POLICY INFORMATION

Policy Title: Research Authorizations Policy and Procedure

Departmental Owner: Chief Compliance, Audit, and Privacy Officer

Version Effective Date: 2/28/24

Last Reviewed: 2/28/24

SCOPE

This policy applies to the following individuals and/or groups:

☒All of the below categories

☐All Employees ☐CT Employees ☐NY Employees ☐Remote Employees ☐Contractors☐Volunteers ☐Students/Interns ☐Vendors

This policy applies to all above listed Nuvance Health workforce members including but not limited to the following locations:

☐All of the below entities

☐Nuvance Health Systems

☐ Danbury Hospital (including New Milford Hospital Campus)	☒ Health Quest Systems, Inc. "(HQSI)"	☐ Western Connecticut Home Care, Inc ("WCHN")
☒Northern Dutchess Hospital	☒ Health Quest Home Care, Inc	☐ Western Connecticut Health Network Physician Hospital Organization ACO, Inc.
☐Norwalk Hospital	☒ Hudson Valley Cardiovascular Practice, P.C. (aka The Heart Center) ("HVCP")	☐Western Connecticut Home Care, Inc
☒ Putnam Hospital	☒ Other HQSI-affiliated Entities Not Listed	☐ Other WCHN-affiliated Entities Not Listed
☒Sharon Hospital		☒Nuvance Health Medical Practices (NHMP PC, NHMP CT, ENYMS & HVCP)
☒Vassar Brothers Medical Center		

POLICY STATEMENT/PURPOSE

To identify the necessary elements of a patient authorization allowing the use, access, and disclosure of a patient's protected health information ("PHI") for research purposes in accordance with the HIPAA Privacy Rule. The authorization may be appended to the back of the informed consent to participate in the research. (See Nuvance Research Authorization Form, if applicable).

DEFINITIONS

See HIPAA Glossary

POLICY

It is the policy of Nuvance Health and its affiliates ("Nuvance") to require patients who participate in a research study to sign an authorization for the use, access or disclosure of the patient's PHI described in the authorization for purposes of the research and to the recipients stated in the authorization, unless the authorization requirement is waived or altered by the Institutional Review Board ("IRB") or the research is a review of records preparatory to research or research on decedents' information with required representations by the researcher. See Nuvance Validation of Authorization Policy. The Nuvance Office of Research and Innovation will maintain all research authorizations. Only the minimum necessary information is to be utilized during research studies.

PROCEDURE

Nuvance has a process in place to review that all potential research patients have a valid authorization form prior to the start of any research activity.

All patients that enter into a research study with Nuvance must have a signed/dated and valid authorization form prior to the commencement of any research activity.

A. ELEMENTS OF A VALID AUTHORIZATION

A valid authorization for research must include:

1. A description of the information to be used or disclosed that identifies the information in a specific and meaningful fashion.
2. The name or other specific identification of the person(s), or class of persons, authorized to make the requested use or disclosure.
3. The name or other specific identification of the person(s), or class of persons, to whom the requested use or disclosure may be made.
4. A description of each purpose of the requested use or disclosure.
5. An expiration date or an expiration event (such as “end of research study” or “none”) that relates to the individual or the purpose of the use or disclosure.
6. A statement of the individual’s right to revoke the authorization in writing and the exceptions to the right to revoke, together with a description of how the individual may revoke the authorization.
7. A statement that information used or disclosed pursuant to the authorization may be subject to re-disclosure by the recipient and no longer be protected by the Privacy Rule.
8. A statement that the provision of research-related treatment may be conditioned on the individual’s provision of the authorization.
9. Signature of the individual and date.
10. If the authorization is signed by a personal representative of the individual, a description of such representative’s authority to act for the individual.
11. IRB number.

B. STAND-ALONE AUTHORIZATION

1. A stand-alone authorization for the use or disclosure of protected health information (“PHI”) for research purposes will generally be signed by the patient at the same time as the consent to participate in the research. However, there may be situations where the stand-alone authorization and the consent to participate in the research are signed separately.
2. The signed authorization for release of information will accompany the information that is released for research purposes.

C. COMPOUND AUTHORIZATION

1. If the Nuvance IRB deems it appropriate, a compound authorization that includes both the authorization for use and disclosure of protected health information for research purposes and the consent to participate in the research may be used.

2. All of the elements described in Section A must be included in the compound authorization.
3. As the signed compound authorization will accompany PHI that is released for research purposes, a compound authorization may only be used when disclosure of the entire form will not violate the privacy rights of the research subjects, as determined by the Nuvance IRB.

ENFORCEMENT

All individuals whose responsibilities are affected by this policy are expected to be familiar with the basic procedures and responsibilities created by this policy. Failure to comply with this policy will be subject to appropriate remedial and/or disciplinary action, up to and including termination of any employment or other relationship, in accordance with this policy.

REFERENCES

45 CFR, Parts 160 and 164

APPROVAL

DocuSigned by:
Jared B Gaynor
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Signature

2/28/2024

Date

Original Effective Date: LHQ= 2/27/14
Revision Dates: 2/28/24
Supercedes: HQ 5.2.28 Research Authorizations Policy;
HQ 5.2.28 Research Authorizations Procedure