1.0 Purpose:

1.1 The Hartford HealthCare Institutional Review Board (HHC IRB) stamp of approval on a document indicates that the document has been reviewed and approved for use by the IRB. This stamp also shows the date the approval was granted.

1.2 The IRB stamp of approval will only be applied to finalized documents and shall appear on each page of the approved document. All documents are stamped electronically within the iRIS system.

2.0 Definitions:

2.1 **IRB Stamp of Approval:** This stamp is applied to all approved documents such as; the consent, recruitment materials and questionnaires (a full list of documents appears in section 3.0 of this policy). Once stamped, a document will become a .pdf document contained in the iRIS study shell.

2.1.1 **Content:** All approved documents will contain an approval date, but only consent and HIPAA documents will contain an expiration date. As in the example below, this expiration date will always be one day prior to the study's renewal date for the following year. The stamp of approval will display as in the example below (the dates and IRB number will be tailored to the study):

HHC-IRB
IRB NUMBER: HHC-2015-XXXX
IRB APPROVAL DATE: 04/08/2015
IRB EXPIRATION DATE: 04/07/2016

2.1.2 **Color:** The stamp of approval is in blue font.

2.1.3 **Location:** The stamp of approval will appear at the bottom right corner of the page.

3.0 Procedure:

3.1 **Which documents contain the IRB stamp of approval?** The general guidance is that any materials given to a subject directly, mailed to a subject or discussed over the phone with a subject should receive the IRB Stamp of Approval. These, as well as additional documents that require approval stamps are listed below:

3.1.1 All types of written consent, assent, and permission forms for studies and sub-studies
3.1.2 Information sheets and verbal consent scripts
3.1.3 Any other materials that provide subjects with the opportunity to learn about an/or facilitate the consent process
3.1.4 All recruitment materials such as; flyers, brochures, advertisements and recruiting letters
3.1.5 All questionnaires, surveys and rating scales that are not incorporated into the protocol
3.1.6 Phone screen forms
3.1.7 All study related instructional forms that are given to patients explaining certain study procedures, such as surgical procedures or MRI procedures, etc.
3.1.8 Protocols (if new or revised)
3.1.9 HIPAA authorization forms
3.1.10 Data collection forms that are not incorporated in the protocol
3.1.11 Investigator brochures
3.1.12 Instructions for use/Package Inserts

3.1.13 DSMB Reports
3.1.14 Internal Note to File documents
3.1.15 Honest broker agreements
3.1.16 Any of the above mentioned documents that have been translated into languages other than English

3.2 **Which documents are acknowledged by the IRB, but not stamped:** The following materials will show as "acknowledged" in the iRIS system. The system will denote the date that the document was acknowledged by the IRB, but will not contain a formal stamp:
3.2.1 Adverse event logs
3.2.2 Correspondence or materials intended only for study staff
3.2.3 Signed consent pages submitted at the time of continuation
3.2.4 Action letters from a sponsor
3.2.5 Sponsor summary of changes documents
3.2.6 Abstracts/Publications/Presentations

3.3 **Which documents are neither stamped nor acknowledged?** The following materials will not receive any stamp of approval or acknowledgement from the IRB:
3.3.1 IRB applications
3.3.2 Rating scales and questionnaires that are part of the study protocol
3.3.3 Any study related materials that would be impossible to stamp such as cognitive tests involving puzzles or games, etc.
3.3.4 Study budgets
3.3.5 Short form consents
3.3.6 Scientific review checklists
3.3.7 Protocols (if there have been no changes since the previous version)

3.4 **Who does the stamping?** A member of the Human Research Protections Program (HRPP) Staff, typically the IRB Administrator processing the particular submission will apply the electronic stamp.

3.5 **When are materials stamped?** Materials will be stamped after they have been reviewed and approved by the IRB.
3.5.1 **Date:** The date in the stamp is the date on which the document was approved.*

*Note: If an application received conditional approval and the documents were revised as part of the requirements for conditional approval, then the approval date stamped on the documents will be the date those materials were fully approved by the IRB.

3.6 **How can the researcher access the documents?** The electronic copies of the stamped materials will be maintained within the iRIS system. They can be accessed by opening the study which is accessible in the investigator's "My Studies" tab in iRIS. Once the correct study is located, the investigator can access the appropriate document in the section titled "Protocol Items." This contains subheadings including "Informed Consent," where Consent and HIPAA documents are housed, and "Other Study Documents," where any other study materials are maintained. The newest stamped version is always labeled as Approved and appears as a pdf document.

3.6.1 Researchers are required to keep the <u>stamped</u> copies of all IRB stamped documents in their regulatory files.
3.6.2 Only a <u>copy</u> of the stamped approved document should be distributed to subjects (see additional guidance in section 4.1.3 of this policy).

3.6.3 Failure to maintain accurate records of IRB approved documents will be considered non-compliance. Continued non-compliance or gross non-compliance of maintaining study documents could result in the suspension of the study activities, disallowed use of study data or closure of the study.

4.0 Guidance:

4.1 **When are researchers required to use a document containing the stamp of approval?**

4.1.1 Any consent materials used during the consent process (including translated consent materials and information sheets) must have a visible and current IRB stamp of approval.

4.1.2 The HIPAA Authorization must have a visible and current approval stamp.

4.1.3 It is recommended that all patient recruitment materials such as flyers, brochures and advertisements have the IRB stamp of approval on them.*

*However, sometimes posting recruitment materials with the IRB stamp of approval is not feasible (i.e. newspaper ads, electronic ads or pre-printed posters from the sponsor). If that's the case than posting the document without the stamp will be allowed, as long as the language in the document has not been altered in any way.

4.2 **Exceptions:** Researchers are not required to use an approved document containing a visible stamp of approval for:

4.2.1 Electronic consents

4.2.2 Electronic advertisements or recruitment materials

4.2.3 Questionnaires, surveys and rating scales*

4.2.4 Phone screening forms

*Many standardized rating scales contain multiple versions, which are indicated by a version date. Please note that any time a questionnaire, survey, or rating scale is stamped as approved by the IRB, the researcher must make certain they are using this same version throughout the study unless they receive approval to use a different version.

4.3 **Materials submitted at the time of continuing review:** The following materials will receive an updated stamp of approval at the time of continuation:

4.3.1 All consent materials will receive an updated IRB stamp of approval indicating the date the study was approved for continuation.

4.3.2 The HIPAA Authorization will receive an updated approval stamp indicating the date the study was approved for continuation.

4.3.3 All other materials will not receive an updated stamp of approval unless they were revised at the time of continuation.

5.0 Documentation:

5.1 Research Administration will maintain all records related to the implementation of this policy, electronic communications, and notifications to investigators, funding or regulatory agencies, etc.

5.2 Records will be archived for a period of at least three years following the termination or completion of the research activities.

6.0 Revision History:

Rev #	Initials	Effective Date	Description of Change(s)
00	PMJ	7/1/11	New issue
01	NS	5/1/15	Updated to include changes to stamping in the iRIS electronic system, as well as which documents will be stamped and how they can be accessed by investigators
02	CLB	3/15/20	General review. No changes.

Element II.3.F. and III.1.F.