

The Consent Process

**Sherri Jarvis, Clinical
Trials Manager
Department of Surgery
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Sherri Jarvis, Clinical Trails Manager

Department of Surgery

Ms. Jarvis is currently the Clinical Trials Manager, Lead Study Coordinator for the Department of Surgery. She has worked at Duke since 1984 in both patient care and research. She received her BS in Nursing, Cum Laude, from the University of Mississippi.

Elements of Consent

- Elements of consent come from 45 CFR 46.116
- The HIPAA elements of consent come from 45 CFR 164.508 (c)

What is informed consent?

- Informed consent is not a single event, or just a “form” to be signed. It is an educational process that takes place between the investigator and the potential subject. It is ongoing throughout the course of the subject’s participation in the study.

Informed Consent is a Process

- Starts with IRB submission
- Requires a plan
- Requires documentation
- Ends with the IRB final report

The Consent Process Includes:

The consent process needs to include full disclosure of the nature of the research and the subject's participation.

There must be adequate comprehension on the part of the potential subjects.

The Consent Process (cont)

- Remember to respect the individual
- Provide privacy
- Environment should be conducive to allowing the potential subject to ask questions

IRB Summary- Process

Describe in detail the steps you will follow

Have documentation to support what you do

Think of problem areas and how to work thru

Be prepared to hit obstacles

It is OK to change your process- **AS LONG
AS THE IRB APPROVES IT FIRST!**

IRB Summary- Time

How much time will you initially spend with potential subjects?

How long will subjects have to decide- **BE HONEST-**

Subject's with Diminished Capacity

How will diminished capacity be assessed?

Who will assess?

Know how to use LAR (legally authorized representative)

Legally Authorized Representative

Court appointed guardian

Health care agent

Spouse

Adult son and/or daughter

Parent

Adult brother and/or sister

Uncle and/or aunt

Other adult kin

Diminished capacity

Describe reassessment- who, when

Re-consent as soon as possible- and re-start the informed consent process!!

Documentation

- Progress note
- E-browser- allows others to see what trials a patient may be participating in
- Remember- it is a process and you should be continually documenting

Example of documentation

- Study coordinator (protocol XXX eIRB #)

The above referenced study was explained to Mr. Jones, informed consent was given to patient. Patient would like to take consent home to discuss with family. Patient is scheduled to RTC on X date. I will follow up with pt then.

Documentation (cont)

- Study coordinator (protocol XXX eIRB #)

Mr. Jones returned to clinic today and has agreed to participate in the above referenced study. He had several questions which I answered. Pt verbalized understanding of the trial. Informed consent was signed, a copy was given to the subject, and a copy was placed in the medical record.

Documentation (cont)

- Continue to document pertinent information about the study
- When the subject returns for visits, it should be documented that the subject is willing to continue in the study

Subject Complaints

- Subjects feel they are coerced- study MD is treating MD
- Lack of privacy
- Remember that subjects have the IRB phone number and can and do call the IRB with complaints

Conclusion

Informed Consent is a process

When in doubt, call the IRB

Treat potential subjects as you or your loved ones would want to be treated