**IRB Policy Statement re Electronic Consent**

The Seattle Children’s Institutional Review Board (IRB), in cooperation with other institutional teams (including IT and Legal) provides this policy statement and guidance on the use of electronic systems and processes to obtain informed consent. This information is intended for both the time that COVID impacts study procedures as well as beyond. The content is largely drawn from a December 2016 guidance document issued by the federal agencies that regulate human subjects research (see Regulatory Guidance References below).

**Use of Electronic Consent (e-consent):** The use of e-consent is an option and alternative to existing means of obtaining consent. Based on equity concerns, its use as the sole means of obtaining consent will not often be justified. The reason is that many subjects may not be able to access/use e-consent means and their exclusion from the research based on this will often not be justifiable.

**IRB Modification Strategy:** If you are planning to submit an IRB Modification to add the use of e-consent and if its approval is time-sensitive, then you are strongly advised to submit this change by itself rather than in combination with other changes. This helps ensure a more expedient review.

1. **Context & General Requirements**

The word “**consent**” is used in this document to mean any of the following:

* Obtaining consent from a subject or a subject’s legally authorized representative;
* Obtaining permission from a parent/legally authorized representative for the participation of a child subject;
* Obtaining assent from a child subject.

The **consent process** has three primary components:

* Providing prospective subjects with information that facilitates comprehension;
* Providing adequate opportunity for the subject to ask questions and consider whether or not to participate;
* Documenting consent.

The term ”**e-consent**” refers to the use of electronic systems and processes that employ some type of electronic media (including text, graphics, audio, video, podcasts, passive and interactive web sites, biological recognition devices, etc.) to convey consent information **and/or** to document informed consent.

Electronic delivery of the information is independent of how (or whether) consent documentation is obtained.

| **Consent Information** | **Documentation of Consent** |
| --- | --- |
| Delivered electronically | Electronic |
| Delivered electronically | On paper |
| Delivered electronically | Waiver of documentation of consent |

There are many electronic alternatives to a paper consent form. Examples include: A consent document that is delivered via email/text message; passive or interactive websites; social media platforms; audio; video; podcasts; or any combination of these.

1. **Requirements**

The use of e-consent requires IRB review and approval. The requirements for a paper-based process apply to an electronic process as well. For example, the information must be delivered in a language understandable to the subject and it must describe the reasonably foreseeable risks. Consent information delivered electronically is subject to the same records retention requirements as paper consent forms. Also, it must be easily retrievable for auditors and monitors.

1. **FDA-Regulated Research**

This policy statement is **not** intended to describe the process for obtaining or documenting e-consent for FDA-regulated research. For FDA-regulated research, the use of electronic systems, archiving, and retention of consent materials must meet the FDA “Part 11” requirements. The e-consent services centrally supported by Seattle Children’s (DocuSign and RedCap) do not currently meet Part 11 requirements. Therefore, they cannot be used for FDA-regulated studies.

1. **IRB Review**

This is the information that should generally be provided in the Protocol/equivalent document (in the Consent section(s)) and consent documentation (as appropriate), if applicable, to facilitate effective IRB review:

1. Identify the electronic means to be used;
2. Identify what means will be used for delivering the consent information and for documenting consent;
3. If applicable, the name of the specific software/application to be used;
4. If applicable, whether audio and/or video will be recorded – and if so, whether it will be recorded within the software/application;
5. What type of information is involved (e.g., private and identifiable and/or protected health information) in the use of e-consent means;
6. The ease of navigating the consent materials for participants and how long it takes;
7. The ability to move backwards and forwards within the electronic system and to stop and continue at a later time;
8. The suitability of the electronic process for the intended audience, taking into consideration the subject’s age, language, comprehension level, and familiarity with technology tools;
9. The availability of study personnel to assist subjects in using the electronic process;
10. The procedures that ensure the electronic process allows subjects to ask questions they may have before signing (e.g., by in-person discussions, telephone calls, videoconferencing);
11. How these means will be used in private settings to protect confidentiality; Study team members should remind subjects to conduct any e-consent discussion in a private location to help ensure privacy and confidentiality (see Best Practice Questions below);
12. How consent documentation will be managed over the life of the study;
13. Describe the process that will be used if additional information (for example, new risk information) must be provided to participants during the research;
14. What alternative way (if any) of obtaining the consent information will be made available to individuals who are not able to receive/access/use the e-consent information system. Some study teams are currently considering creative solutions for such individuals; these potential solutions include snail mail, drive through paperwork for consent, and loaner device/hotspots for e-consenting. If no alternative will be made available (meaning these individuals cannot be enrolled), the IRB will look for a sufficient rationale for this exclusion.
15. **Facilitating Comprehension & Opportunity to Consider**

This refers to the processes used to ensure that subjects understand the information and have adequate time to make an informed decision.

When a study team member obtains consent in person, this will include a question-and-answer opportunity. When consent is not an “in-person” process, the researcher and the IRB must consider how to provide this opportunity and ways of facilitating comprehension. For example, this may be accomplished through telephone calls, electronic messaging (examples: email, text messages), video conferencing, live chat, or other methods. Regardless of the subject’s location, there may also be optional information (for example, hyperlinks or help text) embedded in the electronically delivered material to aid in comprehension of key study elements. Similarly, subjects may be asked questions embedded during the electronic process to gauge their comprehension.

It is recommended to document in a separate note to file/progress note, or with a note under the PI signature line on the consent form, that consent was obtained over the phone/by videoconference with the actual date. Sample language for documentation:

“Discussed with [person] via telephone/videoconference on [insert date] and received signed consent form on [insert date].”

The responsibility for obtaining informed consent resides with the investigator. The investigator cannot delegate authority to obtain informed consent to the electronic system.

If the consent information includes one or more hyperlinks to information on the Internet, the hyperlinks should be maintained and information should be accessible until study completion. The information in these hyperlinks should be included in any printed paper copy, if one is provided.

1. **Requirements**

While this must be addressed, there are no specified requirements about how to implement this component of consent electronically.

1. **IRB Review**

The following information must be provided for the IRB in the Protocol/equivalent document (in the Consent section(s)) to facilitate effective IRB review. Like all research procedures, using an electronic process for this component of consent must be adequately described. It must be clear to the IRB how the circumstances and processes facilitate subject comprehension, ensure subject opportunity to ask questions and receive answers, and ensure subject opportunity to voluntarily consider participation, to the degree appropriate to the study, particularly when this component of the consent process will not be “in-person.” As noted above, there needs to be information provided to the IRB about the ease of navigating the consent materials for participants and how long it takes.

1. **Documentation of Consent**

***Note:*** *It may be appropriate for minimal risk studies to obtain a waiver of the requirement to obtain documentation of consent rather than using an electronic means for documentation of consent.*

DocuSign and RedCap are the providers that have been vetted and are supported by our institution for electronic methods of documenting consent under the federal ESIGN law and the Washington Uniform Electronic Transactions Act.

1. **Requirements**

Electronic documentation must meet the same requirements as paper documentation. For example:

(1) meets all applicable records retention requirements; (2) appropriately protects the confidentiality and integrity of the records; (3) ensures accessibility by an auditor or monitor; (4) captures and records the date that the subject provides consent; and (5) ensures the subject is provided a copy of the signed form. In order to ensure the subject is provided a copy, the electronic informed consent form could include instructions to the subject to print/save a copy of the signed form presented on the electronic device or the signed form could be provided by email/some other means.

In addition, the electronic documentation system must be legally valid within the jurisdiction where the research will be conducted. To ensure compliance with the federal eSIGN law, the following statement(s) must be inserted immediately above the signature section(s) of each applicable form (including Assent forms and legacy IRB forms).

Consent/Permission form statement:

“*If using electronic documentation: You agree this form and any later updates to this form and notices provided in connection with this study may be* ***provided*** *to you in an electronic version. You agree that you are able to* ***electronically receive, review, and save*** *a printed or electronic copy of this form containing your signature. We and you agree to* ***electronically sign*** *this form. We and you agree that* ***our actions*** *to electronically sign this form document your informed consent. We and you agree that our electronic signatures* ***have the same meaning and effect as handwritten signatures***.  *You understand that you can request a paper form if you would prefer to use a paper consent form.”*

Assent form statement:

*“If using electronic documentation (this means using something like a computer or phone instead of paper): You agree this form and any later updates to this form and notices provided in connection with this study may be* ***provided*** *to you in an electronic version. You agree that you are able to* ***electronically receive, review, and save*** *a printed or electronic copy of this form containing your signature. We and you agree to* ***electronically sign*** *this form. We and you agree that* ***our actions*** *to electronically sign this form document your assent. We and you agree that our electronic signatures* ***have the same meaning and effect as handwritten signatures****. You understand that you can request a paper form if you would prefer to use a paper assent form.”*

Please note these statement(s) must be inserted, regardless of whether you are using the Seattle Children’s instance of an e-consent service or another institution’s instance of the same (including the University of Washington).

This requirement (along with others) may prompt study teams to consider having separate consent versions based on whether it is being obtained electronically/not. However, it is anticipated that research teams could also choose to carefully incorporate this (and other requirements) into their existing consent versions by making it explicit that some requirements only apply when using e-consent processes/documentation means.

All consent information and documentation must be maintained for the appropriate period of time as set by regulatory, sponsor, and institutional requirements.

1. **IRB Review**

The IRB needs to be provided the following information in the Protocol/equivalent document (in the Documentation of Consent section) regarding electronic documentation of consent:

1. Enough non-technical detail in the methodology description for the IRB members to fully understand how consent will be documented and how the electronic documentation will be stored so as to maintain its confidentiality, integrity, and availability to the research team and any auditors/monitors.
2. As noted above, what alternative way (if any) of obtaining the documentation of consent will be made available to individuals who are not able to receive or access the e-consent information system. If no alternative will be made available (meaning these individuals cannot be enrolled), the IRB will look for a sufficient rationale for this exclusion.
3. If the research is conducted outside of Washington State, provide confirmation that the electronic documentation of consent is legally effective in that jurisdiction.
4. **Verification of Identity**

This refers to the process used to confirm that the individual who provides the eSignature is the subject (or the subject’s legally authorized representative, guardian, or parent), when the signature is not personally witnessed by a member of the study team.

Many different verification methods are acceptable. For example, verifying someone’s identify can be done by using information from some form of official identification, such as a birth certificate, government-issued passport, or a driver’s license. When subjects are in a remote location, this might involve the subject displaying the document to the study team via video, or by having the subject send a scanned copy or a digital photo (for example, taken with a cell phone) through appropriately secure means to the study team. In addition, the use of security questions to confirm an individual’s identify can be considered (for example: asking the subject to verify the date of the subject’s last clinic/hospital visit).

1. **Requirements**

**Child Identity Documentation.** A child may lack the documentation necessary to verify the child’s identity during the assent process. If so, depending on the study, it may be reasonable for the parent to initially document the child’s assent, which can then be verified when the study team first sees the child.

**Minimal Risk Research**. Researchers and the IRB are encouraged to apply a risk-based approach to this issue. For example, researchers and the IRB may consider how likely it is that someone other than the subject would provide the consent. Social behavioral minimal risk research will not typically warrant such verification (and indeed, may qualify for waiver of the requirement to obtain documentation of consent, as referenced above).

1. **IRB Review**

Below is the information that needs to be provided to the IRB in the Protocol/equivalent document (in the Consent section(s) regarding verification of identity:

1. Enough non-technical detail in the description of the verification methodology for the IRB members to fully understand how it will occur or sufficient rationale for why verification is not required or necessary to protect subjects or the integrity of the research.
2. Procedures to maintain the confidentiality of personal information obtained through the e-consent process (such as subject email addresses, photos of government-issued passports, etc.).
3. **HIPAA Implications**

HIPAA authorizations may be signed electronically, provided the signature is a valid electronic signature under applicable laws and regulations (if it is not, then an alteration of the signature requirement would be needed). DocuSign is a Business Associate of Seattle Children’s. REDCap is a secure, web-based data collection tool that meets HIPAA compliance standards. Both DocuSign and REDCap produce legally binding electronic signatures.

At Seattle Children’s, authorization and informed consent are often combined in one consent document. If a standalone HIPAA authorization form is instead used, then to ensure compliance with the federal eSIGN law, the following statement must be inserted immediately above the signature section of the form.

Standalone HIPAA form statement:

*“If using electronic documentation:* *You agree this form and any later updates to this form and notices provided in connection with this study may be* ***provided*** *to you in an electronic version. You agree that you are able to* ***electronically receive, review, and save*** *a printed or electronic copy of this form containing your signature. We and you agree to* ***electronically sign*** *this form. We and you agree that* ***our actions*** *to electronically sign this form document your authorization. We and you agree that our electronic signatures* ***have the same meaning and effect as handwritten signatures***. *You understand that you can request a paper form if you would prefer to use a paper authorization form.”*

Please note this statement must be inserted, regardless of whether you are using the Seattle Children’s instance of an e-consent service or another institution’s instance of the same (including the University of Washington).

The HIPAA Privacy Rule requires covered entities like Seattle Children’s to provide the individual with a copy of signed authorizations including electronically obtained HIPAA authorizations.

1. **Best Practice Introductory Questions to Participants**

In order to best navigate some of the requirements referenced above, please find here suggested questions to pose to participants that are based on those currently being used by our clinicians for Telemedicine visits:

* 1. “What phone number should I call if we get disconnected? What phone number should I call if there is an emergency and I need to get help for you?”
	2. “Are you in a location where you are comfortable discussing this research and/or your healthcare?”
	3. “Please show me picture ID (often for parent/legally authorized representative of subject) and here is my ID.”
1. **DocuSign**

**Applying through Seattle Children’s IT to use DocuSign**. Please confirm that the intended usage meets current policy and guidelines for eSignature usage. To request access to DocuSign, open a ServiceNow Ticket by self-service or calling the service desk during business hours. In the “General Services” section there is a selection for DocuSign. Based on the new user’s department, ServiceNow will submit an approval request to the Account Owner. Once approved, the user will be added to DocuSign and notified. DocuSign usage will be subject to chargebacks to study teams. Questions can be emailed to ECMMonitoring@seattlechildrens.org.

1. **RedCap \***

**Applying through Seattle Children’s IT to use RedCap**. Please confirm that the intended usage meets current policy and guidelines for eConsent usage. To request access to RedCap, open a ServiceNow Ticket by self-service or calling the service desk during business hours. In the “General Services” section there is a selection for RedCap. You can also request standard REDCap services, including access, using this REDCap form: <https://is.gd/project_access>. Once a user has been added to the REDCap access list, the user can then be given appropriate access to study projects by the administrator of each project. It is the responsibility of project administrators to ensure that all users have appropriate access to study data. The eConsent framework must be enabled on a per-project basis. It is the responsibility of the study administrator or PI to ensure it has been implemented correctly per the study’s IRB terms. Questions can be emailed to REDCap@seattlechildrens.org.

\*All terms of this policy statement apply to the Seattle Children’s instance of RedCap as well as Seattle Children’s RedCap hosted by UW ITHS.

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Regulatory Guidance References:

“Use of Electronic Informed Consent: Questions and Answers, Guidance for Institutional Review Boards, Investigators, and Sponsors”, U.S. Department of Health and Human Services, Office for Human Research Protections and Food and Drug Administration. December 2016

21 CFR Part 11

“Electronic Signatures in Global and National Commerce Act” (ESIGN Act) (Public Law 106-229)

Washington “Uniform Electronic Transactions Act”

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Approved by Seattle Children’s IRB on May 26, 2021

*Douglas Diekema, IRB Chair*

*Laurie Price, Director, Office of Institutional Assurances*