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| **DRAFT IRB Guidance:**  **Obtaining Legally Effective Informed Consent and HIPAA Research Authorization** |
| **The IRB provides this draft guidance document for comment purposes. Please submit any comments to** [**IRB@Downstate.edu**](mailto:IRB@Downstate.edu)    For more information please refer to [IRB Policy & Guidance](http://research.downstate.edu/irb/irb-policies.html) or contact the IRB at 718-613-8480or [IRB@downstate.edu](mailto:IRB@downstate.edu) |

[Introduction 3](#_Toc533781464)

[Form Requirements for Informed Consent and HIPAA Research Authorization 3](#_Toc533781465)

[Informed Consent Form Document Requirements 3](#_Toc533781466)

[Readability of Forms 3](#_Toc533781467)

[Informed Consent Requirements for research which must comply with the International Conference on Harmonization ICH Good Clinical Practice 4](#_Toc533781468)

[Using a Model Informed Consent Form From a Sponsor, CRO, or External IRB 4](#_Toc533781469)

[Single vs. Multiple Consent Forms 5](#_Toc533781470)

[Exculpatory Language Is Not Permitted 5](#_Toc533781471)

[Pregnant Partner Authorization 6](#_Toc533781472)

[Considerations for Obtaining Remote Consent and Electronic Signatures 6](#_Toc533781473)

[Remote Consent 7](#_Toc533781474)

[Electronic consent; Electronic Signatures 7](#_Toc533781475)

[Data Use Agreement (DUA) or Business Associate Agreement (BAA) 7](#_Toc533781476)

[Forms and Materials Used When Enrolling Research Participants with Limited English Proficiency (LEP), and for Those with Low Literacy and Numeracy, Physical Challenges, or a Religious Objection to Signing Documents 8](#_Toc533781477)

[Translation and Certification of Written Research Materials 9](#_Toc533781478)

[Process for Obtaining Informed Consent and HIPAA Research Authorization 12](#_Toc533781479)

[Interpreter 13](#_Toc533781480)

[Obtaining Informed Consent From Those With LEP 13](#_Toc533781481)

[Long Form Process 13](#_Toc533781482)

[Short Form Process 13](#_Toc533781483)

[Process For Obtaining Informed Consent of Individuals with LEP When The IRB Approves A Waiver Of Documentation Of Informed Consent (Waiver Of Signatures) 15](#_Toc533781484)

[Provision of Reasonable Accommodations 15](#_Toc533781485)

[Research Participants with Low Literacy or Numeracy 15](#_Toc533781486)

[Obtaining Informed Consent in Braille 16](#_Toc533781487)

[Obtaining Informed Consent in American Sign Language (ASL) 16](#_Toc533781488)

[Making a Mark 16](#_Toc533781489)

[Signaling Consent 16](#_Toc533781490)

[Audio or Video Consent 17](#_Toc533781491)

[Research Participants with Religious Objections for Signing Documents 17](#_Toc533781492)

[Re-Obtaining the Consent of Research Participants 17](#_Toc533781493)

[References 18](#_Toc533781494)

[Authors 20](#_Toc533781495)

[Review and Approval History 20](#_Toc533781496)

# Introduction

Please refer to [IRB Policy-01](http://research.downstate.edu/irb/irb-policies.html) and the “informed consent” and “information sheet” templates posted on the [IRB electronic submissions web site](http://research.downstate.edu/irb/irb-electronic-submissions.html) to ensure all requirements are met.

Waivers of the requirements of informed consent and HIPAA waivers are discussed in IRB Policy-01. Forms used to requests waivers are available on the [IRB electronic submissions web site](http://research.downstate.edu/irb/irb-electronic-submissions.html).

Additional guidance on the informed consent requirements and process for obtaining informed consent are provided below.

This guidance represents the IRB’s current thinking on this topic; however, the use of the word “must” in this document means the concept is a Downstate policy or regulatory requirement.

The use of the word *“should”* in this document means the concept can be treated as guidance or something is recommended or suggested, but not required. An investigator may use an alternative approach if the approach satisfies regulatory requirements.

# Form Requirements for Informed Consent and HIPAA Research Authorization

### Informed Consent Form Document Requirements

Please refer to [IRB Policy-01](http://research.downstate.edu/irb/irb-policies.html) and the “informed consent” and “information sheet” templates posted on the [IRB electronic submissions web site](http://research.downstate.edu/irb/irb-electronic-submissions.html) to ensure all required elements and additional elements are included in the informed consent, including any required HIPAA authorization language.

Additional guidance on form requirements is provided below.

### Readability of Forms

To the extent possible, the language should be understandable by a person who is educated to 6th to 8th grade level and layman’s terms shall be used in the description of the research. The PI is encouraged to use readability resources, such as:

* [Readability Formulas](http://www.readabilityformulas.com/)
* [MS Word -Test your document's readability](https://support.office.com/en-us/article/test-your-document-s-readability-0adc0e9a-b3fb-4bde-85f4-c9e88926c6aa)

### Informed Consent Requirements for research which must comply with the International Conference on Harmonization ICH Good Clinical Practice

For clinical trials following [ICH-GCP](http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R2__Step_4_2016_1109.pdf) requirements[[1]](#footnote-2), the informed consent must meet the following requirements:

* + Among other materials, the IRB must review and approved the following:
    - Proposed written informed consent form(s)
    - Amendments to consent form(s)
    - Recruitment procedures (e.g., advertisements)
    - Written information to be provided to research participants
    - Information about payments and compensation
    - Any other documents that the IRB may need to fulfil its responsibilities. (**3.1.2)**
  + When a non-therapeutic trial is to be carried out with the consent of the research participant’s surrogate/legally authorized representative (LAR) (see 4.8.12, 4.8.14), the IRB should determine that the proposed protocol and/or other document(s) adequately addresses relevant ethical concerns and meets applicable regulatory requirements for such trials. (**3.1.6)**
  + The IRB must review both the amount and method of payment to participants to assure that neither presents problems of coercion or undue influence
  + Payments to a participant must be prorated and not wholly contingent on completion of the trial. (**3.1.8)**
  + The IRB must ensure that information regarding payment, including the methods, amounts, and schedule of payment, is set forth in the written informed consent form and any other written information. Specify proration of payments in the informed consent form. (**3.1.9)**

### Using a Model Informed Consent Form From a Sponsor, CRO, or External IRB

The IRB may accept the model informed consent form that is created by a sponsor, CRO, or External IRB. However, the IRB may require the use of the template HIPAA authorization language from the DMC informed consent template, unless the model consent form is within compliance of HIPAA regulations and local DMC policy. For an industry-sponsored study, it is best to compare the language from the DMC informed consent template regarding injuries and any additional costs to make sure it is consistent with the sponsor. This language may be altered with the assistance of the IRB and Pre-Award to insure it is consistent with contractual obligations.

When a sponsored project is being conducted at multiple sites, the sponsoring company may require the use of their IRB approved informed consent for uniformity; however, the DMC IRB may recommend or require additional information to the informed consent, to ensure compliance with local laws and policy.

### Single vs. Multiple Consent Forms

A single informed consent document with HIPAA authorization (also known as a compound authorization) may cover uses and disclosures of PHI for multiple activities of a specific research study, including the collection and storage of tissues for that study and for disclosure of information pertaining to genetic studies. A multiple consent form approach may be used when the research involves different research studies (e.g., where a research study collects information for the study itself, and collects and stores PHI or specimens in a central repository for future research). However, the PI may choose to use a tiered consent approach to include options that allow a research participant to opt-in or opt-out of participation of specific research activities or for the future research of coded information or coded specimens.

### Exculpatory Language Is Not Permitted

No informed consent, whether oral or written, may include any exculpatory language through which the research participant or the representative is made to waive or appear to waive any of the research participant’s legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

The examples below would be in **violation** of the informed consent regulations because the waiver or release has the general effect of freeing or appearing to free an individual or an entity from malpractice, negligence, blame, fault, or guilt.

* I waive any possibility of compensation, including any right to sue, for injuries that I may receive by participation in this research.
* If you suffer a research-related injury, neither the institution nor the investigator can assume financial responsibility or liability for the expenses of treatment for such injury.
* If you suffer a research-related injury, your medical expenses will be your responsibility or that of your third-party payer.

**Examples of acceptable language** that may be included in the informed consent are:

* Although future research that uses your samples may lead to the development of new products, you will not receive any payments for these new products.
* By agreeing to this use, you are giving up all claims to any money obtained by the researchers from commercial or other use of these specimens.
* I voluntarily and freely donate all blood, urine, and tissue samples to SUNY Downstate Medical Center and hereby relinquish all property rights, title, and interest I may have in those samples.
* By consenting to participate in this research, I give up any property rights I may have in bodily fluids or tissue samples collected during this research.
* Although the results of research, including your donated materials, may be patentable or have commercial value, you will have no legal or financial interest in any commercial development resulting from the research.
* Tissue obtained from you in this research may be used to establish a cell line that could be patented and licensed. No financial compensation will be provided to you should this occur.
* By consenting to participate, you authorize the use of your bodily fluids and tissue samples for the research described above.
* Because of policy, the SUNY Downstate Medical Center is not able to offer financial compensation should you be injured as a result of participating in this research. However, you are not precluded from seeking to collect compensation for injury related to malpractice, fault, or blame on the part of those involved in the research, including the hospital.
* Because of hospital policy, the SUNY Downstate Medical Center makes no commitment to provide free medical care or payment for any unfavorable outcomes resulting from participation in this research. Medical services will be offered at the usual charge. However, you are not precluded from seeking to collect compensation for injury related to malpractice, fault, or blame on the part of those involved in the research, including the hospital.
* In the event that you suffer a research-related injury, your medical expenses will be your responsibility or that of your third-party payer, although you are not precluded from seeking to collect compensation for injury related to malpractice, fault, or blame on the part of those involved in the research.

### Pregnant Partner Authorization

Investigators may ask a woman who becomes pregnant to be included in a sub-study when she is a research participant or a partner of a research participant.

The authorization should include a statement about withdrawing the pregnant woman’s participation from the main study, if applicable.

The purpose of this authorization is to obtain the information about her pregnancy and its outcome from her medical and obstetric records. This form explains the use and disclosure of PHI.

A template is available on the [IRB electronic submissions web site](http://research.downstate.edu/irb/irb-electronic-submissions.html).

### Considerations for Obtaining Remote Consent and Electronic Signatures

### Remote Consent

With IRB approval, research participants may participate in studies in which they do not have to meet directly with the investigator. In general, informed consent and authorization may be initiated and obtained through the following methods as recruitment policy allows (i.e., telephone contact, email, letter, fax).

Fax transmissions from Downstate should use the approved [HIPAA Facsimile Cover Page](https://www.downstate.edu/hipaa/documents/hipaa-9-attachment-faxcoverpage-feb-2018.pdf).

When a consent document contains PHI, electronic communications containing any health related information for research purposes must comply with [SUNY Downstate HIS-11, “Electronic Communication of Health Related Information.”](http://www.downstate.edu/regulatory/pdf/policies/HIS-11.pdf) The investigator must ensure the consent form obtained via electronic communication has been obtained from the research participant and it must only be sent using an encryption method.

*Note: For FDA regulated clinical trials, either a compliant electronic signature (see below) or the original signature must be obtained on the informed consent document and saved in the research records with other source documents.*

### Electronic consent; Electronic Signatures

With IRB approval, an investigator may obtain electronic consent and obtain electronic signatures, when the IRB waives documentation of informed consent or when all applicable regulatory requirements for an electronic signature are met. For more information on regulatory requirements refer to:

* [FDA Regulations (21 CFR 11): Electronic Records; Electronic Signatures](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=11)
* United States Code Title 15- Electronic Signatures in Global and National Commerce Act, Subchapter I- Electronic Records and Signatures in Commerce (ESign Law), *October 1, 2000*
* New York State Technology Law Article 1- Electronic Signatures & Records Act (ESRA), *September 28, 1999 and amended August 6, 2002*
* 9 NYCRR Part 540- ESRA Amended Regulations, *May 7, 2003*
* NYS Office for Technology- ESRA Guidelines, *May 26, 2004*
* National Archives & Records Administration- Records Management Guidelines for Agencies Implementing Electronic Signature Technologies, *October 18, 2000*
* NYS Archives & Records Administration- Guidelines for the Legal Acceptance of Public Records in an Emerging Electronic Environment, *published 1998*
* 10 NYCRR Part 405.10- Medical Records, *February 25, 1998*
* 42 CFR Section 482.24- CMS Conditions of Participation for Hospitals, Medical Record Services
* Joint Commission Hospital Accreditation Standards- IM.2.20

### Data Use Agreement (DUA) or Business Associate Agreement (BAA)

If informed consent is obtained from a research participant when a limited data set is released outside the institution where the research takes place, a HIPAA authorization should be obtained, indicating the disclosure. A “limited data set” is a data set that is stripped of certain direct identifiers that are specified in the Privacy Rule.

When a limited data set is released outside the institution where the research takes place or obtained from an external source, a Data Use Agreement (DUA) is generally required; however, the Privacy Officer or IRB may consider the approval of a HIPAA authorization or waiver to release the data.

A Business Associate Agreement (BAA) is required when providing a vendor (e.g., transcription service, data center, etc.) with PHI information for the purposes of the research.

Documents which do not use the standard DMC approved template, must be reviewed and approved by General Counsel and the Hospital Privacy Officer, before being presented to the Pre-Awards for signature. Templates are available from the Privacy Officer or .

All original signed and dated forms must be retained in the investigator’s research files, secure but readily retrievable.

When a human research project is determined to be exempt and involves PHI, a HIPAA Waiver, a HIPAA Authorization, a Data Use Agreement (DUA), or a Business Associate Agreement (BAA) is usually still required.

### Forms and Materials Used When Enrolling Research Participants with Limited English Proficiency (LEP), and for Those with Low Literacy and Numeracy, Physical Challenges, or a Religious Objection to Signing Documents

The DMC provides culturally and linguistically appropriate care and support to our patients in many languages, as determined and documented at the time of admission. The common preferred languages of our local community include: English, Haitian Creole, Arabic, Spanish, Russian, Simplified Chinese, and Traditional Chinese. Individuals who do not speak English as their primary language and have a limited ability to read, speak, write, or understand English are considered to have a Limited English Proficiency (LEP).

In order to achieve equitable selection of research participants, it may be desirable to recruit and enroll the individuals who have LEP, particularly to make research available to those who may receive an anticipated direct benefit in our community. Recruitment of research participants with LEP is generally required, if the study holds the prospect of a direct therapeutic benefit to the research participant, and the informed consent must be obtained in the research participant’s preferred language.

This guidance describes a process to obtain effective (and document, when applicable) informed consent, LAR consent, parental permission, child assent, including applicable HIPAA research authorization for individuals who have a LEP and for those with low literacy and numeracy, physical challenges, or a religious objection to signing documents.

A legally authorized representative, (LAR) may provide consent in situations when the research participant is cognitively impaired and the LAR consent process is approved by the IRB. The term legally authorized representative (LAR) should not be confused to mean that a relative or close friend can provide consent for a participant who does not understand English. Assent of an adult research participant that is cognitively impaired must be obtained in the preferred language of the research participant. An interpreter must be available for a research participant with LEP or a LAR with LEP.

For a child with LEP, the pediatric assent must be obtained in his/her preferred language. Either the translated assent or the short form may be used, as approved by the IRB, and an interpreter must be available for the child. The signature of the child is only required on the Short Form or translated assent form, if the IRB approved version of the English assent requires the child’s signature. The IRB may determine that assent is not necessary or that assent may be waived in certain situations.

Informed consent, LAR consent, parental permission, and pediatric assent must be obtained in the preferred language of the individual, to help assure their understanding of the research including an explanation of scientific and medical terms. An interpreter must be available to an individual with LEP whenever there is a research interaction or intervention with him or her, including during times of recruitment, enrollment, obtaining consent. Investigators must carefully consider the ethical and legal ramifications for enrolling a participant when barriers exist. They must allow sufficient time for the Participant’s voluntary decision and allow them to review the documents with a family member or a friend.

### Translation and Certification of Written Research Materials

When recruiting and enrolling research participants with limited English proficiency, all applicable English documents must be approved by the IRB, prior to requesting translations into other languages, as the IRB may require modifications to the English document. Accuracy of translations can be accomplished in different ways depending on the service used to provide the translation and the type of document. In general, the following mechanisms are acceptable:

* **Back-translation**: After the document is translated into the foreign language, it is then translated back into English to determine accuracy of the original meaning. A certificate of translation and the English back-translation is provided. This is considered the best practice by our IRB. We understand that the back-translation may require additional expenses for the sponsor or the investigators but this is an important part of the IRB’s verification of the accuracy of the translated document.
* **Double translation**: With this method, two people translate the same documents and an arbitrator reviews both to determine any differences. Both translators sign the certificate of translation.
* **Other methods deemed appropriate by the IRB**.

For assistance, with translations, please contact Patient Relations Department, at (718) 270-1111.

The Sponsor is expected to pay fees related to translation of participant-facing English documents into other languages, (e.g., informed consent and parental permission documents including HIPAA research authorization language, recruitment materials, surveys, or other applicable materials requiring translation for non-English participants). Fees may range from about $65-$200 per page, depending on the language and service used. Fees for translation are coordinated through the PI. If you anticipate the recruitment of those with LEP into a sponsored clinical trial, please inform the Pre-Awards office so that this may be considered during the CTA negotiations.

If a sponsor does not fund the translation, the Department should pay for the translation. The PI should plan for this in his/her research budget.

The DMC IRB will fund the translation and certification of the short forms in the most common languages anticipated based on hospital statistics. These are available on the IRB Application and Reporting System. If the translation and certificate is required for another language, the Department or sponsor is expected to pay the fees for this service; however, in an emergency or under extreme circumstances, the DMC IRB may consider the approval for the use of the English version of a short form to recruit a participant with LEP when a short form has not already been translated and certified.

All translations of written materials must be appropriately certified before submitting them to the IRB. Be mindful that the consent process begins with recruitment of potential participants; therefore, any advertising that targets individuals with a LEP, must be appropriately translated and certified.

#### Documents for Obtaining Informed Consent From an Individual with LEP

There are essentially three mechanisms for obtaining informed consent from an individual with LEP:

* The **“Long Form process”** involves the translation of the English version of the applicable Long Form
* The **“Short Form process”** involves the use of the English Long Form and a translated Short Form.
* The **“Waiver of Documentation Process”** involves oral consent when the IRB waives the requirement to obtain the signature of the participant.

#### Obtaining IRB Approval of Documents Used in the Long Form Process

As applicable to the particular research, the “Long Form” is considered the consent form, parental/guardian permission form, or a pediatric assent document and includes the required HIPAA research authorization language when PHI is involved.

In general, written translation of the long forms is expected over the use of the short-form process when the research anticipates the enrollment of five or more research participants with limited English proficiency of the same language (e.g., 6 Spanish speaking participants)., for the following types of research:

* Phase 0, 1,1/2, 2, 2a, 2b, or 2/3 Clinical trials which are determined to be greater than minimal risk without any anticipated therapeutic benefit for the research participants
* Studies which are determined to be a minor increase over minimal risk, when there is no direct benefit to the research participant;
* Complex clinical trials; or
* When required by the sponsor.

For the long form process, submit the following for IRB approval:

* Submit long form in English, with applicable signature blocks.
* Submit recruitment materials, interview scripts, or other participant related documents (e.g., surveys, information cards, etc.) in English.

For the long form process, submit the following for IRB approval as an Amendment, once the English versions are approved.

* Translated versions of long form(s).
* Translated interview scripts or other participant related documents.
* Translated recruitment materials, if targeting a population in non-English.
* Certificate of translation(s) for all documents.
* The English back-translation, if obtained and a Word document that shows the comparison (legal backline) of the original English version (approved by the IRB) with the new English back-translation.

#### Obtaining IRB Approval of Documents Used in the Short Form Process

The short form process for obtaining informed consent must be used in conjunction with a verbal interpretation of either the IRB approved long form or an IRB approved written summary of what will be said to the potential research participant.

In general, this process may be used, after IRB approval for the following situations, when it is not possible to anticipate the primary languages of the research participants (or the parent, legal guardian, or personnel representative, as applicable), including:

* When the translation of the long-form is not required, as indicated above.
* When a signature is required for a HIPAA research authorization, even when the IRB waives documentation of signatures on an informed consent document.
* For research participants with apparent low literacy.
* To enroll a research participant PRIOR to the IRB approval of a translated long form, unless prohibited by a sponsor. In this situation, an amendment to translate the long Form MUST BE PROMPTLY submitted for IRB and once it is approved, the IRB stamped translated long form must be promptly provided to the research participant with LEP as an ongoing source of understandable information.

For the short form process, submit the following for IRB approval at the time of initial review:

* Translated short forms in anticipated languages. The short forms are to be edited, prior to submission to the IRB, to include the title of the study and relevant contact information, which may be listed in English.
* If desired, provide a written summary of what will be said to the research participant, when the short form will be used, in lieu of using the entire IRB approved long form with an interpreter.
* Provide certificate of translation for short form if you are using a form that is not pre-certified by the IRB.

For the short form process, submit the following amendment for IRB approval, after the IRB has approved the English versions

* Modify the IRB approved long form(s) in English to include all applicable signature blocks required for the short form process, if they were not included at the time of initial IRB review.
* Translated recruitment materials, if targeting a population in non-English, along with certificate(s) of translation.

# Process for Obtaining Informed Consent and HIPAA Research Authorization

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| **TIP: Informed consent is a “PROCESS,” not just a FORM!!!**  **The “Process” is discussed in this section. See previous sections of this guidance and Policy IRB-01 for “Form” requirements.** |

Investigators must obtain informed consent and HIPAA research authorization, prior to enrolling a research participant into a study and/or conducting any procedures required by the protocol, unless waived by the IRB.

Individuals obtaining consent MUST be identified on the IRB application form.

Although the PI may delegate the responsibility for obtaining consent from research participants to other members of his/her research team, the PI retains ultimate responsible for insuring that each prospective participant is adequately informed about all aspects of the research and understands the information provided.

The consent process does not end with the formal signing of the consent document. Rather, it is an ongoing process that continues throughout the participation in the study. The investigators remain responsible for continued assessment of the research participant’s understanding of what is happening to him/her, his/her willingness to participate and for providing the research participant with any new information that may affect their willingness to participate.

It is the PI's responsibility to train and supervise the study personnel who are obtaining consent.

## Interpreter

When an interpreter is needed at Downstate, follow [UHB Policy PTBR-5: Language Services to Patients with Limited English Proficiency](http://www.downstate.edu/regulatory/pdf/policies/PTBR-05.pdf). When research takes place at another location, the investigators must consult with the policy for the local site.

## Obtaining Informed Consent From Those With LEP

### Long Form Process

Prior to obtaining informed consent, the following steps are recommended:

* Gather the IRB approved stamped long form(s)
* Verify whether the interpreter is eligible and can serve as the impartial witness of the entire consent process. If not, another person will be needed, to serve as an impartial witness.
* Provide copies of the long form(s) (and any IRB approved summary script) to the impartial witness and interpreter so they can review in advance.

Signatures are required from the following individuals:

* Person authorizing the research, such as
  + Adult research participant with capacity to consent,
  + Parent or legal guardian, or
  + Personal representative (LAR)
* Witness (or impartial witness, when applicable)
* Interpreter, and the
* Investigator obtaining the informed consent.

### Short Form Process

Prior to obtaining informed consent, the following steps are recommended:

* Gather the IRB approved documents: IRB stamped English long form(s), IRB stamped translated short form, and IRB stamped English written summary (if applicable).
* Provide copies of the above materials to the impartial witness and interpreter so they can review in advance.
* Verify whether the interpreter is eligible and can serve as the impartial witness. If not, another person will be needed to serve as the impartial witness.
* Refer to the English short form, if needed.

Please refer to the table below for the required signatures for using the short form process. A “Yes” indicates the individual in the far-left column must sign the designated form in the vertical column.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Translated Short Form** | **English Long Form** | **English Assent Form** | **English Written Summary Form** |
| **Adult w/LEP (including Parent, Legal Guardian, or LAR)** | Yes | Yes | Yes, if required by IRB. Usually, N/A. | Yes |
| **Child w/LEP** | Yes, if the IRB requires signature on the English assent form or on the English long form to document assent (typically based on age) | Yes, if the IRB requires signature on the English long form to document assent (typically when the child is between the ages 12-17) | Yes, if the IRB requires signature on the English assent form (typically when the child is between the ages 8-11) | Yes, if the IRB requires signature on the English long form to document assent (typically when the child is between the ages 12-17) |
| **Adult with low literacy or numeracy** | Yes (May use English Short Form, if preferred language is English) | Yes | Yes, if required by IRB. Usually, N/A. | Yes |
| **Witness**  *Note: Must be an “impartial witness” for clinical investigations following GCP requirements* | Yes | Yes | Yes, if required by IRB. | Yes |
| **Investigator obtaining consent** | Yes | Yes | Yes, if required by IRB. | Yes |
| **Interpreter** | Yes | Yes | Yes, if required by IRB. | Yes |

### Process For Obtaining Informed Consent of Individuals with LEP When The IRB Approves A Waiver Of Documentation Of Informed Consent (Waiver Of Signatures)

Prior to obtaining informed consent, the following steps are recommended:

* Gather the IRB approved and stamped information sheet.
* Verify whether the interpreter is eligible and can serve as the witness. If not, another person will be needed to serve as the witness.
* Provide copies of the information sheet to the witness and interpreter so they can review in advance.

Oral consent is obtained without signatures in the presence of the impartial witness with the assistance of the interpreter.

**The signature of the impartial witness, the interpreter, and the investigator obtaining the informed consent should be recorded on an enrollment master list of research participants.**

## Provision of Reasonable Accommodations

Investigators should accommodate the specific needs of the study population or a specific individual on a case by case basis. All accommodations must be approved by the IRB.

Although a competent person who does not read and write well can give informed consent, the investigator and IRB should consider whether any modifications to the informed consent process are necessary to ensure that the informed consent process is understandable.

For example, the investigator could use an audio or video tape of the contents of the consent form or a form with enlarged font, depending on the level of impairment of the visually impaired research participants. Other accommodations are described below.

### Research Participants with Low Literacy or Numeracy

For research participants with apparent low literacy or numeracy, oral presentation of the information contained in the consent form is especially important. When the elements of informed consent are presented orally to the individual, the IRB may consider approving the use of a short form and written summary, which includes a witness to the oral presentation of the informed consent who also signs the consent form. The consent process must conform to all other requirements, including signature of an independent witness

### Obtaining Informed Consent in Braille

For blind research participants who read braille, the IRB may approve a consent document prepared in braille. To assure itself that a braille consent document is accurate; the IRB may require a transcription into print text or review of the document by a qualified person who reads braille. If possible, the research participant will sign or make their mark on the braille consent. The documentation of the consent process must conform to all other requirements, including signature of an impartial witness.

### Obtaining Informed Consent in American Sign Language (ASL)

For deaf research participants who are fluent in ASL, the IRB may approve a consent process using approved ASL and the IRB-approved written consent form. When this process is approved, the individual authorized to consent prospective research participants must use a qualified interpreter fluent in ASL to conduct the consent process and the documentation of the consent process must conform to all other requirements, including signature of an impartial witness.

### Making a Mark

Research participants, who cannot write or physically sign a document, can indicate their consent by "making his/her mark" (e.g., “X”) on the consent form. In this situation, a progress note in the research record (e.g., participant’s case history) should indicate the reason for the lack of a signature. The documentation of the consent process must conform to all other requirements, including signature of an impartial witness.

### Signaling Consent

A person who is physically challenged (for example, physically unable to talk or write or has hearing or visual loss) can enroll in a research study if competent and able to signal consent. The research record (e.g., participant’s case history) must include documentation of the informed consent process unless waived or excepted. The record should include a description of the specific means by which the prospective research participant communicated agreement to take part in the research and how questions were answered. The documentation of the consent process must conform to all other requirements, including signature of an impartial witness.

### Audio or Video Consent

If the research participant is audio or video taped, his/her permission must be obtained to record them.

Adequate information security and confidentiality provisions must also be made.

### Research Participants with Religious Objections for Signing Documents

For research which is not regulated by FDA or DOJ, the IRB may waive documentation of informed consent, if the research participant (or LAR/surrogate) 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.

If a study team anticipates recruitment of individuals that may have a religious objection to signing an informed consent document and/or HIPAA research authorization, they may consider whether the research would qualify for a waiver of documentation of informed consent and/or a HIPAA Alteration.

Refer to additional IRB policies on waivers or consult with the IRB for additional information.

See also: “Signaling Consent.”

# Re-Obtaining the Consent of Research Participants

Consent may need to be re-obtained from research participants due to any of the following reasons:

* Modifications to the protocol and/or consent since the research participant was enrolled, when the changes are more than minor and may change the level of risk (i.e. the information which has been added/deleted may have an impact on risk to research participants and their willingness to participate. The level of risk may decrease or increase because of modifications).
* When a minor research participant was initially enrolled by obtaining his/her parent/legal guardian’s permission and has now reached the age of majority, (s)he can now provide consent on his/her own behalf.
* If minors are enrolled in a repository, they may need to be consented as adults when they turn 18. Generally, if specimens and/or data were collected from a minor, but no new information will be gathered after they have turned 18, re-consent may not be necessary. On the other hand, if new specimens and information will be collected after they turn 18; the investigator will need to obtain their consent as adults for continuation of participation. Plans for seeking consent or a waiver of consent from the IRB along with a justification should be outlined in the research protocol.
* When a cognitively impaired adult research participant, initially enrolled by obtaining the LAR’s permission, has regained capacity to consent on his/her own behalf.
* When research participants are in a longitudinal study for an extended period of time, the IRB generally requires re-consent, every 5 years, or for whatever period is required by the IRB.
* In certain cases, the IRB may approve the use of a short form process to enroll a participant in Clinical Trial of drug, biologic agent or device, but require translation of the Long Form. Upon IRB approval of the amendment for the translated Long Form, it must be provided to the research participant; however, the IRB may require re-consent.
* Any time the IRB or sponsor requires it.

The investigators must use the most recently IRB approved document when obtaining re-consent.

# References

* 10 NYCRR Part 405.10- Medical Records, *February 25, 1998*
* 9 NYCRR Part 540- ESRA Amended Regulations, *May 7, 2003*
* [AAHRP Standards](https://admin.share.aahrpp.org/Website%20Documents/AAHRPP_Accreditation_Standards.PDF)
* Advancing Effective Communication, Cultural Competence, and Patient- and Family- Centered Care: A Roadmap for Hospitals. The Joint Commission. 2010.
* [Clinical Trial.gov website](https://clinicaltrials.gov/)
* DMC Consent Policy
* [DMC HIPAA Facsimile Cover Page](https://www.downstate.edu/hipaa/documents/hipaa-9-attachment-faxcoverpage-feb-2018.pdf)
* [DMC Office of Compliance and Audit Services HIPAA Policy](http://www.downstate.edu/compliance/policies.html)
* [DMC Policy HIPAA-28: Uses and Disclosures for Research Purposes](http://www.downstate.edu/hipaa/documents/HIPAA.28.USESANDDISCLOSURESFORRESEARCHPURPOSES.Rev09.13Final.pdf)
* [DMC Policy IRB-01: Human Research Protections Program](http://research.downstate.edu/irb/irb-policies.html)
* FDA Guidance for informed consent
* [FDA Guidance for Investigator Responsibilities](http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM187772.pdf.)
* [FDA Guidance on Exception from Informed Consent Requirements for Emergency Research](http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM249673.pdf)
* [FDA ICH Guidance Documents](http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/ucm219488.htm)
* [FDA Regulations (21 CFR 11): Electronic Records; Electronic Signatures](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=11)
* [FDA Website: Protection of Human Subjects; Informed Consent and Waiver of Informed Consent Requirements in Certain Emergency Research](http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ucm118995.htm)
* [Health Information Privacy: Research](http://www.hhs.gov/hipaa/for-professionals/special-topics/research/index.html)
* [HHS 45 CFR 2 –Confidentiality of Alcohol and Drug Abuse Patient Records](http://www.ecfr.gov/cgi-bin/text-idx?rgn=div5;node=42%3A1.0.1.1.2)
* [HHS Health Information Privacy Website](http://www.hhs.gov/hipaa/for-professionals/special-topics/research/index.html)
* [HHS Office for Civil Rights (OCR) Health Insurance Portability and Accountability Act of 1996 (HIPAA) or 45 CFR Parts 160, 162, and 164](http://www.hhs.gov/hipaa/for-professionals/)
* Improving Access to Services for Persons with Limited English Proficiency. Executive Order 13166 of August 11, 2000. Federal Registrar Vol. 65, No 159, August 16, 2000. Title 3.
* Managing Incidental Findings in Research Participants Research: Analysis and Recommendations’, Wolf et. al. Journal of Law, Medicine and Ethics, [Volume 36, Issue 2,](http://onlinelibrary.wiley.com/doi/10.1111/jlme.2008.36.issue-2/issuetoc) pages 219–248, Summer 2008.
* [Medicare Clinical Trial Policies](https://www.cms.gov/Medicare/Coverage/ClinicalTrialPolicies/index.html?redirect=/clinicalTrialPolicies/)
* [MS Word -Test your document's readability](https://support.office.com/en-us/article/test-your-document-s-readability-0adc0e9a-b3fb-4bde-85f4-c9e88926c6aa)
* National Archives & Records Administration- Records Management Guidelines for Agencies Implementing Electronic Signature Technologies, *October 18, 2000*
* [National Cancer Institute Central IRB Initiative](https://ncicirb.org/cirb/default.action)
* [New York Codes, Rules and Regulations, Title 14, Department of Mental Hygiene, Part 527, Rights of Patients](https://www.omh.ny.gov/omhweb/policy_and_regulations/)
* [New York Mental Hygiene Law, Article 81](https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&cad=rja&uact=8&ved=0ahUKEwjwycbpkJnMAhUJyj4KHT7bCe0QFggdMAA&url=http%3A%2F%2Fwww.nycourts.gov%2Fip%2Fgfs%2FArticle_81_Law_2008.pdf&usg=AFQjCNGmFr_gaA9epXmzFloU15Dx64xxzg&sig2=qSaQIg4wUbezAn7tvoMMLQ)
* [New York State Public Health Law, Article 24A –Protection of Human Research Participants](https://www.nysenate.gov/legislation/laws/PBH/A24-A) [New York’s Family Health Care Decisions Act (FHCDA) (Public Health Law §29-CC)](https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=5&ved=0ahUKEwi66OqIlJnMAhVLeT4KHTdOA2AQFgg7MAQ&url=https%3A%2F%2Fwww.health.ny.gov%2Fdiseases%2Faids%2Fproviders%2Fregulations%2Ffhcda%2Fai_fact_sheet.htm&usg=AFQjCNG7kzcFNmDCA1qa5g5VW7b21L9gjQ&sig2=dyxkL-ZTSjxcoErVnoF5eg&cad=rja)
* New York State Technology Law Article 1- Electronic Signatures & Records Act (ESRA), *September 28, 1999 and amended August 6, 2002*
* [New York State's Public Health Law 18: Access to Patient Records](http://www.douglasandlondon.com/docs/New-York-State-Public-Health-Law-18.pdf)
* [NIH Guidance: Protecting PHI in Research: Understanding the HIPAA Privacy Rule](https://privacyruleandresearch.nih.gov/pr_02.asp)
* [NY State Department of Health HIPPA Preemption Charts](http://www.health.ny.gov/regulations/hipaa/preemption_charts.htm)
* [NYS 10 NYCRR Part 63 (HIV/AIDS Testing, Reporting and Confidentiality of HIV-Related Information](http://www.health.ny.gov/professionals/ems/pdf/srgpart63.pdf)
* [NYS 1-2.13 NY Estates Powers and Trusts Law](http://www.nysl.nysed.gov/libdev/excerpts/ept11-23.htm)
* NYS Archives & Records Administration- Guidelines for the Legal Acceptance of Public Records in an Emerging Electronic Environment, *published 1998*
* [NYS Civil Rights Law Section 79-L (Confidentiality of genetic tests)](http://codes.findlaw.com/ny/civil-rights-law/cvr-sect-79-l.html)
* [NYS DOH HIPAA Preemption Charts](http://www.health.ny.gov/regulations/hipaa/preemption_charts.htm)
* NYS Office for Technology- ESRA Guidelines, *May 26, 2004*
* [OCR Health Information Technology for Economic and Clinical Health (HITECH) Act, enacted as part of the American Recovery and Reinvestment Act of 2009](http://www.hhs.gov/hipaa/for-professionals/special-topics/HITECH-act-enforcement-interim-final-rule/index.html)
* Office of Human Research Protections’ Guidance “[Obtaining and Documenting Informed Consent of Research Participants Who Do Not Speak English](http://www.hhs.gov/ohrp/policy/ic-non-e.html)”
* [OHRP Guidance: FAQs](http://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/index.html)
* [OHRP Guidance: Informed Consent Requirements in Emergency Research](http://www.hhs.gov/ohrp/regulations-and-policy/guidance/emergency-research-informed-consent-requirements/index.html), for Research not subject to FDA regulations
* Presidential Commission for the Study of Bioethical Issues (Bioethics Commission) report: [Anticipate and Communicate: Ethical Management of Incidental and Secondary Findings in the Clinical, Research, and Direct-to Consumer Contexts](http://bioethics.gov/sites/default/files/FINALAnticipateCommunicate_PCSBI_0.pdf),
* Presidential Commission for the Study of Bioethical Issues (Bioethics Commission) Primer for [IRB Members: Incidental and Secondary Findings](http://bioethics.gov/sites/default/files/IRB%20Primer%20-%20FINAL_0.pdf),
* Presidential Commission for the Study of Bioethical Issues (Bioethics Commission) Primer for [Researchers: Incidental and Secondary Findings](http://bioethics.gov/sites/default/files/Researcher%20Primer%20-%20FINAL.pdf).
* [Protecting Personal Health Information in Research: Understanding the HIPAA Privacy Rule](https://privacyruleandresearch.nih.gov/pr_02.asp)
* [Readability Formulas](http://www.readabilityformulas.com/)
* State of NY, Department of Health. Letter and Question/Answer document: Language Assistance-Meeting the Needs of Patients with Language Barriers. October 25, 2006.
* [SUNY DMC HIPAA-2 Policy: Alcohol and Substance Abuse Information](http://www.downstate.edu/physicians/documents/Alcohol.Substance.Abuse.Info.Policy.pdf)
* [SUNY DMC Policy HIPAA-28, "Uses and Disclosures for Research Purposes."](http://www.downstate.edu/hipaa/documents/HIPAA.28.USESANDDISCLOSURESFORRESEARCHPURPOSES.Rev09.13Final.pdf)
* [SUNY DMC Policy HIPAA-6 on De-Identification of Information](http://downstate.edu/hipaa/documents/HIPAA.6.DEIDENTIFICATIONOFINFORMATION.2013.pdf)
* [SUNY Downstate HIS-11, “Electronic Communication of Health Related Information](http://www.downstate.edu/regulatory/pdf/policies/HIS-11.pdf)
* The Legal Framework for Language Access in Healthcare Settings: Title VI and Beyond. Chen. A.H., Odalman, M.K., and Brooks, J. J. Gen. Intern. Med. 22 (Supple 2): 362-7. 2007.
* Translation of Informed Consent in Clinical Trials. Laventhol, Z and Steiert, A. The Monitor. 2014: Volume 28, Issue 1, pp51-54.
* [UHB Policy PTBR-5: Language Services to Patients with Limited English Proficiency](http://www.downstate.edu/regulatory/pdf/policies/PTBR-05.pdf)
* [U.S. Department of Health and Human Services (HHS) Regulations for Protection of Research Participants under 45 CFR 46 (including Subparts A, B, C, D, and E)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html)
* [U.S. Food and Drug Administration (FDA) regulations under 21 CFR 11, 50, 56, 312, 812, and 814](http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ucm155713.htm)
* United States Code Title 15- Electronic Signatures in Global and National Commerce Act, Subchapter I- Electronic Records and Signatures in Commerce (ESign Law), *October 1, 2000*

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# Review and Approval History

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