Video consent guidance

**What is video consent?**

Video consent means an audiovisual recording describing information in the informed consent form. Short videos can also be used during the informed consent process to help explain some aspects of the study. Video consent, visual images, and graphical media may increase understanding of the study and improve comprehension of procedures. Video consent may be especially helpful when enrolling children or participants with poor literacy/numeracy.

**How can it be used?**

Video consent can be used in several ways:

* On a tablet for use in the clinic or on site.
* Sending a video link to prospective participants via email or text to review on their own before coming on site to sign a paper consent form.
* Sending a video link along with an electronic informed consent form to conduct the consent process remotely.
* Short videos to help explain some aspects of the study embedded in an electronic informed consent form or shown on a tablet when using paper consent forms.

**Video consent is an option in these circumstances (etc)**

**Useful for studies that are complex, recruiting children and/or populations with low literacy or ones that may benefit from visual representations of concepts/procedures**

**Important Points to Consider**:

IRB considerations

Using video consent makes it part of the informed consent process, one of the cornerstones of human research protections. In your IRB application, describe how video consent will be used and include video links or files.

Even with a video consent covering all elements of informed consent, someone on the research team must be available to answer participants' questions. Additionally, participants still need to receive a copy of the consent.

If information in the consent form is amended, any relevant segments of the video consent must also be revised.

When planning to use video consent, consider:

Is the video replacing any part of the consent process? E.g.,

* + the *document itself* in the case where the IRB has granted a waiver of documentation of consent,
  + the *consent conversation* with study personnel, or
  + any *elements* of the informed consent form.

Or is the video supplementing the consent process? E.g.,

* + Opportunity to learn more about the study ahead of the consent process,
  + Embedded videos in an electronic consent form to allow participants to learn more about certain aspects of the study, and/or
  + A brief introduction to the study.

Technical and logistical issues

* Web hosting: identify which site and entity will host the video. Departmental or study-specific websites, Kaltura, YouTube, and other sites can be used. If using a site like YouTube, identify an account to post the video and who owns the account.
* Sound quality: invest in a quality microphone.
* Need for proof that they watched it all and didn't skip ahead? You may consider embedding questions to assess comprehension and/or ensure participants don’t skip ahead.
* Logos – is there a vetting process? Logos for outside IUSM, check with IUH/Esk. Link to policy

**Models of Video Consent**

Indiana Biobank Precision Health Consent – This video covers all elements of informed consent and was produced by IUH Visual Media. Some points to consider are that producing a similar video may be more costly than other options, the video will require a web host, and making revisions to the content may be more difficult than other options.

* + <https://bcove.video/2AmJnu6>
  + Contacts: Brooke Patz and IU Health visual media
  + Used as their consent conversation. QUestions can be asked by contacting study team, and paper versions are available. Participants receive an emailed, signed copy of the consent. Done on a tablet in clinic or sent via email/text to participants.

Komen Tissue Bank – This video covers all elements of informed consent and was produced by a study team member using voiceover of PowerPoint. Some points to consider are that producing a similar video would require a high quality microphone, may be easier to create within the research team than other options, and making revisions to content may be easier than other options.

* + Example: <https://www.youtube.com/watch?v=jQme34KuBdk> (previous version)
  + Contacts: Julia von Arx
  + Describe process

External examples? Other models?

References:

<https://www.appliedclinicaltrialsonline.com/view/engagement-shift-informed-consent-digital-era>

<https://www.nejm.org/doi/full/10.1056/NEJMra1603773>

Tait AR, Voepel-Lewis T. Digital Multimedia: A New Approach for Informed Consent? *JAMA.* 2015;313(5):463–464. doi:10.1001/jama.2014.17122