Ascension St. John Hospital

Research Vitals

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As we come to the end of 2020, most of us are happy to throw the 2020 calendar out and hope that 2021 will be a better year.

Because of the pandemic, there has been an increase in research activities from residents, fellows and faculty. There have been many new opportunities for collaboration. New and life-saving treatments have been brought to patients suffering from COVID-19.

In the coming year, while we all hope to see COVID-19 under control, it will be fantastic if this increased interest in research and collaboration continues. Hopefully we won't need a pandemic to spark our research curiosity!

Congratulations to all of the investigators who have had protocols approved and abstracts and papers published. While research productivity is important for intellectual and scientific growth and progress, COVID-19 research has had a higher cause: trying to keep patients alive.

Thank you to the research staff, the IRB staff, the Ascension St. John IRB members and all of the research coordinators who played a vital role in conducting these research studies. Nothing can be accomplished without your contribution.

Wishing you Happy Holidays and a Healthy, Happy 2021!

Dr. Susanna Szpunar

Director, Biomedical Investigations and Research
Susan.szpunar@ascension.org

Citing References in Journal Articles

When writing protocols, journal articles or case reports, one can get confused about the proper way to cite your sources, so that you are not committing plagiarism.

According to the Merriam-Webster dictionary, "to plagiarize" means "to steal and pass off (the ideas or words of another) as one's own: use (another's production) without crediting the source". Another definition is "to commit literary theft[1]."

In the world of "cut and paste", it becomes much easier to accidently misuse other's work, by not citing it correctly.

So a few simple tips:

1. When referring to an idea or statement that is not your own, make sure you cite the complete source.
    - Each journal, in the "instructions for authors" will specify what format to use. If you use a program such as EndNote®, you can select the appropriate format from a drop-down list.

2. If you include the source's words **verbatim**, then you must add quotations around the sentence (s) in addition to the citation.

3. Be careful about paraphrasing. Taking someone else's statements and rewording them slightly can still be considered plagiarism. You must restate the idea or concept, *in your own words, without altering the meaning of the concept.* You must also still put in the citation.

Plagiarism is a serious offense; it is considered a form of scientific misconduct. Most of the time, it happens unknowingly/by mistake. Be careful when writing and editing papers to cite references correctly!

[1]"Plagiarize." *Merriam-Webster.com Dictionary*, Merriam-Webster, https://www.merriam-webster.com/dictionary/plagiarize. Accessed 14 Dec. 2020

Happy Holidays!

Congratulations to Dr. Saravolatz and the Vaccine Research Unit!

Dr. Saravolatz and the newly-formed vaccine research unit commenced their first COVID-19 vaccine trial in early December. Congratulations to the team on this exciting new step in research at Ascension St. John!

Specific thanks to:

- Dr. Louis Saravolatz and all of the ID doctors
- The Vaccine Research Unit:
  - ☆ Holly Berndt-Hilu, Clinical Trial Manager
  - ☆ Sharon Valenti
  - ☆ Karen Forman
  - ☆ Michelle Costante
  - ☆ Kathleen Riederer
  - ☆ Joan Pawlak
  - ☆ Arminohi Inofak
  - ☆ Meghan McDermott
  - ☆ Lynne Rossier
  - ☆ Samantha Juszczyk
  - ☆ Barbara Pieper
  - ☆ David Pieper

This work would not have been possible without the support of Drs. Grady and Bellovich, our corporate legal department, and the Ascension St. John IRB!

Special Section on Obtaining Consent for Research during the Pandemic

How do I obtain signed informed consent from a hospitalized patient who is in isolation when a COVID-19 infection control policy prevents us from entering the patient's room to collect a signed informed consent form?

FDA regulations generally require that the informed consent of a trial participant (in this case, a hospitalized patient) be documented by the use of a written consent document that typically includes the elements of informed consent, as described in 21 CFR 50.25, and that has been approved by the IRB and signed and dated by the trial participant or their legally authorized representative at the time of consent (21 CFR 50.27(a)). When feasible, we recommend a traditional method of obtaining and documenting informed consent using a signed paper copy of the consent form or use of electronic informed consent. If neither of these approaches are possible, the following procedures would be considered to satisfy the FDA's informed consent documentation requirement.

Method 1: A photograph of the signed informed consent document can be transmitted to the trial staff

1. An unsigned consent form is provided to the patient by a person who has entered the room.
2. The investigator/designee arranges a telephone call or video conference call with the patient (and, if desired and feasible, additional individuals requested by the patient (e.g., next of kin)).
3. To ensure that patients are approached in a consistent fashion, a standard process should be used that will accomplish the following:
   - Identification of who is on the call.
   - Review of the informed consent document with the patient by the investigator/designee and response to any questions the patient may have.
   - Verbal confirmation by the patient that their questions have been answered, that they would like to participate in the trial, and that they have signed and dated the informed consent document that is in their possession.

Happy Holidays!

4. The patient (or an individual in the room) takes a photograph of the signed informed consent document and sends it to the investigator/designee.
5. A trial team member enters the photograph into the trial records along with an attestation that states how that photograph was obtained and that it is a photograph of the informed consent document signed by the patient.

Method 2: A witness can attest to the signature, but a photograph of the signed informed consent document cannot be transmitted

1. An unsigned consent form is provided to the patient by a person who has entered the room.
2. The investigator/designee arranges a three-way telephone call or video conference call with the patient, a witness who is not otherwise connected with the clinical investigation, and, if desired and feasible, additional individuals requested by the patient (e.g., next of kin). Alternatively, in lieu of using a witness, a recording of the conversation can be made.
3. To ensure that patients are approached in a consistent fashion, a standard process should be used that will accomplish the following:
   - Identification of who is on the call.
   - Review of the informed consent document with the patient by the investigator/designee and response to any questions the patient may have.
   - Verbal confirmation by the patient that their questions have been answered, that they would like to participate in the trial, and that they have signed and dated the informed consent document that is in their possession.
4. When using a witness, documentation in the trial records includes:
   (1) a signed and dated attestation by the witness who participated on the call that the patient confirmed their agreement to participate in the trial and signed the informed consent document; and (2) a signed and dated attestation by the investigator/designee stating why the informed consent document signed by the patient was not retained (e.g., due to potential contamination of the document by infectious material).

   When using a recording in lieu of a witness, documentation in the trial records includes:
   (1) the recording of the conference call; and (2) a signed and dated attestation by the investigator/designee who participated on the call stating why the informed consent document signed by the patient was not retained (e.g., due to potential contamination of the document by infectious material).

   When either Method 1 or 2 is used to document informed consent, the resulting documentation should be:
   (1) collected and archived, as either original paper copies or appropriately certified electronic copies (e.g., using a validated process for scanning paper copies), and (2) retained according to applicable FDA record retention requirements as part of the trial record.

   If the patient is unable to provide informed consent and there is a legally authorized representative, investigators must obtain written consent from the patient's legally authorized representative in accordance with 21 CFR 50.27(a).

How do I obtain informed consent from a patient unable to travel to a clinical trial site where electronic informed consent is not an option?

Investigators may also need to obtain informed consent from a potential trial participant or their legally authorized representative when these individuals are unable to travel to the site where the investigator is located due to COVID-19 illness or travel restrictions. (continued on next page)

When investigators do not have electronic informed consent (eIC) capabilities, methods of obtaining informed consent other than a face-to-face consent interview may still be acceptable if those methods allow for an adequate exchange of information and documentation, and a method to ensure that the signer of the consent form is the person who plans to enroll as a participant in the clinical investigation or is the legally authorized representative of the trial participant.

Example: The consent form may be sent to the trial participant or their legally authorized representative by facsimile or email, and the consent interview may then be conducted by telephone when the trial participant or their legally authorized representative can read the consent form during the discussion. After the consent discussion, the trial participant or their legally authorized representative can sign and date the consent form.

Options for returning the document to the clinical investigator may include facsimile, a photographic image sent through electronic means, scanning the consent form and returning it through a secure email account, or posting it to a secure Internet address, especially if there are concerns about having the participant mail a potentially contaminated consent document. Alternatively, the trial participant may bring the signed and dated consent form to his/her next visit to the clinical site, if restrictions on traveling to the clinical trial site are alleviated or mail it to the clinical investigator. The case history for each trial participant must document that informed consent was obtained prior to participation in the trial. In addition, the person signing the consent form must receive a copy of the consent form. Although FDA regulations do not require the trial participant's copy to be a signed copy, FDA recommends that a copy of the signed consent form be provided.

The trial participant or their legally authorized representative must sign and date the informed consent form before the investigator may conduct any study-related procedures involving the participant. Where it is not feasible for investigators to receive the signed consent form prior to beginning study-related procedures, the investigators should have the prospective trial participant or legally authorized representative confirm verbally during the consent interview that the participant or legally authorized representative has signed and dated the form. In addition, the overseeing IRB must review and approve the planned informed consent process.

How can informed consent be obtained and documented from a prospective trial participant (or legally authorized representative) when they cannot print and sign a paper copy of the consent form provided electronically by the investigator/designee, they cannot electronically sign the informed consent form, and providing a paper copy of the consent form via mail/courier is not feasible within the time frame for enrollment into the clinical trial?

Where a prospective trial participant (or legally authorized representative) is unable to print the informed consent document provided electronically by the investigator/designee, an electronic signature process is not available, and the prospective trial participant must meet time-sensitive eligibility criteria, the investigator may consider using the following alternative process to satisfy FDA requirements for obtaining and documenting informed consent:

1. The investigator/designee provides the prospective participant (or legally authorized representative) with an electronic version of the informed consent document.
2. The investigator/designee arranges a telephone call or video conference call with the prospective participant (or legally authorized representative), the investigator/designee, a witness who is not otherwise connected with the clinical investigation and, if desired and feasible, additional participants requested by the prospective participant (e.g., next of kin). Alternatively, in lieu of using a witness, a recording of the conversation can be made. (continued)

3. To ensure that the prospective participant (or legally authorized representative) is approached in a consistent fashion, a standard process should be used that will accomplish the following:
   a. Identification of who is on the call. b. Review of the informed consent document with the prospective participant (or legally authorized representative) by the investigator/designee and response to any questions the prospective participant (or legally authorized representative) may have. c. Verbal confirmation by the prospective participant (or legally authorized representative) that their questions have been answered and that they would like to participate in the trial.
4. Verbal confirmation by the participant (or legally authorized representative) that they signed and dated a blank piece of paper with a written statement that they voluntarily agree to participate in the protocol, noting both the Protocol 'NUMBER' and brief protocol title.
5. After signing and dating the newly created document, the trial participant (or legally authorized representative) sends a photograph of the signed and dated statement by facsimile, text message, or email to the investigator/ designee; OR returns the document to the investigator by mail at a later date, or at a future study visit that might occur in person.
6. When using a witness, documentation in the trial records includes a signed and dated attestation by the witness who participated on the call that the patient confirmed their agreement to participate in the trial and signed the document referenced above.
7. When using a recording in lieu of using a witness, documentation in the trial records includes the recording of the conference call.
8. After the signed and dated document is received by trial staff, it should be appended to a copy of the consent document that was reviewed with the trial participant (or their legally authorized). Additionally, a note in the trial records should be made explaining the circumstances of why informed consent was obtained through an alternative method. The case history for each trial participant must document that informed consent was obtained prior to participation in the trial.

*****This alternative approach must be reviewed and approved by the IRB overseeing the trial as required under FDA regulations. *****

More information can be found at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-guidance-conduct-clinical-trials-medical-products-during-covid-19-public-health-emergency

Happy Holidays!

During this time, the Research and IRB staff are working remotely. The best way to contact us is by email.

"Keep Christmas in your heart all year long. It will leave less room for cholesterol."

SEMCME Update

Faculty Development Workshops

Self-directed learning by Larry Fischetti:

- A six-part virtual workshop series held 1-2pm on Jan 15th, Jan 29th, Feb 12th, Feb 26th, Mar 12th and Mar 26th

43rd Annual Research Forum: will be held virtually in May 2021. More information to come.

Michigan QI summit: will be held virtually in May 2021. More information to come.

For more information on these events, visit: https://semcme.org/

Research and IRB Staff

Susanna Szpunar, PhD	Director, Biomedical Inv. & Research	Susan.szpunar@ascension.org
Deborah LaBuda	Administrative Asst. II	Deborah.spampinato@ascension.org
Lee Bowen, MPA, CIP, CHRC	IRB Coordinator	Lee.booze-battle@ascension.org
Karen Hagglund, MS	Clinical Scholar	Karen.hagglund@ascension.org
Alice Mar, BA	Clinical Scholar	Alice.mar@ascension.org
Shelby Miller, MPH	Clinical Scholar	Shelby.miller@ascension.org
Kathleen Riederer, MT, ASCP	Research Scientist, ID Lab	Kathleen.riederer@ascension.org
Othuke Abada, MS	Clinical Scholar	Othuke.abada@ascension.org
Natalie Smith, BA	IRB Coordinator	Natalie.smith5@ascension.org
Grace Imel, BS	Research Assistant	Grace.imel@ascension.org

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