

## **GUIDANCE – REMOTE CONSENTING**

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Prisma Health IRB allows for remote consenting in specific situations that may vary from study to study. You must speak with an IRB coordinator to determine if your study can be approved for remote consenting.

The Prisma Health IRB follows Prisma Health institutional policies and guidelines for remote consenting.

If your study has been approved for the use of the remote consenting process, please follow the below guidelines:

- 1) A remote consent will be considered by the IRB if the research participant and/or their legally authorized representative is not physically present for the consent process.
- 2) You must upload the remote consenting signature page to the end of the informed consent document for the study.
- 3) The research participant and/or their legally authorized representative must be provided a copy of the consent document prior to the consent discussion and the signing of the consent form. The document may be provided electronically via email, fax, or mailed via USPS.
- 4) The consent process must be witnessed by two (2) impartial witnesses (employees of Prisma Health). The witnesses must be present for the entire consent conversation, and both witnesses must sign the remote consenting signature page.
- 5) The participant will sign and date the hard copy that they were previously provided and should return the hard copy with their signature and date to the study team at the first office visit or via email, fax, or USPS.
- 6) The investigator will sign on the investigator signature line on the main consent document at the end of the consent conversation when the patient signs their copy.
- 7) The investigator will note on their hard copy of the consent form that the consent conversation took place remotely.
- 8) An executed copy of the entire consent form must be provided to the study subject and/or their legally authorized representative.
- 9) Consent requirements for participation in research that is time sensitive, i.e. emergency treatment such as stroke or cardiac events, will be reviewed and the requirements for consent determined by the IRB.
- 10) Study teams should note that remote consent is not the same as eConsent. eConsent is not permitted at Prisma Health.
- 11) The IRB reserves the right to alter and/or edit any requirements or approvals of remote consenting as needed.