordinating Committee’s meeting. NeHC is requested to forward applications for consideration by the NHIN Coordinating Committee to the committee members at least one week prior to the meeting at which the application will be considered. Through the application, the Applicant shall demonstrate to the satisfaction of the NHIN Coordinating Committee that, at the time the application is submitted, it meets the applicable eligibility requirements set forth in Section III.A. of this policy. When determining whether an Applicant meets the eligibility requirements, the NHIN Coordinating Committee may consider the Applicant’s past participation in the NHIN, if any.

As the application is under review, the NHIN Coordinating Committee may consult with the Applicant, request additional information regarding the application and proposed services and/or exchanges, suggest changes or modifications to the application including the supporting documentation or make other recommendations the NHIN Coordinating Committee deems reasonably necessary during the evaluation. In addition, the NHIN Coordinating Committee may request verification of elements of the application including screen shots, audit log excerpts, metrics or system demonstrations. The NHIN Coordinating Committee may request that the Applicant modify and resubmit the application and/or supporting documentation. If an Applicant fails, or declines, to provide requested information or modify its application, then the NHIN Coordinating Committee may defer or decline the application.

Any Applicant may withdraw its application at any time by informing the Coordinating Committee of such withdrawal. With respect to applications for participation on the Coordinating Committee through a Definitive Plan, the NHIN Coordinating Committee may consult with the remaining parties in the Definitive Plan to determine how such withdrawal impacts the status of the remaining parties and whether the Definitive Plan should continue, be modified and resubmitted, or withdrawn. If the Definitive Plan is continued or resubmitted, the NHIN Coordinating Committee will review it in accordance with this policy.

With respect to applications for participation on the Coordinating Committee through Definitive Plans, all communication by the NHIN Coordinating Committee regarding the overall contents of the application shall be with all Applicants party to the Definitive Plan unless waived by one or more of the Applicants. The NHIN Coordinating Committee may address any issues or concerns that relate primarily to one or more of the Applicants with those Applicants only.

Upon any determination for acceptance or rejection of an application, the Applicant shall be informed of the decision of the NHIN Coordinating Committee as well as supporting reasoning for the decision. If rejected, the Applicant may submit a new application for consideration by the NHIN Coordinating Committee after correcting the identified deficiencies.

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In any event, NEHC is requested to update the application record maintained by NEHC under Section III.B., above with the decision of the NHIN Coordinating Committee.

1. Applications for Participation in the NHIN

Upon a determination by the NHIN Coordinating Committee that an application to participate in the NHIN is complete, the NHIN Coordinating Committee shall determine, consistent with its Operating Procedures, whether to preliminarily accept or reject the application and communicate this decision to the NHIN Implementation Team. Upon a determination by the NHIN Coordinating Committee that the Applicant meets the Eligibility Criteria in Section III.A and its responses on the application and any supporting documentation are adequate for acceptance of the Applicant as a Participant, it will request the Applicant complete all technical testing in accordance with the NHIN Validation Plan to assess compliance with the applicable NHIN Performance and Service Specifications for those services the Applicant will support.

At the next scheduled meeting of the NHIN Coordinating Committee after results of technical testing are complete and received by NeHC, the NHIN Coordinating Committee shall consider the results. During consideration of the technical testing results, the NHIN Coordinating Committee may consult with the Applicant, request additional information, notify the Applicant of items that require remediation to comply with the NHIN Performance and Service Specifications or suggest changes to the Applicant's implementation of the NHIN Performance and Service Specifications. The Applicant shall notify the NHIN Coordinating Committee of its election to remediate or not remediate any non-conformance of its implementation of the NHIN Performance and Service Specifications: (http://healthit.hhs.gov/portal/server.pt?open=512&objID=1194&parentname=CommunityPage&parentid=6&mode=2&in_hi_userid=10882&cached=true).

If the Applicant elects not to remediate any non-conformance, the application shall be considered to be withdrawn. The NHIN Coordinating Committee may hold an application pending completion of any needed remediation, changes or modifications as well as any needed follow up technical testing to ensure the Applicant is able to meet the NHIN Performance and Service Specifications.

a. Acceptance

If the Applicant meets the Eligibility Criteria in Section III.A, the Applicant's responses on the application and any supporting documentation are adequate for acceptance, and the Applicant has successfully completed all technical testing, the NHIN Coordinating Committee shall conditionally accept the Applicant as a Participant.

The NHIN Coordinating Committee's acceptance of the Applicant as a Participant is conditioned on the Applicant being able to begin exchanging data in production via the NHIN within one-hundred and twenty (120) calendar days following the date the NHIN Coordinating Committee conditionally accepts the Applicant as a Participant. Between the time that the NHIN Coordinating Committee conditionally accepts the Applicant as a

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Participant and the Applicant becomes a Participant, the following activities will occur:

- The NHIN Implementation Team shall coordinate with the Applicant regarding the specific date on which the Applicant’s system will be operational, in production and ready to exchange information with other NHIN Participants in production.
- The NHIN Implementation Team will issue the Applicant its Production Digital Credentials.
- Applicant shall provide the NHIN Implementation Team the required information to add the Applicant to the NHIN service registry. ONC will confirm that the information supplied is accurate by testing the information provided.
- NeHC will arrange for the NHIN Coordinating Committee to execute the DURSA Joinder Agreement after consulting with the Applicant regarding its readiness to begin exchanging information with NHIN Participants in production. NeHC will maintain documentation related to the application process, including copies of the executed DURSA Joinder Agreements.
- Once the Joinder has been signed and delivered to the Applicant by the NHIN Implementation Team, the NHIN Implementation Team will publish the Applicant’s Digital Credentials in the production registry. At this point the Applicant becomes activated as a Participant in the NHIN. Other NHIN Participants will be able to identify the new Participant and begin exchanging health information with that new Participant.

If an Applicant is unable to go into production as a NHIN Participant within the one-hundred and twenty (120) calendar day timeframe or on another date mutually agreed upon by the NHIN Coordinating Committee and Participant, the Applicant may request an extension from the NHIN Coordinating Committee. The NHIN Coordinating Committee may accept or deny the extension request. If the extension request is denied, it shall have the same effect as a rejection and be treated in accordance with Section III.C.1.b. of this policy. If the extension request is accepted, it shall result in the extension of the timeframe for the Applicant to go into production. The NHINCC, Applicant and the NHIN Implementation Team will work together to identify a new specific date on which the Applicant’s system will be operational, in production and ready to exchange information with other NHIN Participants in production. Applicants shall have the ability to submit multiple extension requests, each of which will the NHIN Coordinating Committee will review and disposition.

An Applicant’s formal acceptance as a Participant takes effect on the date the Applicant’s system is operational in a production environment and able to exchange data with other NHIN Participants and when the Applicant’s Digital Credentials are added to the NHIN service registry.

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b. Rejection

If, after reasonable consultation and requests and the reasonable opportunity to do so, the Applicant has been unable to meet the eligibility criteria or to provide adequate responses to those items on the application or sufficient supporting documentation as reasonably requested by the NHIN Coordinating Committee; has been unable to successfully complete all technical testing; or has been unable to go into production exchanging data via the NHIN by the agreed upon date, the Applicant’s request to join the NHIN as a Participant may be rejected.

2. Applications to Serve on the NHIN Coordinating Committee Through a Definitive Plan

Upon a determination by the NHIN Coordinating Committee that an application to serve on the NHIN Coordinating Committee through a Definitive Plan (“Definitive Plan”) is complete, the NHIN Coordinating Committee shall determine, consistent with its Operating Procedures, whether to accept or reject the Definitive Plan and communicate this decision to the NHIN Implementation Team. Acceptance may be unconditional or may be conditioned upon the Applicant reasonably achieving milestones set forth in the Definitive Plan or other requirements the NHIN Coordinating Committee deems reasonably necessary to best assure that the Definitive Plan is met.

a. Acceptance

If the Applicant meets the Eligibility Criteria in Section III.A and the Applicant’s responses on the application and any supporting documentation are adequate for acceptance, the NHIN Coordinating Committee may accept the Applicant as a member of the NHIN Coordinating Committee through a Definitive Plan. Upon acceptance, each Applicant (now a “Definitive Plan Member of the NHINCC”) shall be promptly notified of the acceptance including any conditions placed upon the acceptance of the Definitive Plan by the NHIN Coordinating Committee. Each Definitive Plan Member of the NHINCC shall appoint an individual representative to be added to the NHIN Coordinating Committee after which the Definitive Plan Member of the NHINCC may enjoy the full benefits of membership on the NHIN Coordinating Committee consistent with the NHIN Coordinating Committee’s Operating Procedures.

After conditional acceptance of a Definitive Plan, should the conditions not be reasonably met given all the facts and circumstances surrounding the Definitive Plan and upon reasonable notice and discussion, the NHIN Coordinating Committee may terminate a Definitive Plan consistent with its Operating Procedures.

b. Rejection

If, after reasonable consultation and requests and the reasonable opportunity to do so, the Applicant has been unable to meet the Eligibility Criteria or provide adequate responses to those items on the application or sufficient supporting documentation as reasonably requested by the NHIN Coordinating Committee, the Applicant’s application to serve as a member of

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the NHIN Coordinating Committee through a Definitive Plan may be rejected.

IV Definitions:

Applicant: The entity or agency that submits an application for participation in the NHIN or on the NHIN Coordinating Committee through a Definitive Plan.

DURSA: Data Use and Reciprocal Support Agreement

All other capitalized terms, if not defined herein, shall have the same meaning as set forth in the DURSA.

VI References:

DURSA

Application for New Participants in the NHIN and NHIN Coordinating Committee

VII Related Policies and Procedures:

VIII Version History:

	Date	Author	Comment
1	6/24/09	Randy Sermons	Original – NHIN Review and Acceptance Operating Policies and Procedures for Participation and Definitive Plan were separate.
2	10/19/09	Mariann Yeager	Combined the two operating policies and procedures into a single document. Created a separate document for Participation Changes, Suspension and Termination.
3	10/21/09	Mariann Yeager	Included edits / comments from the 10/20 Team review call.
4	10/28/09	Mariann Yeager	Revised based upon input from the 10/28 Team review call.
5	11/4/09	Aaron Seib, Randy Sermons, Erin Whaley, Mariann Yeager	Revised based upon input from the 11/3 Team review call.
6	11/27/09	Erin Whaley and Steve Gravely	Revised based on input from the 11/5 and 11/19 CC calls.
7	12/02/09	Aaron Seib	Update document with approved changes to reflect CC approval on 12/02/09
8	2/10/10	Alex Baker	Revised with specification of appropriate roles for NHIN Implementation Team and NeHC staff.