PROCEDURE STATEMENT:

Health Quest Systems, Inc. and its’ affiliates (“HQ”) have a process in place to review that all potential research patients have a valid authorization form prior to the start of any research activity.

PROCEDURE:

All patients that enter into a research study with HQ 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 HQ 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 HQ IRB.
DEFINITIONS:

See glossary

ENFORCEMENT:

All individuals whose responsibilities are affected by this process are expected to be familiar with the basic procedures and responsibilities created by this process. Failure to comply with this process 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 process.

REFERENCES:
45 CFR, Parts 160 and 164
5.2.28 Research Authorizations Policy

POLICY HISTORY:
Supersedes: 2/27/14
Original Implementation Date: 2/27/14
Date Reviewed: 3/13/19
Date Revised: 2/27/14, 3/13/19

APPROVAL:

W.A. McNulty by 3.31.20

Policy Owner Date