**Informed Consent for Human Subjects Research at Johns Hopkins during the COVID-19 Emergency**

Introduction:

As the COVID-19 pandemic continues, Johns Hopkins is dedicated to the safety of research participants and study teams. To minimize the risk of transmission during the informed consent process, outlined below are the acceptable consent practices for COVID-19 participants.

**Minimal Risk research with a waiver of documentation of consent (oral consent):**

Example scenarios:

* Oral consent for individuals who are not hospitalized [e.g., outpatient], but may be asked to contribute to research. An in-person research encounter may not occur or could be minimal [e.g. picking up a testing kit from a tent].
* Oral consent occurs remotely by telephone between a consent designee and a participant, to reduce risk to study personnel.
* Oral consent is conducted by a study team member who will have a *clinical interaction* with the participant, but the research activities qualify for a waiver of documentation.
* Oral consent is obtained from a Legally Authorized Representative (LAR) who is not physically present.

Oral consent procedures:

**Consenting a prospective participant:**

* In preparation for the consent process download the form [Documentation Form for COVID-19 related Research Using an Oral Consent Process](https://www.hopkinsmedicine.org/institutional_review_board/news/covid19_information.html/documentation_covid%20oral_consent.docx)
* An IRB approved consent designee uses the IRB approved oral consent script to discuss the study with the participant and confirm willingness to participate
* The IRB approved consent designee reviews the mandatory questions on the form [Documentation Form for COVID-19 related Research Using an Oral Consent Process](https://www.hopkinsmedicine.org/institutional_review_board/news/covid19_information.html/documentation_covid%20oral_consent.docx) with the prospective participant
* If the participant agrees to participate and the questions are satisfactorily addressed, the consent designee completes the form
* A study team member with EPIC access completes the documentation in EPIC, via the following mechanism:
* Open a new “Documentation” Encounter for the patient:
* Epic menu (top left) > Patient Care > Encounter
* Look up patient
* Click the “New” button
* Select a Type of “Documentation”
* Enter the patient’s Progress Note/NoteWriter section.
* For COVID-19 Minimal Risk patients, enter “.COVID19RCHMINRISK” for the “COVID-19 Research Consent: Minimal Risk” statement and hit “Enter.”
* Fax the completed documentation of oral consent form to EPIC for upload (410-367-7382)

 **Consenting a LAR for decisionally impaired participants:**

* In preparation for the consent process download the form [Documentation Form for COVID-19 related Research Using an Oral Consent Process](https://www.hopkinsmedicine.org/institutional_review_board/news/covid19_information.html/documentation_covid%20oral_consent.docx)
* An IRB approved consent designee uses the IRB approved oral consent script to discuss the study with the LAR and confirms permission to participate
* The IRB approved consent designee reviews the mandatory questions on the form [Documentation Form for COVID-19 related Research Using an Oral Consent Process](https://www.hopkinsmedicine.org/institutional_review_board/news/covid19_information.html/documentation_covid%20oral_consent.docx) with the prospective participant’s LAR
* If the LAR agrees on behalf of the participant and the LAR’s questions are satisfactorily addressed, the consent designee completes the form
* A study team member with EPIC access completes the documentation in EPIC, via the following mechanism:
* Open a new “Documentation” Encounter for the patient:
* Epic menu (top left) > Patient Care > Encounter
* Look up patient
* Click the “New” button
* Select a Type of “Documentation”
* Enter the patient’s Progress Note/NoteWriter section.
* For COVID-19 Minimal Risk patients, enter “.COVID19RCHMINRISK” for the “COVID-19 Research Consent: Minimal Risk” statement and hit “Enter.”
* Fax the completed documentation of oral consent form to EPIC for upload (410-367-7382)

**Greater than Minimal Risk Research where written signature is typically required (documented informed consent):**

Example Scenarios:

* Participant signature is needed when an investigational drug is being studied to treat COVID-19 or its symptoms (e.g., a vaccine), and the participant is in clinical isolation.
* An incapacitated COVID-19 patient can participate only with the signature of a LAR and the LAR is not physically present

Written Informed Consent Procedureswhere a remote consent process is needed**:**

**Consenting a prospective participant:**

Please follow these specific COVID-19 related informed consent procedures with prospective participants where a remote consent process is needed.

Each participant must be provided with a copy of the IRB-approved consent form to aid in the consent conversation before the consent process begins. The consent form may be provided to a participant in isolation in one of the following ways:

* Authorized clinical or research personnel provides an unsigned hard-copy consent form; or
* An electronic copy of the consent is presented to the participant on a mobile device [examples: tablet used for clinical interactions, participant’s personal phone, or a phone provided by the study-team.].

Informed Consent procedures for study participants:

* The IRB-approved consent designee, and, if required, physician/mid-level provider (MLP) may participate in the consent process remotely via phone or other communication platform [see options in the resource section below].
* A third-party witness must participate in the entire consent conversation. Wherever possible a witness from the trained JH witness pool should be used.
* All parties must introduce themselves and their role in the consenting process.
* The consent form is provided to the participant and is reviewed in detail. The participant is next invited to ask any questions and to have them addressed by the study team.
* The physician/MLP discusses the studies risks and alternatives per the [physician/mid-level provider consent policy](https://www.hopkinsmedicine.org/institutional_review_board/guidelines_policies/organization_policies/111_14.html).
* If the participant is interested in joining the research study, the participant should be asked to sign the consent document
	+ Signature may occur by signing the physical document or if the consent is delivered electronically by the participant clicking “I agree” to participate.
* The consent designee and witness must verify the participant physically signed the consent document
	+ By viewing via video conference; or
	+ Obtaining a photo of the signed consent document; or
	+ Obtaining verbal confirmation from the participant that he/she signed the consent form or agreed to participate electronically.
* To reduce any transmission risks, the hard-copy consent, if signed by the isolated participant, cannot be removed from the participant’s space. In order to obtain the other required signatures a separate copy of the informed consent form is to be used to secure the following:
	+ The signature and date of the consent designee
	+ The signature and date of physician/MLP (“mid-level provider”) on the appropriate signature page
	+ The signature and date of the witness on the COVID-19 witness attestation page
* The consent designee should return all signed components as one combined document to a study team member with EPIC access.
* A study team member with EPIC access completes the documentation in EPIC, via the following mechanism:
* Open a new “Documentation” Encounter for the patient:
* Epic menu (top left) > Patient Care > Encounter
* Look up patient
* Click the “New” button
* Select a Type of “Documentation”
* Enter the patient’s Progress Note/NoteWriter section.
* For COVID-19 Greater Than Minimal Risk patients, enter “.COVID19RCHGREATERRISK” for the “COVID-19 Research Consent: Greater Than Minimal Risk” statement and hit “Enter.”
* As required, fax the signed completed consent form to EPIC for upload (410-367-7382)
* The study team must retain the completed consent document in its entirety (i.e., all pages of the consent form) in the study record or participant binder

**Consenting a LAR for decisionally impaired participants**

Presenting the informed consent form to a LAR:

It is presumed that in most cases, due to visitor restrictions or the potential for the LAR to be in self-quarantine, the LAR will not be physically present to participate in the consent process and this process will occur remotely. As with participants, the LAR must be provided with a copy of the IRB-approved consent document before the consent process begins. An electronic copy of the consent should be provided where possible. In the event that this is not possible, the study team must mail a copy of the consent form.

Informed consent procedures using a LAR:

* The consent designee, and, if required, physician/MLP may participate in the consent process remotely via phone or other communication platform [see options in the resource section below].
* A third-party witness must participate in the entire consent conversation. Wherever possible a witness from the trained JH witness pool should be used.
* All parties must introduce themselves and their role in the consenting process.
* The consent form is reviewed in detail and the LAR is provided an opportunity to have all questions addressed.
* The physician/MLP discusses the studies risks and alternatives per the [physician/mid-level provider consent policy.](https://www.hopkinsmedicine.org/institutional_review_board/guidelines_policies/organization_policies/111_14.html)
* If the LAR affirms, acting on the prospective participant’s behalf, agrees to join the study, ask the LAR to sign the consent document by
	+ Signing the physical document; or
	+ If the consent is delivered electronically by the participant clicking “I agree” to participate.
* If the consent document has been provided to the LAR by mail or email prior to the consent conversation, the full signed and dated consent form can be returned to the study team by mail, fax, email or by a photo of the entire signed consent document. If emailed, the document or photo should be returned electronically to the study team through secure electronic means. If the LAR is not able to deliver the signed document electronically, research procedures may be initiated based on the verbal attestation of signature but the hard copy must be returned via mail.
* The consent designee and witness must verify and document the LAR signed the consent document
	+ By viewing via video conference; or
	+ Obtaining a photo or scanned copy of the signed consent document
	+ Obtaining verbal confirmation from the LAR that he/she signed the consent form
* Once the LAR documentation is confirmed the following signatures must be secured:
	+ The consent designee must sign and date the primary consent document
	+ The physician/MLP must sign the physician/MLP consent signature page
	+ The witness must sign the COVID-19 witness attestation page.
* The consent designee should return all signed components as one combined document to a study team member with EPIC access.
* A study team member with EPIC access completes the documentation in EPIC, via the following mechanism:
* Open a new “Documentation” Encounter for the patient:
* Epic menu (top left) > Patient Care > Encounter
* Look up patient
* Click the “New” button
* Select a Type of “Documentation”
* Enter the patient’s Progress Note/NoteWriter section.
* For COVID-19 Greater Than Minimal Risk patients, enter “.COVID19RCHGREATERRISK” for the “COVID-19 Research Consent: Greater Than Minimal Risk” statement and hit “Enter.”
* As required, fax the signed completed consent form to EPIC for upload (410-367-7382)
* The study team must retain the completed consent document in its entirety (i.e., all pages of the consent form) in the study record or participant binder

Resources available to facilitate the informed consent dialogue:

* + - * A ZOOM session between with the participant/LAR, study-team, and witness (<https://livejohnshopkins.sharepoint.com/sites/epictraining/Epic%20Training%20Dropbox%20DocLib/Clinical%20Communications%20-%20Using%20Zoom%20to%20Talk%20with%20Your%20Provider.pdf>)
			* Other video-conferencing modalities between participants using On the Fly video (<https://livejohnshopkins.sharepoint.com/sites/epictraining/Epic%20Training%20Dropbox%20DocLib/On%20the%20Fly%20Research%20Video%20Visits%20for%20Research%20Coordinators.pdf>)
			* **The JH Witness Pool**. This is a group of research volunteers trained to perform the witness role as part of the consent process for greater than minimal risk research. Study teams should consult with the JHU Consent Pool Coordinator in advance of study initiation to discuss consenting needs. Please e-mail JHUCOVIDconsentsupport@jhmi.edu
			* **The JH Consenter Pool**. This is a group of research volunteers trained to perform research consent procedures. Study teams should consult with the JHU Consent Pool Coordinator in advance of study initiation to discuss consenting needs. Note: individuals enlisted in the Consenter Pool *must be added to the study team* for individual research studies and be IRB approved before consenting for any specific research study. Please e-mail JHUCOVIDconsentsupport@jhmi.edu
			* When obtaining oral consent, please use the following form to document the oral consent process: [Documentation of Oral Consent COVID-19 form](https://www.hopkinsmedicine.org/institutional_review_board/news/covid19_information.html/documentation_covid%20oral_consent.docx)

Mechanisms for Delivering Informed Consent Electronically.

* + - * Interested study teams may pursue the use of MyChart, as a means to deliver the IRB-approved consent document electronically to prospective participants or their LARs via MyChart. Prospective participants would have to have a MyChart account or establish one in order to access the consent through this platform. The MyChart team is available to assist study teams in creating an electronic delivery mechanism for consent that will have a built in “agree to participate” component. Investigators/study teams should be advised there is a cost associated with a MyChart build. For additional information about this option, please contact Benjamin Smith at bsmit159@jhmi.edu.