Guidance on Remote Consent Discussion and Documentation Related to COVID-19 Concerns

In the event of a health pandemic (i.e. COVID-19 declared on March 11, 2020) documenting consent from subjects utilizing methods other than pen and paper will be permitted. The use of electronic signature may be required when visitor and employee entrance restrictions are enacted in study site hospitals. Only when a subject or LAR is not physically permitted to enter the hospital will an electronic signature via remote consent be permitted.

PENN MEDICINE / PENN DENTAL / UPHS (HIPAA Covered Entities)
Options for Consent Discussions
1. **Telemedicine Visits** - [www.pennmedicine.org/for-patients-and-visitors/find-a-program-or-service/connected-health](http://www.pennmedicine.org/for-patients-and-visitors/find-a-program-or-service/connected-health) provides virtual consent option.
   - Consent should still be documented in PennChart as well via a note.
2. **Phone call**

Options for Consent Documentation
3. **RedCap**: Teams can use RedCap to document consent, but they should **not** have participants sign or write their name in the system since it is not HIPAA compliant, nor Part 11 compliant. Teams may use a RedCap link to document attestation and understanding after the consent discussion.
4. **Posted Mail**: Consents may be mailed and signed by the participants, and then mailed back to the study team for signature, with a consent discussion occurring via phone call or telemedicine visit.
   - A consent note should be drafted to explain the difference in signature dates between the research participant and the study team.
5. **MyPennMedicine**: Consent verbiage can be added into a correspondence / message to the participant and then sent to the participant, as a means of consent documentation. A participant cannot sign in the system.
   - Please see a workflow example in the appendix below.
6. **Veeva SiteVault**: SiteVault can be used to send a consent form to a participant and have them review and read. The participant can print, add their wet signature and send a picture back to the research team. This could be done via text or email based on the participant’s preference. If utilizing email, please inform the participant that email is not a secure means of transfer of PHI prior to transfer. The participant should maintain the original copy and the study team should retrieve the original signed version at a later date.
7. **Docusign**: If teams have access to Docusign and use it in a HIPAA compliant manner they may utilize it: [https://www.docusign.com](https://www.docusign.com). Note that to use Docusign a Business Associates Agreement would need to be executed between the covered entity and Docusign. Teams would need to confirm this is in place prior to utilizing Docusign for this purpose. Information on Docusign and HIPAA is available online here: [www.docusign.com/sites/default/files/Docusign_HIPAA_Compliance_Overview.pdf](http://www.docusign.com/sites/default/files/Docusign_HIPAA_Compliance_Overview.pdf)

ALL OTHER SCHOOLS
Options for Consent Discussions
1. **Video Conferencing Programs (Skype, Facetime, Blue Jeans, etc.)** provide a virtual consent discussion option.
Options for Consent Documentation

2. **Qualtrics**: Teams can use Qualtrics to document consent or have participants electronically sign. Please see: [www.qualtrics.com/support/survey-platform/survey-module/editing-questions/question-types-guide/specialty-questions/signature](http://www.qualtrics.com/support/survey-platform/survey-module/editing-questions/question-types-guide/specialty-questions/signature)

3. **Docusign**: If teams have access to Docusign, they may utilize it: [https://www.docusign.com](https://www.docusign.com)

4. **Posted Mail**: Consents may be mailed, signed by the participants, and then mailed back to the study team for signature.
   - A consent note should be drafted to explain the difference in signature dates between the research participant and the study team.

5. **E-Mail**: Consents may be emailed to participants, signed, and then mailed or emailed back to the study team for signature. A consent note should be drafted to explain the difference in signature dates between the research participant and the study team.

**Appendix**

1) Run find patients associated with my research study report and select send patient message from the communication dropdown:

![Image of find patients associated with my research study report](image)

2) In the form that opens click to add a questionnaire, select the questionnaire and you can change the display name:
3) Click the green plus to create a smartphrase for the study consent, copy and paste consent wording into this document (screenshots do not work), this can be shared with other users in the sharing section.
University of Pennsylvania
Universal Consent for Use of Data and Biospecimens
RESEARCH SUBJECT INFORMED CONSENT
AND HIPAA AUTHORIZATION FORM

Protocol Title: Penn Medicine BioBank
Principal Investigators: Daniel J. Rader (215) 873-4176 & Michael D. Feldman (215) 662-6003
BioBank Contact: JoEllen Weaver (215) 349-5027

Because you are receiving clinical care at the University of Pennsylvania Health System (UPHS), you are being asked to grant permission to use any and all information placed in your medical record for potential future research purposes. If applicable, you also are being asked to grant permission for use of any biospecimens (for example: blood, urine, bodily fluid or tissue collected as part of your clinical care) that remain after regular clinical care to be stored and potentially used for future research purposes.

Storage and potential future use of medical record data and/or biospecimens is a common research practice and allows for researchers to learn new information about many different medical conditions.

During your time at UPHS, any time that blood or tissue is removed as part of your care, the removed specimens will be examined in the Department of Pathology. The Department of Pathology will determine the amount needed for your health care. With this consent, blood and tissue in excess of the amount needed for your care may be released for research purposes.

Researchers from Penn, other universities, the government, and drug- or health-related companies can apply to use the materials. A scientific and ethics review committee will review each request.

Approved researchers from Penn may want to use portions of your health information that they will need for their research. If you consent, health information that may be used and/or released includes the following:
- Name
- Medical record number
- Dates such as date of birth, medical events, and follow-up

4) Use the dot phrase to pull in the consent, review wording and click accept and send:
5) For the patient they will see the consent body in their inbox with a link to the yes/no questionnaire: