Electronic Signatures to Document Consent/Parental Consent

From the OHRP <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent/index.html>

[**Can an electronic signature be used to document consent or parental permission?**](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent/index.html#nodequeue_14-page_4-14)

Yes, under certain circumstances. First, the investigator and the IRB need to be aware of relevant laws pertaining to electronic signatures in the jurisdiction where the research is going to be conducted. See **Ohio Revised Code** <http://codes.ohio.gov/orc/1306>

Unless the IRB waives the requirement for the investigator to obtain a signed consent or permission form based on the HHS regulations at [45 CFR 46.117(c)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.117), a written consent or permission form, which may be an electronic version, must be given to and signed by the subjects or the subjects' legally authorized representatives or the parents of subjects who are children. Some form of the consent document must be made available to the subjects or the parents of subjects who are children in a format they can retain. OHRP would allow electronic signature of the document if such signatures are legally valid within the jurisdiction where the research is to be conducted.

OHRP does not mandate a specific method of electronic signature. Rather, OHRP permits IRBs to adopt such technologies for use as long as the IRB has considered applicable issues such as how the electronic signature is being created, if the signature can be shown to be legitimate, and if the consent or permission document can be produced in hard copy for review by the potential subject. One method of allowable electronic signatures in some jurisdictions is the use of a secure system for electronic or digital signature that provides an encrypted identifiable “signature.” If properly obtained, an electronic signature can be considered an “original” for the purposes of recordkeeping.

[**Is a faxed copy of the signed consent or parental permission form acceptable to document informed consent?**](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent/index.html#nodequeue_14-page_4-15)

Yes, if it is more convenient for the subjects or parents of children who are subjects to fax a signed copy of the consent or permission form to the investigator, the research subjects or parents may fax the signed form. The subjects or parents need not provide the investigator with the original signed consent or parental permission documents. -OHRP
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(I would also include scanned documents as being acceptable. Retention of the documents, whatever the format, is required.)

Ohio Revised Code
see <http://codes.ohio.gov/orc/1306>