Upcoming QA Live Webinar

Deviations vs Deficiencies

Tuesday, June 11th, 2024 @ 11:00am Central

Registration information will be upcoming in SWOG Broadcast Emails, CTSU Broadcast Emails, and SWOG's Spring Group Meeting in Seattle.

Best Practices for Informed Consent

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SWOG CANCER RESEARCH NETWORK

NCI National Clinical Trials Network
a National Cancer Institute program

NCI Community Oncology Research Program
A program of the National Cancer Institute of the National Institutes of Health

Disclosure to Participants

- To receive contact hours:
  - You must attend at least 80% (50 minutes), of the educational activity and complete all the required questions on the post-activity evaluation.
  - You can access the evaluation through the link that will be shared during the program.
  - You will receive your certificate within approximately one week after completing the evaluation.
- No one with the ability to control content of this activity has a relevant financial relationship with an ineligible company.
- This nursing continuing professional development activity was approved by the Maryland Nurses Association, an accredited approver by the American Nurses Credentialing Center's Commission on Accreditation.
- The expiration date for the enduring activity is March 15, 2026.

Historical Review

The Nuremburg Code, Declaration of Helsinki, and Belmont Report were all developed and put in place in reaction to ethical abuses by researchers.

GCP Key Point - The protection of human rights, safety, and well-being of human subjects is the foremost concern in the conduct of clinical trials.

Historical Review

Nuremburg Code

In 1949, the Nuremburg Code was born out of the criminal trials of Nazi researchers who conducted unethical experiments on humans during WWII.

The Code is a set of 10 points that establishes a foundation for voluntary consent of research subjects as well as most of the key ethical principles of modern human subjects research.

Historical Review

Nuremburg Code

1. The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion, and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment. The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.

Historical Review

Nuremburg Code

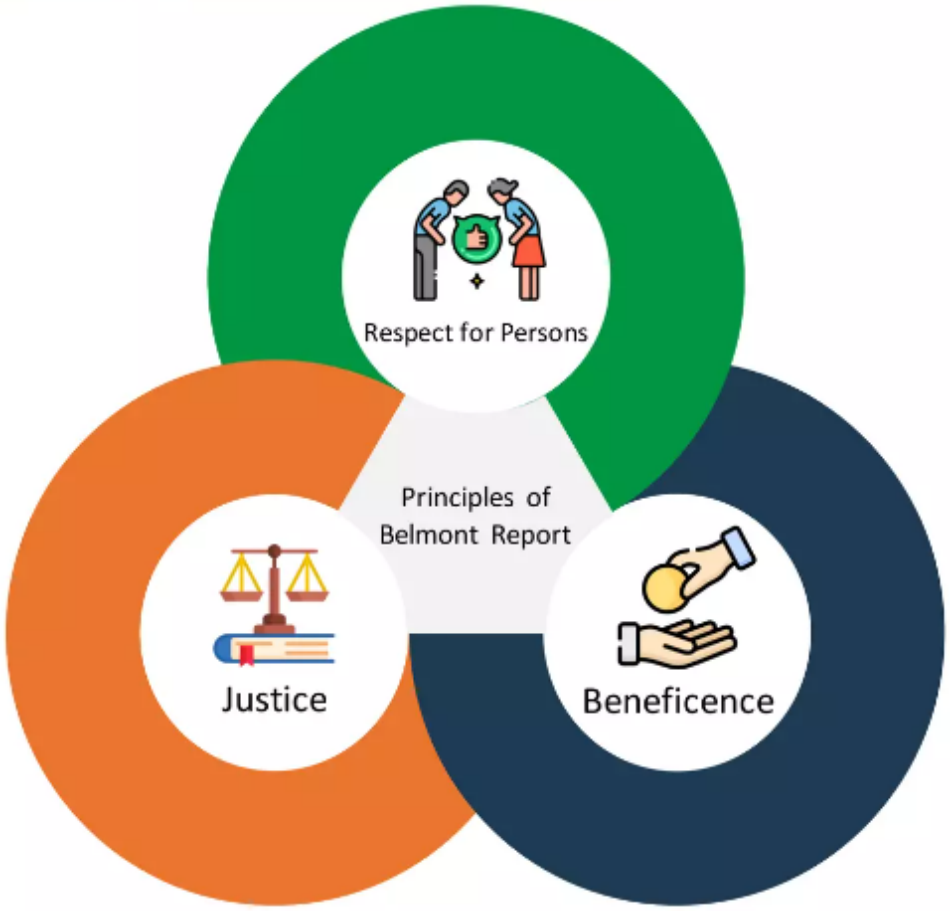
9. During the course of the experiment, the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.

Historical Review

Declaration of Helsinki

In 1964, the Declaration of Helsinki took the ethical principles for conducting research on humans to a new level through the efforts of the World Medical Association.

Historical Review



Belmont Report

In 1979, the Belmont Report was published by the National Commission and joined the Nuremburg Code and Declaration of Helsinki as a fundamental policy document describing the application of ethical principles such as respect for persons, beneficence, and justice in the conduct of behavioral and biomedical research involving humans.

https://www.slideshare.net/ClinosolIndia/the-belmont-report-three-benchmark-rules

The Document - Regulations

ICH GCP (ICH E6(R2) - Four Key Principles:

#2.3 The rights, safety, and well-being of the trial subjects are the most important considerations and should prevail over interest of science and society.

#2.7 The medical care given to, and medical decisions made on behalf of, subjects should always be the responsibility of a qualified physician or, when appropriate, of a qualified dentist.

#2.9 Freely given informed consent should be obtained from every subject prior to clinical trial participation.

#2.11 The confidentiality of records that could identify subjects should be protected, respecting the privacy and confidentiality rules in accordance with the applicable regulatory requirement(s).

The Document – CIRB/Boilerplate

What is boilerplate language?

- It's the institution's standard template language that is inserted into a CIRB-approved model consent form. Boilerplate language is not the same thing as your institution's template consent form.

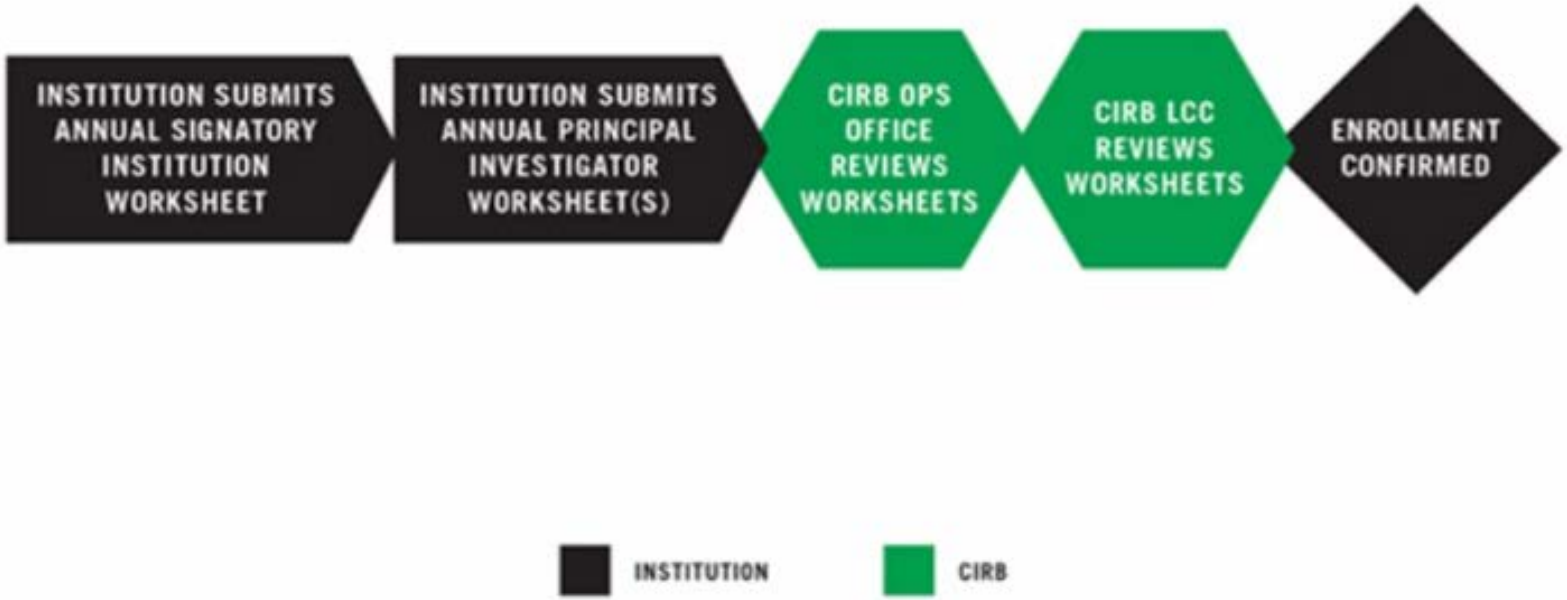
Some examples of boilerplate language are:

- Local contact information.
- State and local laws pertaining to informed consent.
- Institutional policy related to research on NCI-funded studies.

The Document – CIRB/Boilerplate

All trials under the NCI CIRB must use the CIRB-approved model consent forms as a basis for local consent forms.

- Site-specific boilerplate language must be approved by the CIRB. This submission takes place via the Annual Signatory Institution Worksheet



The Document – CIRB Implementation

When the Network distributes an amendment to a study, any changes to the consent form included as part of the amendment need to be made. Within 30 days of an amendment, the Signatory Institution must update any CIRB-approved boilerplate language not already implemented in the consent document for all studies open to enrollment. If the only change to the consent form as a result of the amendment is the Protocol Version Date, the Protocol Version Date must be updated in the institution's consent form.

Changes already approved as part of the amendment and changes to the Protocol Version Date do not require further CIRB review.

Who Can Obtain Informed Consent?

Principal investigators are responsible for assuring that all investigators obtaining consent are qualified and appropriately trained to explain the research and assess participant comprehension as described below. Any person who may obtain consent in a study should be listed in the IRB application as key personnel, though the person need not be listed as an investigator in the consent document itself.

https://irb.ucsf.edu/obtaining-and-documenting-informed-consent#Qualifications-of-person-obtaining-consent

Who Can Obtain Informed Consent?

Individuals who are knowledgeable about the protocol must obtain consent from subjects for participation in a study. Specifically, they must be able to describe the purpose, procedures, benefits, risks, and alternatives to participation in the study. They must be able to answer subjects' questions about the protocol and about risks of the research procedures and alternatives.

The PI must identify all individuals who will obtain consent and attest that they fit the above criteria. The PI is ultimately responsible for ensuring that ethically and legally valid consent is obtained from all research subjects.

Determination of Capacity

It is important that the individual who provides consent is assessed to determine if they are impaired and if they have the capacity to make a fully informed decision about participation in the study or if they require the assistance of a legally authorized representative (LAR).

The potential participant should be assessed for alertness, memory, language, and whether the potential participant can distinguish between past and present.

Witness/Legally Authorized Representative

Per Federal regulations, LAR means “an individual, or judicial, or other body authorized under applicable law to consent on behalf of a prospective research subject to the subject’s participation in the procedure(s) involved in the research” (45 CFR 46.102(c) and 21 CFR 50.3(l)).

The 2018 Revised Common Rule provided clarification to supplement this definition. Specifically, “in jurisdictions where there is no applicable law for allowing an LAR to provide consent on behalf of a prospective research subject, LAR means an individual recognized by institutional policy as acceptable for providing consent in the non-research context on behalf of the prospective research subject to the subject’s participation in the procedure(s) involved in the research” (45 CFR 46.102(i)).

Witness/Legally Authorized Representative

Effective 10.03.2022

Revised Guidance Regarding The Requirements For Using A Witness

The NCI CIRB has updated its guidance regarding the requirements for a witness. Witnesses will no longer be required by NCI. The inclusion of a witness in the remote consent process is now dictated by local institutional policy and must follow FDA and OHRP requirements.

Assent

- The CIRB makes a determination regarding the requirement for assent and the age determination.
- Institutions enrolling children must obtain assent from any child in the age range determined by the CIRB.
- Local policy determines the documentation of the assent.
- If a child in the age range determined by the CIRB cannot provide assent, an Assent Waiver must be requested from the CIRB and obtained prior to enrollment of the child.

https://ncicirb.org/institutions/institution-quickguides/special-considerations/determining-assent-requirements

Consenting Non-English Speakers

What are the requirements for including non-English speakers in a study?

As required by The Department of Health and Human Services (DHHS) regulations (45 CFR 46.116 and 45 CFR 46.117) and FDA regulations (21 CFR 50.25 and 21 CFR 50.27):

- Unless written consent has been waived as a requirement for the study, the participants who do not speak English must be provided with:
  1) A written consent document in a language understandable to them AND
  2) An interpreter fluent in both English and the participant's spoken language to aid in the consent process

Is there more than one type of written consent form for non-English speakers?

Depending upon the research, the written consent document can be either:

a) a translation of the entire English version of the approved consent document OR
b) a “short form” consent document stating that the elements of consent have been fully presented orally

CTSU Short Form Consent Library

Reconsent

How do I determine whether or not re-consent is required?

If the Study Chair or the CIRB requires study participant consent using the most recent amendment, the CIRB notes this determination in the amendment review Outcome Letter.

If the Study Chair indicates re-consent is required when the amendment is distributed but the CIRB does not, then the Study Chair's direction takes precedence.

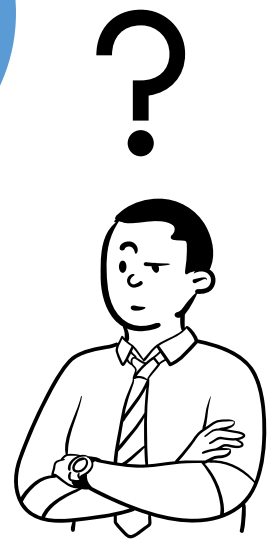
If local policy requires re-consent when the Study Chair or CIRB do not, then local policies should be followed.

Informed Consent

A process, not a document

The Process of decision making

Understand + Appreciation + Reasoning = Express a choice



Solomon, et.al (2021); Kadam (2017)

Poll question

How do you assess patient understanding during the informed consent discussion?

A. Ask the patient if they understand?
B. Ask if the patient has any questions?
C. Teach Back/Talk Back throughout
D. Other
E. I don’t conduct consent discussions.

Assuring Comprehension

- “Investigators are responsible for ascertaining that the subject has comprehended the information . . Because the subject’s ability to understand is a function of intelligence, rationality, maturity and language, it is necessary to adapt the presentation of the information to the subjects' capacities”[1]
- As the risk increases, the obligation on the researcher increases as well.

[1]The Belmont Report 1979;
Solomon, et.al (2021); Kovane, et.al (2022); O’Sullivan, et.al. (2021); Godskesen et.al. (2023)

https://www.youtube.com/watch?v=72SM8E0h2Ts

Factors inhibiting informed consent

- Time
- Environment
- Literacy
- Capacity
- Therapeutic Misconception

SWOG CANCER RESEARCH NETWORK

O'Sullivan (2021); Doerr (2018); Perni, et.al (2023)
https://www.vecteezy.com;

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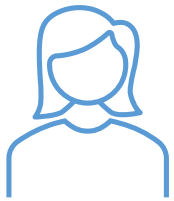
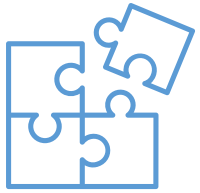
Facilitating Quality Decision Making



Know your patient

Adult Teaching Learning Theory



Teaching Aids

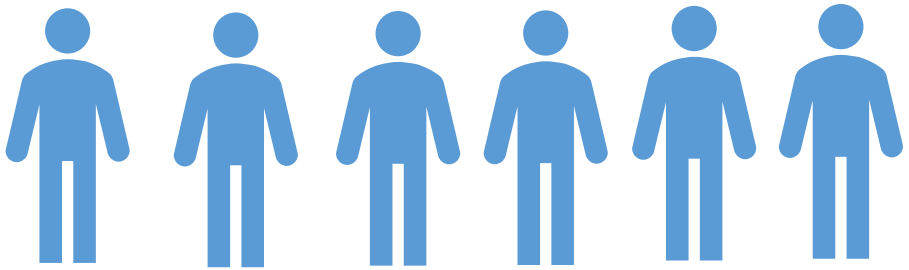
Coleman (2023); Gregersen, et.al. (2022); Kadam (2017); Pike (1989); Laird (1985)

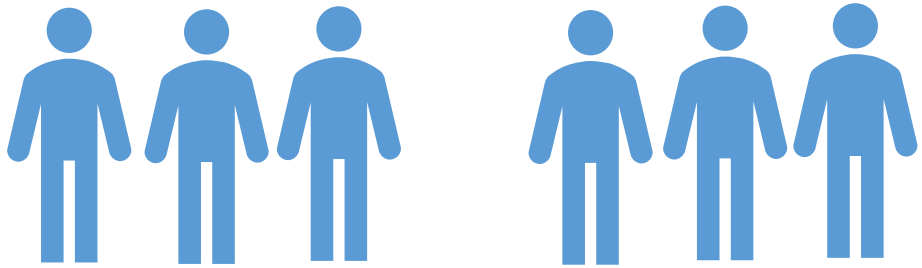
Multi-Media

- Mixed evidence
- Randomization & Placebo's
  - OHRP Video: https://www.youtube.com/watch?v=MmpF1zxfQZ8
  - NCI Randomization: https://www.youtube.com/watch?v=e-RH60crR64
  - Stand up to Cancer/ Placebos: https://www.youtube.com/watch?v=QBWBl-0s61w
- IRB Review

Perni, et.al (2023); Kadam (2017);

Metaphors

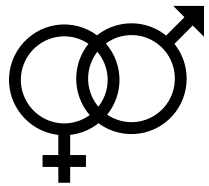




Arm 1 Arm 2

Randomization:

- Coin toss
- Drawing numbers out of a hat for a team.
- The sex of a baby

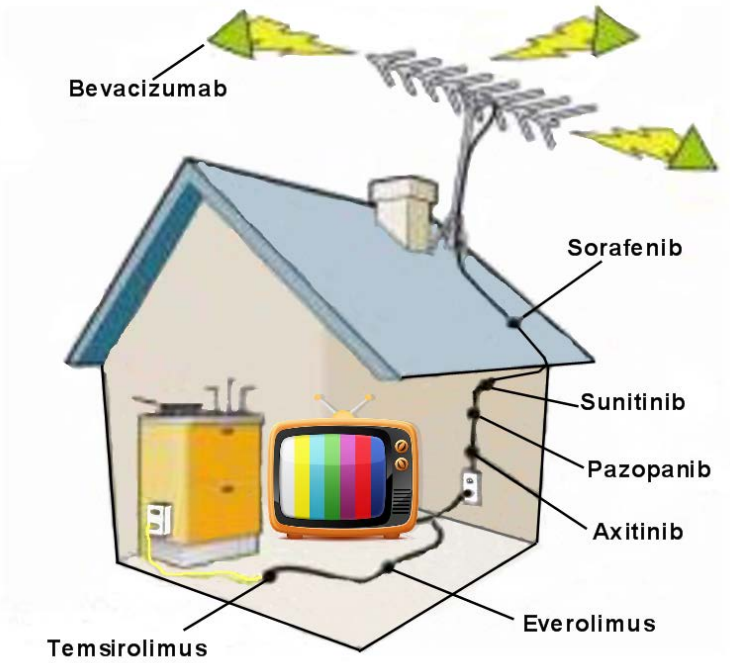


Placebo

People Cut outs

O'Sullivan et.al. (2021); Kadam (2017); Grady (2018)

Explaining Treatment



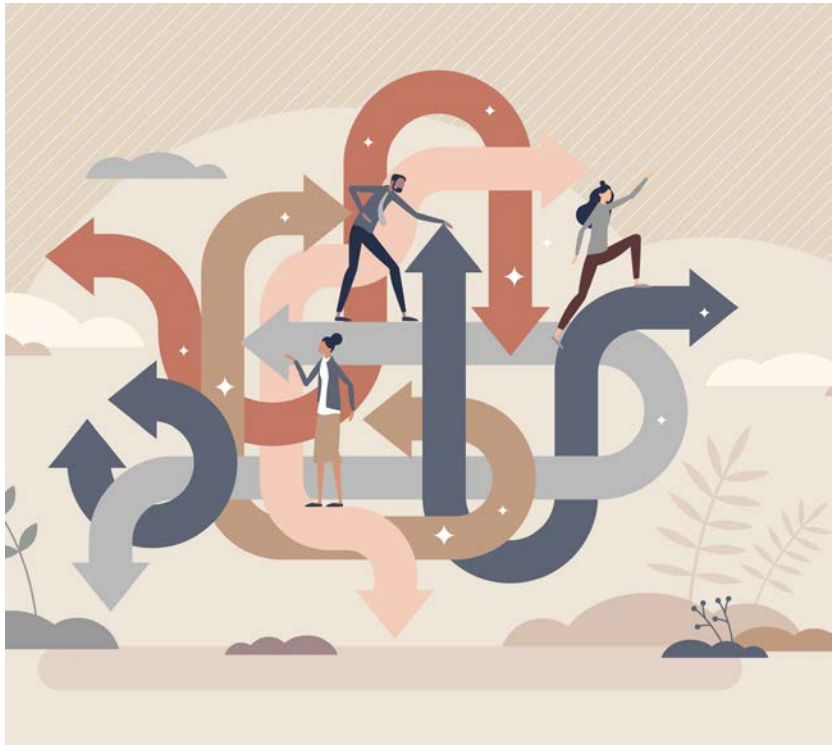
Chemotherapy

Targeted therapy

Immunotherapy

Kadam (2017); Wood (2013)

Assessing understanding



- Teach back/ Talk Back
- Open ended Questions
- Patient Stories
- Side Effect percentage
- Post consent process phone call

Perni, et. al (2023); O'Sullivan et.al (2021); Grady (2018); Kadam (2017)

You are asked to review a consent with a prospective patient. After describing the two treatments and randomization, the patient says, “So, my information will be put into a computer, and I will receive the treatment that is best for me.” What is the best response:

A. That is correct.
B. I think you get the idea, lets go on.
C. Although some of your health history is collected, it is used to make sure the groups are alike. The treatment is assigned randomly.
D. Answer C, & consider using a teaching aid for stratification & randomization

Questions?