BC 10.190 - Research Consent Process and Documentation

I. POLICY:

The ethical conduct of research is based upon the voluntary consent of Participants who have been appropriately informed about a study's risks and benefits. There exist limited situations in which prior written consent is not required. The Principal Investigator (PI) conducting research at Baystate bears the responsibility of ensuring full compliance with both federal and state regulations through the language of the consent document. This process includes adequately informing all potential research participants about the study's risks and benefits. Additionally, the PI must obtain voluntary informed consent from each participant or their legal representative before enrolling them in the study, unless federal regulations exempt the research or the Institutional Review Board (IRB) determines and documents that informed consent can be waived. For most research, documentation of the informed consent is required to establish the Participant was accurately and adequately informed about the research study and that no study-related procedures were initiated prior to obtaining informed consent.

II. PURPOSE:

The purpose of this policy is to define the requirements for obtaining and documenting informed consent of research participants at Baystate Health affiliated entities including but not limited to: Baystate Medical Center ("BMC"), Baystate Wing Hospital ("BWH"), Baystate Franklin Medical Center ("BFMC"), Baystate Noble Hospital (BNH), and the University of Massachusetts Chan Medical School – Baystate. It applies to obtaining consent under general requirements or routine circumstances as well as identifies procedures for obtaining informed consent with special circumstances.

III. SCOPE:

This policy applies to all employees, medical staff, associate professional staff, teachers, students, residents, fellows, volunteers, contractors, consultants, agents, and others associated with BH who are involved in Research or any professional scholarly activities at any BH affiliated entities including but not limited to: Baystate Medical Center ("BMC"), Baystate Wing Hospital ("BWH"), Baystate Franklin Medical Center ("BFMC"), Baystate Noble Hospital (BNH), and the University of Massachusetts Chan Medical School – Baystate.

IV. DEFINITIONS:

Informed Consent:. The informed consent process involves an exchange of information and continuous communication between the Investigator and the potential participant. The consent process starts when a potential participant is first introduced to a research activity through advertisement or approach by a researcher and continues when the individual voluntarily confirms their readiness to take part in a clinical research study after being informed about all the relevant aspects of the study that are relevant to their decision to participate. Informed consent is documented by means of a written, signed, and dated Informed Consent Form (ICF). After consent is granted, the informed consent process remains in effect throughout the entire research activity, concluding either when the participant chooses to conclude their participation or when the study itself comes to a close.

Investigator: A person responsible for the conduct of the clinical research at a study site. If clinical research is conducted by a team of individuals at a study site, the investigator is the responsible leader of the team and may be called the principal investigator.

Legally authorized representative (LAR): An individual authorized by applicable law to consent, on behalf of a prospective Participant, to the Participant's participation in the clinical research.

Sub-investigator: Any individual member of the clinical research team designated and supervised by the investigator at a research site to perform critical research-related procedures and/or to make important research-related decisions (e.g., associates, residents, research fellows).

Participant: An individual who participates in a clinical research, either as a recipient of the investigational product(s) or as a control.

V. PROCEDURE:

A. Obtaining written consent from the Participant

1. Before involving a human participant in research covered by this policy, an investigator shall obtain the legally effective informed consent of the participant or the participant's legally authorized representative.

2. An investigator shall seek informed consent only under circumstances that provide the prospective participant or the legally authorized representative sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence.

3. The information that is given to the participant or the legally authorized representative shall be in language understandable to the participant or the legally authorized representative.

4. The prospective participant or the legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.

5. Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective participant or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.

6. Informed consent as a whole must present information in sufficient detail relating to the research and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective participant's or legally authorized representative's understanding of the reasons why one might or might not want to participate.

7. No informed consent may include any exculpatory language through which the participant or the legally authorized representative is made to waive or appear to waive any of the participant's legal rights, or releases or appears to release the investigator, the sponsor, the

institution, or its agents from liability for negligence.

B. Basic Requirements for Informed Consent at a Baystate Health and its affiliated entities (45 CFR46.116 (b) and 21 CFR 50.25)

When obtaining informed consent, all clinical research studies at Baystate Health and its affiliated entities will use the current Baystate Health informed consent template as modified and approved for the particular study by the Baystate IRB or an IRB to which the Baystate IRB has deferred review.

All informed consent procedures will conform to the current approved Baystate Human Research Protection Program SOPs and checklist when obtaining informed consent.

C. Documenting the Consent Process

In keeping with federal regulations, consent materials must be provided to prospective participants/LARs in a language that is understandable to them. For Investigators who enroll non-English speakers (or those with a limited ability to understand or read materials in English), materials to be used with or by these participants must be translated into a language that is understandable to them. Written consent documents, regardless of the language in which they are written, must contain all the elements of consent required by the current approved Baystate template and HRPP SOPs.

In accordance with federal regulations, an investigator or their designee may verbally present the required information to enable a potential participant/LAR to make an informed decision about participating in research, instead of using a translated consent form. However, this verbal presentation must have a witness, and the participant must receive a written summary of the presentation, along with a copy of the short form written consent document, confirming that the elements of consent were verbally presented.

In situations where an individual with limited English language skills becomes a potential participant and there is no IRB-approved written translation of the consent document available, a short-form consent can be used. This short-form consent contains a summary of the informed consent elements found in the long-form consent. To ensure accurate interpretation, an interpreter must be arranged through the Interpreter & Translation Services Department unless a provider is fully fluent of the potential participant's language. It is crucial for the potential participant to have a clear understanding of the information presented during the consent document signing or subsequent discussions. Failure to achieve this clear understanding would result in the inability to obtain legally effective informed consent, and consequently, the participant cannot be enrolled. When this procedure is used with potential participants/LARs who do not speak English:

- The verbal presentation and the short form written document should be in a language understandable to the potential participants/LARs;
- The witness should be fluent in both English and the language of the participant/LAR.
- The approved English language informed consent document may serve as the summary, as long as it is read by the interpreter in the language understandable to the participant/LAR;
- At the time of consent:
- the short form document should be signed by the participant/LAR;

- the summary should be signed by the person obtaining consent as authorized under the protocol;
- the short form document and the summary should be signed by the witness.
- A full written translation of the consent long form should be requested from Translation Services and provided to the participant as soon as it becomes available.

A copy of the consent document will be given to the Participant or LAR.

All Participants who have been consented to an active study must be entered and have their Participant status updated within 48 hours (2 business days) of consent signature and/or enrollment in OnCore.

Potential study Participants who sign the Informed Consent Form (ICF) but who are later determined to be ineligible or refuse to participate will have the date of consent and reason ineligible/or reason refused entered in OnCore.

D. Witness to the Consent Process

A witness is required in the following circumstances:

- If the IRB approves the use of the "short form" (see previous sections); and
- When a participant cannot read, and the consent document must be read to them.

The witness is required to sign and date the consent form. The witness signature attests that the information in the consent form (and other written documents, as applicable to the research) was accurately explained to and understood by the participant/LAR, and that the informed consent was given freely. The witness should be independent of the research. Translators for non-English speaking participants/LARs may be used as witnesses, however Investigators must determine whether the translator is appropriately trained to assess the attestation standard, and if not, a translator and a witness must be retained.

A copy of non-English language materials to be used with or by participants/LARs need to be submitted to the IRB, with an accompanying Translation Attestation Form. The Translation Attestation Form is intended to provide an alternate to back-translations of translated documents, confirm that each appropriate document has been translated, and to verify the documents' authenticity to the English version of the IRB approved materials (e.g., consent, data collection forms).

E. Waivers and Alterations of Informed Consent

Investigators may request that the IRB waive the requirement for consent or alter some or all of the elements of consent if the IRB finds that one of options (1) to (5) below applies:

1. *Waiver or Alteration Involving Public Benefit and Services Programs*

- The research or demonstration project is to be conducted by or pursuant to the approval of state or local officials and is designed to study, evaluate, or otherwise examine:
  - ✓ public benefit or service programs;
  - ✓ procedures for obtaining benefits or services under those programs;
  - ✓ possible changes in or alternatives to those programs or procedures; or
  - ✓ possible changes in methods or levels of payment for benefits or services under those programs

- The research could not practicably be carried out without the waiver or alteration

2. ***General Waiver or Alteration of Consent***

- The research involves no more than minimal risk to the participants;
- The research could not practicably be carried out without the requested waiver or alteration;
- If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
- The waiver or alteration will not adversely affect the rights and welfare of the participants; and
- Whenever appropriate, the participants/LARs will be provided with additional pertinent information after participation. Investigators may be asked to provide justification for additional information to support that the above criteria are satisfied.

3. ***Screening, Recruiting, or Determining Eligibility***

The IRB may approve a research study in which the investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective participants with the informed consent of the prospective participant/LAR without granting a waiver, if either of the following conditions are met:

- The investigator will obtain information through oral or written communication with the prospective participant or legally authorized representative, OR
- The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

4. ***Waivers and Alterations of Consent for FDA-Regulated Studies***

The IRB can alter, some or all of the elements of informed consent, or waive the requirements to obtain informed consent when it finds and documents that:

- The clinical research involves no more than minimal risk (as defined in 21 CFR 50.3(k) or 56.102(i)) to the participants
- The waiver or alteration will not adversely affect the rights and welfare of the participants
- The clinical research could not practicably be carried out without the waiver or alteration
- Whenever appropriate, the participants will be provided with additional pertinent information after participation. If the investigator is not providing this information, they must provide the rationale for why it is not necessary to provide additional information after participation.

5. ***Waiver of Documentation of Consent [45 CFR 46.117(c)]***

An IRB may waive the requirement for the investigator to obtain a signed informed consent form for some or all participants if it finds any of the following:

- That the only record linking the participant and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each participant (or legally authorized

representative) will be asked whether the participant wants documentation linking the participant with the research, and the participant's wishes will govern;

- That the research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context; or
- If the participants or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to participants and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide participants or legally authorized representatives with a written statement regarding the research.

F. **Obtaining consent for research involving a child**

(1) Investigators can seek IRB approval for children to participate in clinical research under the following circumstances:

- Clinical research not involving greater than minimal risk
- Clinical research involving greater than minimal risk but presenting the prospect of direct benefit to individual participants
- Clinical research involving greater than minimal risk and no prospect of direct benefit to individual participants, but likely to yield generalizable knowledge about the participants' disorder or condition.
- Clinical research not otherwise approvable that present an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

(2) Requirements for permission by parents or guardians and for assent by children

- In addition to the criteria (1) for the participation of children in clinical research, the IRB must be convinced that adequate provisions are made for soliciting the assent of the children when the children are capable of providing assent.
- The determination of whether children are capable of providing assent must take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in clinical research under a particular protocol, or for each child, as the IRB deems appropriate.

(3) The assent of the children is not a necessary condition for proceeding with the clinical research if the IRB determines:

- That the capability of some or all of the children is so limited that they cannot reasonably be consulted, or
- That the intervention or procedure involved in the clinical research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the clinical research.

(4) Even where the IRB determines that the participants are capable of assenting, the IRB may still waive the assent requirement if it finds and documents that:

- The clinical research involves no more than minimal risk to the participants;
- The waiver will not adversely affect the rights and welfare of the participants;
- The clinical research could not practicably be carried out without the waiver; and
- Whenever appropriate, the participants will be provided with additional pertinent information after participation.

(5) The IRB must determine that the permission of each child's parents or guardian is granted.

- Where parental permission is obtained, the IRB may find that the permission of one parent is sufficient for clinical research to be conducted (clinical research not involving greater than minimal risk) or (clinical research involving greater than minimal risk but presenting the prospect of direct benefit to individual participants).
- Where clinical research is covered by (clinical research involving greater than minimal risk and no prospect of direct benefit to individual participants, but likely to yield generalizable knowledge about the participants 'disorder or condition) or (not otherwise approvable that present an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children) and permission is to be obtained from parents, both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

(6) Permission by parents or guardians must be documented

(7) When the IRB determines that assent is required, it will also determine whether and how assent must be documented.

G. Obtaining electronic consent

- Follow the procedures as outlined in the HRPP SOP Electronic Informed Consent
- Locate the prospective participant and/or LAR and request to provide information about the study. Verify the identity of the prospective participant/LAR if the process is to take place remotely.
- Provide the link to the electronic consent document to the prospective Participant/LAR
- Telephone or video conference call may be used when obtaining consent from a LAR if the research is time sensitive and the LAR is not on site. When using telephone or video consent, the LAR must sign and date the consent document and scan and return it via secure email, facsimile or a photographic image sent through secure electronic means.
- Follow the procedure as outlined above for obtaining consent using a verbal consent process.
- If the Participant/LAR verbally consents to study participation, provide instructions for documenting signature and date.
- Ensure a copy of the consent document or a link to access the document is provided to the Participant/LAR.

VI. POLICY REFERENCES:

BH HRPP SOP October 28, 2022
HRPP SOP Fact Sheet: translations and use of interpreters
Baystate Health Policy CO9.100 Health Care Decisions.

VII. REGULATORY OR JOINT COMMISSION REFERENCES:

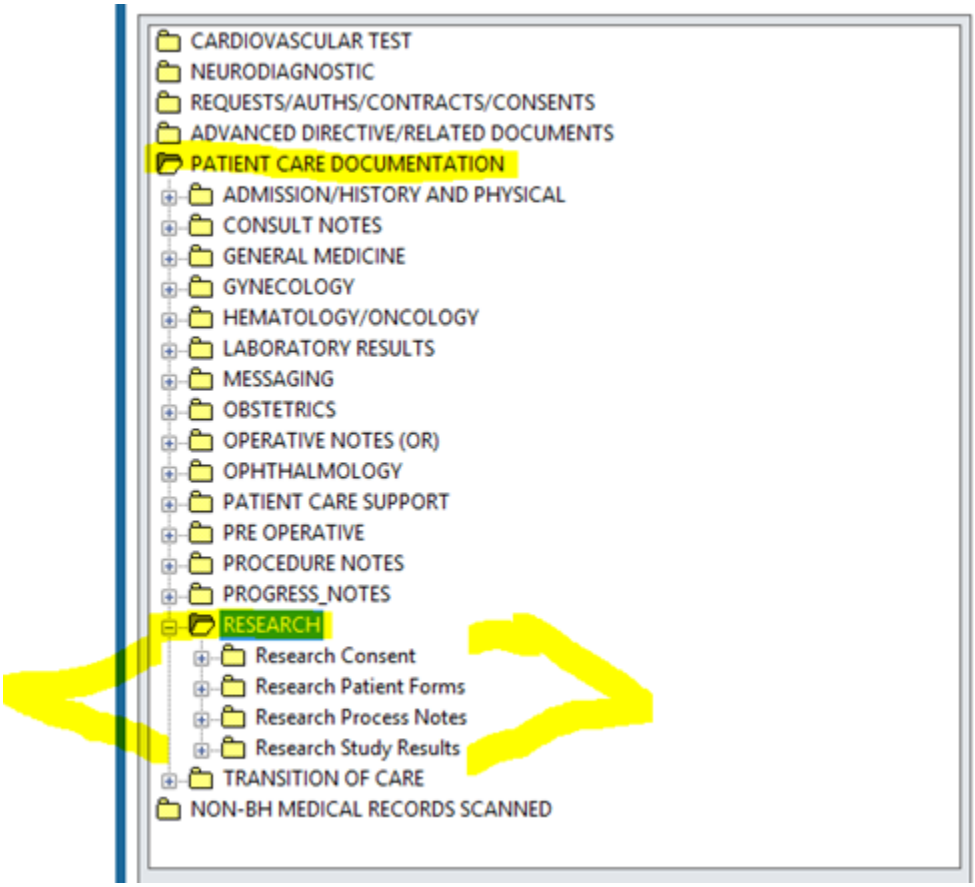
45 CFR46.111 Criteria for IRB approval of research
45 CFR 46.116 General requirements for informed consent
45 CFR 46.117 Documentation of informed consent
45 CFR 46.408 Requirements for permission by parents or guardians and for assent by children
21 CFR 50.20 general requirements for informed consent
21 CFR 50.25 Elements of informed consent
21 CFR 50.27 Documentation of informed consent
21 CFR 50.55 Requirements for permission by parents or guardians and for assent by children
21 CFR 312.60 General responsibilities of investigators
21 CFR 312.62 Investigator recordkeeping and record retention
21 CFR 812.100 General Responsibilities of Investigators 21 CFR 812.140 Investigator records
21 CFR Part II Electronic records, electronic signatures
Guidance for Industry Use of Electronic Records and Electronic Signatures in Clinical Research Under 21 CFR Part I June 2017
Use of Electronic Informed Consent in Clinical Research — Questions and
Answers, Guidance for Institutional Review Boards, Investigators, and. Sponsors December 2016
Guidance for industry Investigator responsibilities- Protecting the rights safety and welfare of study Subjects, October 2009
Guidance for industry, Computerized Systems Used in Clinical Research May 2007
June 2023 E6(R2) Good Clinical Practice: integrated Addendum to ICH E6(R1) Guidance for industry

APPROVALS:

		Date:
Approved:	Policy Management Committee	1/16/2024
Policy Owner	Shemetra Owens, Human Research Protection Program Gerard Coly, Clinical Trials Program	
Originating Author/Title:	Gerard Coly, Clinical Trials Program &Jennifer Pacheco, Chief Research Compliance and Integrity Officer	
Reviewers	Jennifer Pacheco	
Replaces		NEW
Original Effective Date		1/16/2024
Review Dates (no revisions)		
Revision Dates		

Appendix A Procedure for Documenting in CIS

1. Locate the research document folders in CIS:



2. Documents can either be scanned into these folders or a powernote can be created within CIS and filed into one of these folders. Documents should be scanned into the following folders:

   - Research Consent: this will be used only for the research consents. All other patient consents will be filed in the general consent folder found under Requests/Auths/Contracts/Consents.
   - Research Patient Forms: this will be used for any document the *patient* has completed, such as a questionnaire.
   - Research Process Notes: this will be used for all patient care documentation completed by providers (MD, Nurse or Ancillary)
   - Research Study Results: this is for lab/imaging results that are received by paper from an outside lab or imaging center. Any lab work completed by BRL will be sent to the normal lab folder structure current in place within CIS.

3. Once the documents are ready to be filed within CIS, the practice will have 3 options to send them to HIM:

1) If the documents are in an electronic format, they can be emailed to the HIM fax number where the documents will be dropped directly into the HIM scan queue.
    a. The email address is: **4137958003@fax.bhs.org** (Please send a test email to ensure you are able to send one)
    b. If using this process, the user MUST type **Research Documents** into the Participant line so the HIM team will be alerted as to how to file the documents **

2) Send the documents via fax to HIM where the documents will be dropped directly into the HIM scan queue.
    a. The fax number is **413-795-8003**
    b. A coversheet will need to be used so the HIM team will be alerted as to how to file the documents (See Appendix B)
    c. Once the documents are faxed, they will need to be stored for a minimum of 6 months by the project team and can then be destroyed.

3) Send the documents via courier to HIM where they will be scanned and processed. This option will take longer to get the documents into CIS due to the travel time to HIM and the prep/scan processing time.
    a. A coversheet will need to be used so the HIM team will be alerted as to how to file the documents (See Appendix B)

Appendix B: Coversheet for Scanning Research Documents

Coversheet Information:

Attached you will find a generic coversheet that can be used by your practice.
We recommend the practice complete the first 2-line items (practice name & contact number) before printing the document for use. It will save the staff time when processing, they will just need to date the document and check off the process being used.
The coversheet is key to the success of this new process; the user will need to ensure it is complete and CHECK the box for the processing option they have selected.

Please note: If this coversheet/fax sheet is not used, the documents will be filed within the record and NOT in the research folders **

Coversheet that should be used when faxing or sending courier. The different boxes are for if you fax the documents over but then need to send HIM the documents for them to store would select first box. If just sending via courier and they need to scan and store that is the second box.:

Research Documents Scanned

Coversheet

Practice Name: <type before printing>

Phone Number: <type before printing>

Name:

Date:

Process the batch: Check appropriate box:

☐ Fax the batch to 795-8003, then use courier to send the documents to HIM.

☐ Use courier to send the batch to HIM, ***HIM~ Please Scan***

If you are emailing the Subject line will be what is used to let them know is for research. The actual email is what becomes the cover page, and they will use the information in the email on where to file the documents. So, make sure you type Research Documents in Subject line and if is for only one patient could put the CMRN in Subject line or body of email. If information is for

more than one patient would need patient name and CMRN numbers and what document is associated with which patients.

It is also helpful if you tell them what folder to put the document in – so if consent would say research consent, if patient forms would say that, etc.