

Overview

The concept of informed consent is rooted in two important historical documents, the [Nuremberg Code](#) and the [Belmont Report](#). (See the Introduction to this Standard Operating Procedures Manual for a summary of the implications of these historical sources for the IRB approval process.)

The informed consent process is a fundamental mechanism to ensure respect for persons (a Belmont principle) and individual autonomy by making sure that individuals' consent to participate in the study as subjects is a thoughtful, consensual, and voluntary act. Thus, informed consent is at the core of research ethics and therefore of IRB review. We hold that it is a process, *not a one-time event concluded upon the issuance of a piece of paper*.

Our guiding principle is that subjects' consent must be knowledgeable and voluntary. The informed consent process must provide enough information and time to absorb it, and should encourage each prospective subject to explore his or her own values in such a way that these can be reflected in the decision being taken.

The following sections describe procedures the IRB follows to ensure this outcome.

- A) [Evaluation of compliance](#)
- B) [Protection of vulnerable subjects](#)
- C) [Participant understanding and voluntary decision-making](#)
- D) [Documentation of informed consent process](#)
- E) [Waiver or alteration of consent process](#)
- F) [Exceptions in emergency situations](#)
- G) [Monitoring the consent process in ongoing research](#)

REFERENCES:

AAHRPP STANDARD II-7: The Research Review Unit, including the IRBs, has and follows written policies and procedures that require informed consent to be solicited from research participants or their legally authorized representatives and verify that this requirement is met.

[RU ORSP Informed Consent guidance](#)

[OHRP IRB Guidebook, Chapter 3.B.](#) (1993) Robin Levin Penslar, J.D., principal author and editor.

[OHRP Informed Consent Checklist](#)

[OHRP Informed Consent Tips](#)

[45 CFR 46](#)

Lilford, R.J. (2003). Ethics of clinical trials from a Bayesian and decision analytic perspective: whose equipoise is it anyway? *BMJ* 326, 980-981.
<http://bmj.com/cgi/content/full/326/7396/980>

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¹Robert Amdur, M.D. (2003). *The Institutional Review Board Member Handbook*. Sudbury MA: Jones and Bartlett Publishers.

A. Evaluation of compliance

What key elements does the IRB use to evaluate a study's informed consent process?

Three key elements constitute the informed consent process:

- Presenting information to the prospective research subject
- Providing adequate opportunity for the individual to ask questions and have them answered
- Documenting the voluntary decision to participate in a coercion-free environment.

The Rutgers University IRB reviews all proposed research to determine how the investigator intends to embody these three key elements in the research:

- The procedures used to obtain informed consent should be designed to educate the potential subjects in terms they, *or their designees*, can fully understand. Explanation of the study's purpose, duration, experimental procedures, alternatives, risks and benefits must be presented in such a way that the complete understanding of the subject is assured.
- Investigators must assure that individuals have enough information and time to get answers to any questions they have.
- And the research protocol must describe how the voluntary decision is to be documented, and provide the specific text of the proposed informed consent document.

Whether a study qualifies for exempt status, expedited or full review, the *Rutgers University* IRB requires investigators to submit their research design and informed consent process and have IRB approval before recruiting subjects. An investigator's consent process and documents must be shown to be appropriate to the population and risk level of the proposed research. (See Section B, following, [protection of vulnerable subjects](#).)

The RU IRB also requires investigators to use only the consent form that was submitted to the IRB and approved. (See Section D, [documentation of the informed consent process](#).)

REFERENCE:

AAHRPP II-7.A. The RRU evaluates compliance with policies and procedures on seeking informed consent from participants or their legally authorized representatives, and assent, when possible, from participants who cannot give consent.

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B. Protection of vulnerable subjects

What does the term ‘vulnerable subjects’ mean?

The principle of Respect for Persons in the Belmont Report requires us to treat individuals as autonomous agents, and to protect people with diminished autonomy. The term “vulnerable” is used to describe people whose autonomy may be compromised in making decisions about participating in research or have diminished cognitive capacity.¹

Vulnerable populations include, for example, children, cognitively impaired individuals, and prisoners. In addition, any subjects whose circumstances reduce the autonomy of their decisions are vulnerable.

The *Rutgers University* IRB considers risks inherent in all potential subjects’ situations, relationship to the investigator, and other factors, to assess risks to the consent process. For example, in research sponsored by an organization where the employees are the subjects of the research, each employee is potentially vulnerable to explicit or implicit pressures to participate. Students are similarly exposed as subjects in the research projects conducted by faculty or instructional staff. These pressures reduce individuals’ autonomy, because the subjects may feel compelled to participate if their bosses or teachers want them to. The subjects may believe that they are in vulnerable power relationships with these authority figures, and consent to participate in research only for that reason. Consent under these conditions *may not be* genuine consent.

Therefore, we also educate investigators and the university community to increase awareness of the risks and researchers’ responsibilities in ensuring that the informed consent process is comprehensive. Considerations the IRB uses to evaluate the balance of risk and benefits of research are described in these SOPs in [Standard II-4](#).

This section describes the steps the University and the IRB take to ensure that research projects identify and protect vulnerable subjects.

What does the IRB consider to ensure that proposed studies protect vulnerable subjects?

The following are among the chief concerns of the IRB in reviewing research with vulnerable subjects:

Genuinely voluntary consent. The Rutgers University IRB reviews proposals which involve vulnerable subjects in research with awareness of the additional measures required to ensure that consent is thoughtful and coercion free, and that it is a truly voluntary act.

Self-determination. The principle of self-determination, however, requires the IRB to ensure that individuals are not protected so much that they are *prevented* from making their own decisions about research participation. The pool of subjects for the research should be as diverse as possible given its aims.

Eliminating coercive aspects. In any proposed research, the IRB may require investigators to revise the process to eliminate coercive aspects, or to improve the clarity and transparency of consent material, or they may reject protocols that cannot do so.

Anonymity. The IRB recommends that research with vulnerable subjects be anonymous whenever possible, in observational or survey studies not involving medical procedures. Studies with vulnerable populations often involve the risk that the institution in which they are housed (the school, workplace or prison, for example) can use the information obtained in the course of the research adversely against the subject. But if no names of subjects are linked to their survey responses or observational data, and if steps are taken to avoid reporting the data in demographic groups that would identify individuals, there is no chance of this occurring. The subject and/or parent or guardian must still consent to anonymous research, but since it has less chance of being used improperly, the IRB is more likely to approve it.

The ORSP website offers IRB members and investigators detailed [Informed Consent Guidance](#) and sample forms, explaining federal regulations and OHRP guidance. The following paragraphs summarize the protections the IRB looks for in evaluating research protections for the following vulnerable populations:

- [Children](#)
 - 1) [Assent of children](#)
 - 2) [Parental permission](#)
 - 3) [Wards of the State](#)
 - 4) [Parental permission in New Jersey](#)
- [Individuals with cognitive impairment](#)
- [Prisoners and juvenile offenders](#)
- [Rutgers University students](#)

What Informed Consent procedures are required to protect children?

Following are the Federal regulations:

1) Assent of Children

Investigators need to demonstrate that they have made adequate provisions for asking for children's assent (agreement) to participate in the study, when the children are capable of providing assent. Assent is usually required in addition to

parental permission; in rare cases, the requirement for parental permission may be waived (see the [Parental Permission](#) section below).

To determine whether children are capable of assenting, the IRB will review whether the investigator has taken into account the age, maturity, and psychological state of the children involved. In some cases, all children who participate in a particular study may be capable of providing assent, and in other cases, only some of the children may be capable. The investigator is not obligated to require that ALL of the children in a study must or must not agree to participate so long as provisions are provided to ensure the fair treatment of all children.

The IRB may waive assent if the children are not cognitively able to understand the concept of participating in a particular study, or if participation is likely to benefit the child and the benefit can only be obtained by participation. Even where the subject children are capable of assenting, the IRB may still waive the assent requirement under circumstances in which Consent may be waived (See [Standard II-7.E.](#)).

There is no required format for children's assent. The format and content of an assent statement may be highly variable, but it must be tailored to the particular child or children involved. The investigator submits the proposed text of the assent to the IRB with the protocol for review. The IRB will verify that it is developmentally appropriate, offers an explanation of the study, and provides the child with the opportunity to agree to participate or refuse participation. A [sample](#) is available on the ORSP website.

Written documents, as well as oral scripts, are acceptable. The child may be asked to sign a document or agree orally, and the investigator must document any oral assent.

2) Parental Permission

Permission from one or both parents or guardians is required when a minor will be involved in research. Assent (agreement) from the child must be sought wherever feasible, but may or may not be required, depending upon the particular study and characteristics of the child (see the [Assent of Children](#) paragraphs above). Under very specific circumstances, the requirement for parental permission may be waived by the IRB (see item d. below).

The following paragraphs describe the four categories of circumstances when the permission of either one or both parents (or guardians) is required.

Category a. When is the permission of one parent sufficient?

The permission of one parent is sufficient for research in which one of the following circumstances is true:

- The study presents no greater than minimal risk to children

or

- The study presents more than minimal risk to children but the intervention or procedure holds out the prospect of direct benefit for the individual child, or involves a monitoring procedure that is likely to contribute to the child's well being. In this case, the protocol must meet all of the following conditions:
 - The risk must be justified by the anticipated benefit to the child;
 - The relation of the anticipated benefit to the risk must be at least as favorable to the child as that presented by available alternative approaches;
- and
- The investigator adequately provides for soliciting the assent of the children and permission of their parents or guardians.

When must the investigator get the permission of both parents or guardians (categories b. and c.)?

Unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child, both parents (or guardians) must give their permission when study risk is greater than minimal and the study is not expected to contribute to the individual child's well being:

Category b. Permission of both parents is required when an intervention or procedure presents more than minimal risk to children and does not hold out the prospect of direct benefit for the individual child subject, or when a monitoring procedure which is not likely to contribute to the well being of the child presents more than minimal risk. In this category, the IRB must find all of the following conditions in order to approve the research:

- The risk represents a minor increase over minimal risk;
 - The intervention or procedure presents the subject children with experiences that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;
 - The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition;
- and
- The investigator makes adequate provisions for soliciting assent of the children and permission of their parents or guardians.

Category c. When research cannot be approved under categories a. or b. described above, it may be approved by the Secretary of the Department of Health and Human Services (DHHS) after expert consultation and public review or by the IRB (if it is not funded by DHHS), if it meets other stringent conditions. To be approved by DHHS or the IRB, research in this category must meet all of the following conditions:

- The research must present a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;
- The research will be conducted in accordance with sound ethical principles;
- The investigator has made adequate provisions for soliciting the assent of children and the permission of their parents or guardians, as set forth in [45 CFR 46.408](#).

Category d. When may the IRB waive parental consent requirements?

If the IRB determines that a research protocol is designed for conditions or for a subject population where it is not reasonable to require parental or guardian permission to protect the subjects (for example, neglected or abused children), the IRB may waive the consent requirements described above, under two provisions:

- An appropriate mechanism for protecting the children who will participate as subjects in the research is substituted

and

- The waiver is not inconsistent with Federal, state or local law.

3) Wards of the State

What are the limitations on including Wards of State in research?

Investigators are further limited in how they may include children who are wards of the State or any other agency, institution, or entity (Wards of the State include juvenile offenders). Children in these circumstances can be included in research described in Categories b. and c. under [Parental Permission](#) above, only if the research meets one of the following additional requirements:

- The research is related to their status as wards;

or

- The research is conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

Required appointment of a Child Advocate

If the IRB approves research involving wards of the state under the limitations described above, the IRB must also require that an advocate be appointed for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or *in loco parentis*. *The IRB can nominate a member of the IRB to act as the advocate as long as the advocate is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization.*

One individual may serve as advocate for more than one child. The advocate must be an individual who has the background and experience to act in, and who agrees to act in, the best interests of the child for the duration of the child's participation in the research.

4) Parental permission in New Jersey

Federal regulations define children as “persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.” *New Jersey state law defines the age of majority, or the age at which one acquires the full legal rights of an [adult](#), to be 18 years of age (N.J. Stat. Ann. §§ 9:17B-1, -3).*

In regard to the child’s assent and parental consent, the regulations above apply in New Jersey. *If a court has granted custody of a child to a youth authority (such as the Division of Youth and Family Services [DYFS]) within the NJ Department of Human Services, then this authority has to consent, and not the parents, who by virtue of loss of custody have lost authority over the child. If a court has not granted custody (which sometimes happens if the parents were not judged to have contributed to the cause of a child’s delinquency), then one or both parents must consent. Except as noted above in the information about [Assent of Children](#), the investigator must seek the assent of the minor.*

What steps are required to protect individuals with cognitive impairment?

The ORSP [Informed Consent Guidance](#) describes a number of special considerations in the consent process for individuals who have cognitive impairments. These are summarized in the following paragraphs.

Informed Consent in NIH-funded programs

NIH policy guides Informed Consent to research involving cognitively impaired subjects that is funded through any of the intramural programs of the National Institutes of Health. This policy sets out, in matrix form, conditions under which cognitively impaired subjects may participate in research of varying risk. See the NIH Information sheet at <http://ohsr.od.nih.gov/info/sheet7.html>.

Presumption of competence

As a general rule, all adults, regardless of their diagnosis or condition, should be presumed competent to consent unless there is evidence of serious mental disability that would impair reasoning or judgment. Even those who do have a diagnosed mental disorder may be perfectly able to understand the matter of being a research volunteer, and quite capable of consenting to or refusing participation. Mental disability alone should not disqualify a person from consenting to participate in research; rather, there should be specific evidence of individuals' incapacity to understand and to make a choice before they are deemed unable to consent.

When should the IRB consider using an independent agent to assess capacity to consent to research?

Typically, it is the consent interviewer who assesses the capacity to consent to research. However, when research is proposed that involves potential subjects that may lack the capacity to consent and is greater than minimal risk, the IRB may consider using an independent agent to assess capacity. The IRB may require a licensed clinical psychologist, psychiatric social worker, or gerontologist to assess capacity to consent in this case.

What are the standards that should be used to assess capacity to consent?

The level of capacity that is required to consent will vary from study to study depending on the complexity of the decisions to be made. For example, a blood draw requires less capacity than involvement in a placebo-controlled drug study. The IRB and investigators should consider the following four standards when assessing the capacity of a subject that may be cognitively impaired.

- *At all risk/benefit ratios, the subject should possess the ability to evidence an autonomous and thoughtful choice; more specifically, the subject should be able to communicate a yes or no decision.*
- *At all risk/benefit ratios, the subject should possess the ability to understand the relevant information presented about the research procedures and what the consent information includes. For example, the subject should be able to understand that they have the right to withdraw from the study with no penalty or loss of benefits to which the subject is otherwise entitled.*
- *For research that involves more than minimal risk, the subject should possess the ability to understand what the research participation involves, what the likely outcomes of the research are, and the possible consequences of participating in the research (including both risks and benefits).*
- *For research conducted at the most unfavorable risk/benefit ratios, the subject should possess the ability to manipulate information rationally. For example, decisions should be consistent with the religious, moral, and other beliefs of the person.*

Who should be considered the representative for subjects who have been deemed incompetent to consent to research?

The representative identified to make health care decisions on the patient's behalf is generally the individual who should make decisions regarding the patient's participation in IRB-approved clinical research studies. If the patient has a valid

Durable Power of Attorney for Healthcare (“DPOA”) or a court-appointed guardian, this person should make the decisions regarding participation in research. In the case of adult patients who do not have a valid DPOA or court-appointed guardian or conservator, the representative should be an adult who has exhibited special care and concern for the patient, who is familiar with the patient’s personal values, and who is reasonably available. Consideration shall be given, if possible, in order of descending preference for service as a representative to:

- *The patient’s spouse;*
- *The patient’s adult child;*
- *The patient’s parent;*
- *The patient’s adult sibling;*
- *Any other adult relative of the patient; or*
- *Any other adult who satisfies the requirement of exhibiting special care and concern for the patient, who is familiar with the patient’s personal values, and who is reasonably available.*

Any decisions made by the subjects representative must be made in accordance with the patient’s individual health care instructions, if any, and other wishes, if known to the representative. If the patient has not given individual health care instructions, and the patient’s specific wishes are not known, decisions are to be made in accordance with the representatives determination of the patient’s desires or best interests in light of the patient’s personal values and beliefs to the extent they are known.

What conflicts of interest must the IRB consider?

Persons formally adjudged incompetent have a court-appointed guardian who must be consulted and consent on their behalf. Officials of the institution in which incompetent patients reside (even if they are the patient's legal guardians) are not generally considered appropriate, since their supervisory duties may give rise to conflicting interests and loyalties. Family members or others financially responsible for the patient may also be subject to conflicting interests because of financial pressures, emotional distancing, or other ambivalent feelings common in such circumstances. The IRB (and investigators) should bear this in mind when determining appropriate consent procedures for cognitively impaired subjects.

What procedures can investigators develop to enhance the possibility of consent?

Procedures can sometimes be developed to enhance the possibility that cognitively impaired individuals can consent for themselves. Criteria for determining competence might vary according to the degree of risk or discomfort presented by the research procedures and the extent to which therapeutic gains can be anticipated. The setting in which consent is sought and the person seeking it can also influence a potential subject's ability to comprehend or appreciate what is being asked. The National Commission recommended that, in certain cases, the

IRB appoint a consent auditor to determine whether proposed subjects consent, assent, or object to their participation in research, especially if the research involves more than minimal risk and no foreseeable direct benefit.

Such care for setting and circumstances applies to the consent process for all subject populations, but has particular importance in supporting the autonomy of children and others with emotional or cognitive challenges, and their right to participate.

Required certification in the consent document for individuals determined incompetent to consent

In addition to the elements of informed consent described above, consent documents for individuals who are determined to be incompetent to consent must contain a signature line for a legally authorized representative, Subjects may also be asked to provide assent, if they are capable of doing so.

Here is a sample certification statement that may be included in consent forms intended for legally authorized representatives of subjects who are cognitively impaired:

"As the legally authorized representative, your signature authorizes the participation of (name of subject) in this research study, which has been explained to you. The investigator has offered you the opportunity to ask questions, and they have been satisfactorily answered."

What steps are required to protect prisoners?

In addition to the consent procedures below, prisoners are given exceptional protections as research subjects under Federal regulations because their circumstances lend themselves to a variety of types of coercion.

From the [OHRP guidance](#) on research involving prisoners:

“The provisions of [45 CFR 46] Subpart C apply to any research conducted or supported by HHS in which prisoners are subjects. This includes situations where a human subject becomes a prisoner after the research has commenced. As the Purpose section of the regulation notes: "Inasmuch as prisoners may be under constraints because of their incarceration which could affect their ability to make a truly voluntary and uncoerced decision whether or not to participate as subjects in research, it is the purpose of this subpart to provide additional safeguards for the protection of prisoners [involved in human subjects research] ... These concerns apply whether the research involves individuals who are prisoners at the time of enrollment in the research or who become prisoners after they become enrolled in the research. In the latter situation, it is unlikely that review of the research and the consent document contemplated the constraints imposed by incarceration.”

The Rutgers IRB applies the standards of [45 CFR 46 Subpart C](#) to all research affecting prisoners, regardless of how the research is funded. This includes situations where a subject becomes a prisoner after the research has begun. In addition, the IRB must certify with DHHS its approval of all DHHS-funded research involving prisoners.

Federal standards for research with prisoners require the IRB to consult with experts in penology, medicine and ethics as appropriate, and to include a prisoner representative on the board when research with prisoners is reviewed. As OHRP guidance states: “In the absence of choosing someone who is a prisoner or has been a prisoner, the IRB should choose a prisoner representative who has a close working knowledge, understanding and appreciation of prison conditions from the perspective of the prisoner.”

Juvenile offenders are [Wards of the State](#), discussed above.

[OHRP guidance](#) on research involving prisoners includes the full text of the applicable Federal Regulations and definitions of minimal risk. ORSP administrators include this guidance in all reviewers’ packets. It is summarized here:

Federal regulations define minimal risk differently for prisoners

Minimal risk is defined differently for research with prisoners than for other types of research. Here are both definitions:

- For research that involves prisoners: [\[45 CFR 46.303\(d\)\]](#) "Minimal risk" is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.
- For research that does not involve prisoners: [\[45 CFR 46.102\(i\)\]](#) *Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Restrictions imposed on research involving prisoners

Because prisoners are least capable of resisting coercion, federal regulations restrict the kinds of research that may be done using prisoners as subjects. The IRB can approve proposed research with prisoners only with all of the following seven findings (when HHS funds the research, OHRP must also certify the findings):

- 1) The study design proposes a permissible category of research [\[45 CFR 46.306\(a\)\(2\)\]](#):
 - A. Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects
 - B. Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects.

If neither of these categories applies, then the research can be approved only by the Secretary of Health and Human Services after consultation and public notice in the Federal Register. It must be one of the following types of research:

- C. Research on medical or social and psychological conditions particularly affecting prisoners as a class
 - D. Research on innovative or accepted practices which have the intent and reasonable probability of improving the health or well-being of the individual subject.
- 2) Advantages a prisoner gains by participation are not of such magnitude as to compromise prisoners' autonomy in giving consent
 - 3) Risks are commensurate with those that would be taken by any subjects who are not prisoners
 - 4) Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners
 - 5) The information needed for consent is presented in language which is understandable to the subject population
 - 6) Participation in the research must have no effect on parole or conditions of incarceration, and prisoners must know this when consenting to participate
 - 7) Any follow-up examination or care of participants after the end of their participation is provided for, taking into account the varying lengths of individual prisoners' sentences, and the investigator has made provisions to inform participants of this fact.

What happens if a research subject becomes a prisoner?

Subpart C applies whenever any human subject in a research protocol that comes under federal regulations becomes a prisoner at any time during the study, not only where the research targets prisoners as subjects. In a situation where a subject becomes a prisoner after enrollment in a study that was not reviewed and approved as prisoner research, the PI must notify the IRB promptly. According to OHRP guidance,

“All research interactions and interventions with, and obtaining identifiable private information about, the now-incarcerated prisoner-subject must cease until the requirements of subpart C have been satisfied with respect to the relevant protocol. [The IRB must so notify the PI unless the IRB Chair makes the exception noted in the next paragraph.]

”NOTE: OHRP has allowed one important exception. In special circumstances in which the principal investigator asserts that it is in the best interests of the subject to remain in the research study while incarcerated, the IRB Chairperson may determine that the subject may continue to participate in the research until the requirements of subpart C are satisfied.

”Upon receipt of notification that a previously enrolled research subject has become a prisoner, the IRB should promptly re-review the protocol in accordance with the requirements of subpart C if the principal investigator wishes to have the

prisoner subject continue to participate in the research.”

What steps are taken to protect Rutgers University Students?

Rutgers University is aware that the circumstances of students reduce their autonomy in deciding whether or not to participate as subjects in research. The Rutgers Board of Governors has approved protective procedures designed to reduce the element of coercion or influence in any use of Rutgers students as subjects in the research projects conducted by faculty or instructional staff. These procedures are incorporated, with a full explanation of the principles involved, in the [Application for IRB review of human subjects research, Appendix A](#). The investigator attests to having read these procedures by signing the page.

Following are the protective measures University members are asked to adopt:

“... [I]ndividual faculty members and instructional staff, students, and departments that use students as experimental subjects, or that maintain "subject pools" of students from which investigators may draw research participants, are asked to adopt procedures meeting the following conditions:

1. Before they enroll in a course, students must be informed of the possibility that they may be asked to serve as research subjects in experiments under direction of the faculty.
2. If there is a course requirement that students serve as research subjects in such experiments, then alternative ways must be provided for students to meet this requirement. During the first week of classes, students should receive a written description of the various ways of meeting the requirement.
3. Each department that regularly requires students to act as research subjects should establish a committee composed of faculty and students to review the research projects involved. This committee should be responsible for hearing and acting on any student complaints in connection with the research-participation requirement.
4. All members of the faculty who invite students to act as subjects in their research must [complete the Human Subjects Certification Program](#) and become acquainted with the ethical standards that govern *research activities involving human subjects*.

REFERENCES

AAHRPP II-7.B. The RRU has and follows written policies and procedures requiring that prospective participants whose decision-making capacity may be in question are appropriately protected.

¹Robert Amdur, M.D. (2003). *The Institutional Review Board Member Handbook*. Sudbury MA: Jones and Bartlett Publishers, p. 25.

²*Ibid.* p. 26.

Susan J. Delano (2002). Research Involving Adults with Decisional Impairment. In *Institutional Review Board: Management and Function* (Eds. Robert J. Amdur and Elizabeth A. Bankert). Sudbury MA: Jones and Bartlett Publishers, pp. 389-393.

ORSP Human Subjects website [Informed consent Guidance and samples](#).

OHRP [Guidance on the involvement of Prisoners in Research](#) Revised 5/23/2003

Rutgers University [IRB Application, Appendix A](#) Use of Rutgers Students as Experimental Subjects in Research.

[NIH Information sheet #7](#), Research involving cognitively impaired subjects: A Review of some ethical considerations.

Procedure documents in M:\LSz\Procedures

C. Participant understanding and voluntary decision-making

The RU ORSP guidelines make clear to investigators and reviewers alike that Informed Consent is a process whose intent is to support the autonomy of prospective subjects in making a decision that they fully understand and willingly undertake. It is not a mere signature. In the application for IRB review, investigators describe how they will inform prospective subjects, and provide the actual forms or scripts they will use. The IRB makes recommendations when they are necessary to improve subject understanding and voluntary decision-making.

What is the scope of informed consent?

In order to make an informed choice about whether to participate in a study, potential subjects must understand what participation will mean to them:

- The intent of the study
- How they are to participate in the study (e.g., the research procedures to be followed)
- What kind of risks it poses to them and what benefits, if any, they are likely to derive
- Whom to contact if a problem arises.

The principal investigator must provide this information with the subject or the subjects legally appointed representative, provide sufficient opportunity for subjects to ask questions and have them answered, and, if applicable, re-state the information in the consent document.

ORSP gives investigators detailed [guidelines and examples](#) on its website for the IRB's informed consent requirements. The following section, [Documentation of informed consent process](#), describes the elements that investigators must include in the consent form itself.

When the research requires deceiving the subjects, how does the investigator handle informed consent?

Some behavioral research necessitates that subjects be initially deceived about the true purpose of the study as their behavior would be altered if they knew the real objectives, and the veracity of the data would be compromised.

However, deception may increase risk: whenever possible, investigators should construct research designs that avoid the need to deceive subjects, in order to minimize potential negative effects such as guilt, embarrassment, or psychological stress that may result as a consequence of the deception.

According to the authors of the *IRB Handbook* (Amdur 2003, 115-116)

By definition, deceptive procedures eliminate the possibility of fully informed consent. As a consequence, the [[American Psychological Association](#)] ethics code makes this explicit statement: ‘Psychologists never deceive research participants about significant aspects that would affect their willingness to participate.’ Although participants may not be fully informed, obviously they should be informed of as much as possible without threatening the ability of the researcher to test the true hypothesis of the study. Rutgers University recommendation is that the IRB should not approve a consent document that contains inaccurate information. Specifically:

- The consent document should never be used as part of the deception in that it should not include anything that is untrue or misleading.
- The consent document should reveal as much as possible to the participant regarding the procedures in the study.
- The consent document need not explain the details of the study if this will eliminate the capability of the study to inform the process under investigation. A useful guideline to keep in mind is that the experimenter-subject relationship is a real relationship ‘in which we have responsibility toward the subject as another human being whose dignity we must preserve.’

Also, provisions should be made for giving subjects a full debriefing after their participation in the study. This debriefing should inform the subject of the true aims of the study and deal with any problems that may arise because of the deception. Subjects should also be reminded that they can still withdraw from the study at this point and to have research data obtained about them be destroyed. See [Standard II-4B](#) for more information regarding research using deception.

When the validity of the research demands deception, the [Informed Consent Guidance](#) available on ORSP’s website spells out the issues for investigators, and the steps they need to take to protect their human subjects adequately. Standard II-4.B. describes what the IRB considers in evaluating research that involves deception.

How does an investigator make sure that subjects understand what they are agreeing to?

It is important to make the process of informing subjects and gaining their consent clear and complete. When subjects are not fluent in the language in which the research is being conducted, extra effort must be made to ensure their full understanding before they agree to participate, and also that they understand what is being asked of them while the research is in progress. This may mean providing translators and/or a copy of the informed consent documentation in their own language.

In describing the procedures, investigators should use “lay language” (short sentences and everyday vocabulary) orally and in the consent document. In English, for example, the following exchanges can be made:

Professor/Scientist/Lawyer Words

People Words

Administered	Given
Adverse	Bad
Approximately	About
Terminated	Stopped
The information gained may help scientists better understand	We may learn
Voluntary	Up to you
Unusual situations	Problems

Several websites offer lay English language equivalents for professional terms. The examples above are from Duke University's list of [Problematic Consent Form Words and Alternatives](#). The best check, of course, is learning from the subjects if they understand the agreement. *Some guidelines can be found [above](#) in Standard II-7.B.*

What sort of language should never appear in an informed consent form?

Federal regulations specifically forbid the use of exculpatory language in the informed consent document. Exculpatory language has been broadly defined by OHRP as "any language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights". Examples of some statements containing exculpatory language are as follows and should be avoided:

- I agree that the medical center will not pay me for any injuries that I might sustain as a result of participating in this research
- I agree that everything in this consent form is adequate and complies with the regulations.
- I understand that I will not sue the sponsor or the investigator for negligence
- Subjects agree to hold harmless all institutions, investigators, or sponsors affiliated with or in any way a part of this research protocol

As a general rule, it is best to simply set forth the simple facts of the research proposal and the institution's intent. The following two examples would not be considered exculpatory:

- The University Medical School has no policy or plan to pay for any injuries you might receive as a result of participating in this research protocol.
- As part of the research protocol, the investigators will extract some cells from the blood you have donated. The university may commercialize some of these cells that derive from the research. The university does not plan to share any profits with the subject from whom the cells were obtained.

REFERENCES:

AAHRPP II-7C. The RRU reviews the content of the consent process, including the consent document, if any, and the process through which it is obtained from each participant, focusing on measures to improve participant understanding and voluntary decision-making.

Procedure documents in M:\BR\Procedures

ORSP website [guidelines and samples](#).

Extensive indexes of lay language for informed consent in English:

- (University of California and Stanford):
<http://over.ucdavis.edu/HumanSubjects/HSDefinitions/HSGLOSSARY.htm>
- [Duke University Lay language equivalents](#)

Laurie Sloan, Jay Hull & Robert J. Amdur (2003). Deception of Research Subjects. In Amdur, R. *The Institutional Review Board Member Handbook*. Sudbury MA: Jones and Bartlett Publishers, Chapter 3-6.

Michele Russell-Einhorn & Thomas Publisi (2002). Exculpatory Language in Informed Consent Documents. In Amdur, R. & Bankert, E. *Institutional Review Board: Management and Function*. Sudbury MA: Jones and Bartlett Publishers, pp.239-241

[Revised APA ethics code \(2002\)](#) sections 8.07 and 8.08.

D. Documentation of informed consent process

How does the IRB evaluate the proposed informed consent process?

Investigators must document the procedure they will use to inform subjects in the informed consent process, as well as the agreement gained. The agreement itself is captured in a written consent form that the IRB approves. The subject or the subject's legally authorized representative signs it, and the investigator gives a copy to the person signing the form.

The ORSP website provides [detailed guidance on informed consent](#) for investigators and for IRB reviewers.

This section describes the components of the consent form.

Why a formal consent form?

The consent form has two purposes: (1) it is a record of the information provided to potential research subjects so they can make an informed choice about participating in a study, and (2) it documents their decision to participate.

Under certain [circumstances](#), the IRB is authorized to waive the requirement for written documentation of the informed consent process, or approve a consent procedure that alters or waives some or all of the elements of informed consent.

In the standard process, the investigator explains or reads the information in the consent form to the subject or the subject's legally authorized representative, who also reads the consent form before signing it. *Consent is documented in the following two ways depending on the presentation of study information:*

1. A **written consent document** *that embodies all the elements of informed consent required by 45 CFR 46.116 and may be read to the subject or the subject's legally authorized representative and the investigator gives either the subject or the representative adequate opportunity to read it and get answers to any questions before it is signed.*
2. A **short form written consent document** can be used that simply states that the elements of informed consent required by 45 CFR 46.116 have been presented **orally** to the subject or the subject's legally authorized representative. The subject or the subject's legally authorized representative then signs this short form written consent document. The IRB must also see and approve a written summary of what is to be said to the subject or the representative. This summary must be signed by both the person obtaining consent from the subject and a witness to the oral presentation. The subject receives a copy of the summary but does not need to sign it.

What elements must always be in the informed consent form?

Unless the IRB specifically waives any of the following elements, Investigators must include each of them in every consent form:

1. A statement that the study involves research
2. An explanation of the purposes of the research
3. The expected duration of the subject's involvement
4. A description of the procedures to be followed
5. Identification of any procedures, which are experimental
6. A description of any reasonably foreseeable risks or discomforts to the subject

The [ORSP guidelines](#) list the following as examples of risks to be described, if they are present:

- **Physical** - pain, physical discomfort, injury, illness or disease brought about by the methods and procedures of the research;
- **Psychological** - anxiety, fear, stress, confusion, embarrassment, depression, guilt, shock, loss of self-esteem, and/or altered behavior, occurring during the research situation or later, as a result of participation;
- **Social** - alterations in relationships with others that are to the disadvantage of the subject, including embarrassment, loss of respect of others, labeling with negative consequences, or diminishing the subject's opportunities and status in relation to others;
- **Economic** - cost to subjects for procedures, loss of wages or income, damage to employability;
- **Legal** - risk of criminal prosecution or civil lawsuit when research methods reveal that the subject has or will engage in conduct for which the subject or others may be criminally liable;
- **Loss of confidentiality** - confidentiality is presumed and must be maintained unless the investigator obtains the express permission of the subject to do otherwise. Risks include invasion of privacy, as well as the social, economic, and legal risks outlined above.

7. A description of any benefits to the subject or to others, which may reasonably be expected from the research
8. A disclosure of appropriate alternative procedures or courses of treatment, if any, which might be advantageous to the subject
9. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained, and the methods proposed to ensure it
10. For research involving more than minimal risk, an explanation as to whether any compensation is available, and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained
11. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject

12. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled.

Are there additional elements of consent for specific research projects?

Depending on the research project, investigators may need to include one or more of the following elements:

- A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable
- Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent
- Any additional costs to the subject that may result from participation in the research
- The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject
- A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject
- The approximate number of subjects involved in the study.

How does the research team know the consent form they are using is current and approved?

In April 2000, the Rutgers University IRB implemented a policy requiring that the consent document display the IRB approval and expiration dates. The intent of this policy is to assure that subjects enrolling in research studies sign the current version of the consent form.

The IRB stamps approved consent forms with the approval date and expiration date. Investigators may use either copies of this stamped form, or a form that contains exactly the same text as the stamped form, and carries in a footer the notation, "Approved by Rutgers University Institutional Review Board for the Protection of Human Subjects: *date*. Expires: *date*."

When does the consent process and document fall under the Health Insurance Portability and Accountability Act (HIPAA) requirements?

Documentation of HIPAA compliance under Federal regulations is not related to IRB review. Rutgers University ORSP is reviewing policy whether members of the Rutgers University IRB will serve as a Privacy Board when requested. However, there may be instances when investigators include HIPAA agreements as an adjunct to the Informed Consent process.

Entities covered by HIPAA requirements include organizations or individuals that provide health care, including mental health care, and conduct one or more specific transactions involving patients' Protected Health Information (PHI) related to health claims or billing electronically. Examples of covered entities include a healthcare provider, a health plan, or a health plan clearinghouse.

Under HIPAA, patients must explicitly authorize any use or disclosure of their Protected Health Information for purposes other than treatment, payment, or Other Healthcare Operations (TPO). Research uses of PHI require that the subject sign a HIPAA-compliant consent form, or that the researcher obtain a waiver of authorization from a Privacy Board or an IRB.

HIPAA informed consent requirements are in addition to the informed consent process that this Standard describes: they do not replace the informed consent process. Subjects' authorization may be combined with the research consent form, or it may be a separate document, but several elements are required, such as to whom the PHI will be disclosed, how long it will be retained, and the extent to which it is protected by the parties to whom it is disclosed. A Minimum Necessary Standard applies for purposes other than TPO, that is, the researcher may access only the PHI that is absolutely necessary to the approved research plan.

When Rutgers University researchers are performing any study in their role as members of a covered entity or if the research will be conducted at a site that is a covered entity, then the requirements of the HIPAA Privacy Standard (Privacy Rule) are directly applicable. Most such research conducted by Rutgers University faculty, staff or students takes place under the auspices of one of the university hospitals, and is reviewed by the hospitals' IRBs, so the RU IRB seldom needs to verify that the consent forms and processes are HIPAA-compliant.

The provisions of the Privacy Rule also apply indirectly if the researcher *receives* PHI from a covered entity. The covered entity may only release ("disclose") PHI to an outside party under specific circumstances: the subject has specifically authorized it (and the authorization is documented), the PHI is completely de-identified, a limited data set is generated, requiring a Data Use Agreement, or the IRB waives the authorization. The Minimum Necessary Standard also applies to this situation. A covered entity may also disclose PHI to researchers if the purpose is solely to prepare a research protocol; however, the researcher may not remove any PHI from the covered entity.

REFERENCES

AAHRPP II-7.D. The RRU has and follows written policies and procedures requiring that the investigator has and follows a procedure for properly documenting informed consent.

OHRP Guidance D(2) recommends affixing approval and expiration dates to informed consent documents and requiring that these dated documents be used in obtaining consent.

ORSP *Policies and Procedures*, VI. Stamped Consent Form.

Procedure documents in M:\LSz\Procedures

E. Waiver or alteration of consent process

When might the IRB waive or alter the consent process?

An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects, based on either of the following findings:

- That the only record linking the subject and the research would be the consent document, and the *principal risk* would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern;

Or

- That the research presents *no more than minimal risk* of harm to subjects, and it involves no procedures that would normally require written consent outside of the research context.

In cases where the IRB waives informed consent documentation, the IRB may require the investigator to provide subjects with a written statement regarding the research.

What latitude does the IRB have to approve an investigator's consent procedure that alters or waives some or all of the elements of informed consent?

The IRB has *some latitude depending on the research*. According to federal policy, an IRB may approve a consent procedure that does not include some or all of the [elements of informed consent](#) or alters them; or it may waive the requirements to obtain informed consent. However, the IRB may do this only where it can document either of the following circumstances:

- The research or demonstration project will be conducted by, or subject to the approval of, state or local government officials, and is designed to study, evaluate, or otherwise examine:
 - public benefit or service programs;
 - procedures for obtaining benefits or services under those programs;
 - possible changes in or alternatives to those programs or procedures; or
 - possible changes in methods or levels of payment for benefits or services under those programs; and the research could not practicably be carried out without the waiver or alteration.

Note: This is circumstance is extremely rare.

Or

- The research meets the constraints of federal regulations:
 - It involves no more than minimal risk to the subjects;
 - The waiver or alteration will not adversely affect the rights and welfare of the subjects;

- o The research could not practicably be carried out without the waiver or alteration;
- o Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

REFERENCES

AAHRPP II-7.E. The RRU has and follows written policies and procedures for approving waiver or alteration of the consent process.

[OHRP Guidance on Written IRB Procedures](#), B(3): In approving a waiver, the IRB must document four findings which should be included in the minutes, with protocol-specific information. 45 CFR 46.116(d) states:

(d) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

- (1) the research involves no more than minimal risk to the subjects;
- (2) the waiver or alteration will not adversely affect the rights and welfare of the subjects;
- (3) the research could not practicably be carried out without the waiver or alteration; and
- (4) whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Procedure documents in M:\LSz\Procedures

[Further detail](#) on this guidance is available on the ORSP website.

F. Exceptions in emergency situations

Federal regulations do not permit exceptions to informed consent in emergency situations. *In no way does the federal regulation attempt to limit the authority of the physician to provide emergency medical care.* However, physicians who use investigational device(s) or medication in the course of emergency medical care *cannot consider the patient as a research subject at the time of the emergency or anytime in the future.* As the majority of researcher carried out at Rutgers is social-behavioral in nature, this section will not be applicable to the majority of researchers.

What are the FDA requirements for using investigational drugs, devices, or biologics for emergency care?

FDA regulations allow for the use of investigational drugs only if that research is approved by an appropriately constituted IRB. However, the FDA does have provisions for emergency exemptions for the use of investigational drugs, agents, biologics or devices free from IRB review. Emergency use is defined as;

“a life threatening situation in which no standard acceptable treatment is available, and there is insufficient time to convene a quorum for full-board IRB approval. [21 CFR 56.102(d)]”

OHRP Guidance on Written IRB Procedures, A(3) :**IRB Review in Emergency Situations.** DHHS regulations do not permit human subject research activities to be started, even in an emergency, without prior IRB review and approval. It is the policy of the Rutgers University IRB that when emergency medical care is initiated without prior IRB review and approval, the patient may not be considered a research subject under 45 CFR Part 46. Such emergency care may not be claimed as research, nor may any data regarding such care be included in any report of a prospectively conceived research activity. When emergency care involves investigational drugs, devices, or biologics, FDA requirements must be satisfied before any emergency use of an investigational drug, agent, biologic or device commences.

If the conditions of an emergency situation have been met, prior IRB approval is not required in order to provide one patient the test article. Rather, the IRB must be notified either before or within 5 days of the emergency use of the test article. The investigator must generate a letter to the IRB Chairperson describing the emergency-use situation. The letter must document that the situation is an emergency situation as defined above. The IRB Chairperson or appropriate designee (IRB member with appropriate medical knowledge) reviews the situation to verify that an emergency situation does indeed exist and that there is not enough time to convene a full-board IRB meeting. The IRB will then generate a letter to be signed by the IRB Chairperson acknowledging the notification of emergency use of the test article. This letter simply states acknowledgement of the notification of emergency use, it should not indicate any sort of IRB review or approval

of the situation. FDA regulations require that any subsequent use of the investigational product at the institution have prospective IRB review and approval. The only exception to this provision is if the IRB has not had sufficient time to convene a meeting to review a protocol. Subsequent emergency use of an investigational (unapproved) medical device may not occur unless the Investigator or another person obtains approval of an Investigational Device Exemption (IDE) for the device and its use. If an IDE application for subsequent use has been filed with the FDA and the FDA disapproves the IDE application, the device may not be used even if the circumstances constituting an emergency exist.

It is important to note that none of the above supersedes the informed consent process. Even in an emergency situation, informed consent must be sought and the patient must be informed that the treatment they are receiving is experimental in nature. This consent form is typically not a standard consent form with IRB review and approval but is usually provided by the drug sponsor or manufacturer who is providing the investigational drug, agent, biologic or device.

When is it appropriate to waive informed consent in emergency research?

In addition to the above regulations to waive informed consent, federal regulations allow the waiver of informed consent in emergency research if certain conditions have been met. Emergency research is defined as

“research conducted in participants who are in a life-threatening or emergent situation, where available treatments are unproven or unsatisfactory, and the collection of valid scientific evidence, which may include evidence obtained through randomized placebo-controlled investigations, is necessary to determine the safety and effectiveness of particular interventions [21CFR50.24(a)(1)]”.

The IRB can review and approve a clinical investigation not subject to FDA regulations without requiring the informed consent of all research subjects be obtained if the IRB (with the concurrence of a licensed physician who is a member of or consultant to the IRB and who is not otherwise participating in the clinical investigation) finds and documents each of the following:

- The research does not meet FDA regulations as stated in 21 CFR 56.
- The target population for the research is in a life-threatening situation, available treatments are unproven or unsatisfactory, and the collection of valid scientific evidence, which may include evidence obtained through randomized placebo-controlled investigations, is necessary to determine the safety and effectiveness of particular interventions.
- Obtaining informed consent is not feasible because:
 1. The subjects will not be able to give their informed consent as a result of their medical condition;

2. The intervention under investigation must be administered before consent from the subjects' legally authorized representatives is feasible; and
 3. There is no reasonable way to identify prospectively the individuals likely to become eligible for participation in the clinical investigation.
- Participation in the research holds out the prospect of direct benefit to the subjects because:
 1. The subjects are facing a life-threatening situation that necessitates intervention;
 2. Appropriate animal and other preclinical studies have been conducted, and the information derived from those studies and related evidence support the potential for the intervention to provide a direct benefit to the individual subjects; and
 3. The risks associated with the investigation are reasonable in relation to what is known about the medical condition of the potential class of subjects, the risks and benefits of the proposed intervention or activity.
 - The clinical investigation could not practicably be carried out without the waiver.
 - The proposed investigational plan defines the length of the potential therapeutic window based on scientific evidence, and the Investigator has committed to attempting to contact a legally authorized representative for each subject within that window of time and, if feasible, to asking the legally authorized representative contacted for consent within that window rather than proceeding without consent. The Investigator must agree to summarize efforts made to contact legally authorized representatives and make this information available to the IRB at the time of continuing review.
 - The IRB has reviewed and approved informed consent procedures and an informed consent document consistent with Federal regulations and IRB policies and procedures. The informed consent procedures and the informed consent document are to be used with subjects or their legally authorized representatives in situations where use of such procedures and documents is feasible.
 - Additional protections of the rights and welfare of the subjects will be provided, including, at least:
 1. Consultation (including, where appropriate, consultation carried out by the IRB) with representatives of the communities in which the clinical investigation will be conducted and from which the subjects will be drawn;
 2. Prior to the initiation of the clinical investigation, public disclosure to the communities in which the clinical investigation will be

conducted and from which the subjects will be drawn of plans for the investigation and its risks and expected benefits;

3. At the completion of the clinical investigation there are plans for Public disclosure of sufficient information to apprise the community and researchers of the study. The information must include the demographic characteristics of the research population and results of the clinical investigation.
4. Establishment of an independent data and safety monitoring committee to exercise oversight of the clinical investigation; and
5. If obtaining informed consent is not feasible and a legally authorized representative is not reasonably available, the Investigator must commit to attempting to contact within the therapeutic window, the subject's family member who is not a legally authorized representative, and asking whether he/she objects to the subject's participation in the clinical investigation. The Investigator will summarize efforts made to contact family members and make this information available to the IRB at the time of continuing review.

If the emergency research is subject to FDA regulations, than all the above conditions must be met and documented by the IRB as well as the following:

- Procedures must be in place to inform, at the earliest feasible opportunity, each subject, or if the subject remains incapacitated, a legally authorized representative of the subject, or if such a representative is not reasonably available, a family member, of the subject's inclusion in the clinical investigation, the details of the investigation and other information contained in the informed consent document, specifically that the he/she may discontinue the subject's participation at any time without penalty or loss of benefits of which the subject is other wise entitled.
- If a legally authorized representative or family member is told about the clinical investigation and the subject's condition improves, the subject is also to be informed as soon as feasible.
- If a subject is entered into a clinical investigation with waived consent and the subject dies before a legally authorized representative or family member can be contacted, information about the clinical investigation is to be provided to the subject's legally authorized representative or family member, if feasible.
- All clinical investigation records, including regulatory files, must be maintained for at least 3 years after the completion of the clinical investigation and will be accessible for inspection and copying by the regulatory authorities, as applicable.
- Clinical investigations that are granted an exception to the informed consent requirement under this section must be performed under a separate investigational

new drug application (IND) or investigational device exemption (IDE) that clearly identifies that the clinical investigation may include subjects who are unable to consent. The submission of these clinical investigations to the FDA for a separate IND/IDE is required even if an IND for the same drug product or an IDE for the same device already exists. Applications for this IND/IDE may not be submitted as an amendment to the existing IND/IDE.

- If the IRB determines it cannot approve a request for exception from informed consent requirements in emergency research because the clinical investigation does not meet the criteria according to Federal regulations, IRB policies and procedures, or other relevant ethical concerns, the IRB must document its findings and provide these findings promptly in writing to the clinical investigator who will forward to the sponsor of the clinical investigation.

REFERENCES:

AAHRPP II-7.F. The RRU has and follows written policies and procedures for making exceptions to informed consent requirements in protocols for emergency situations and appropriately reviews such protocols.

Elizabeth A. Bankert & Robert J. Amdur. (2002) "Compassionate Use" and Emergency Exemption from IRB Approval. In Amdur, R. & Bankert, E. *Institutional Review Board: Management and Function*. Sudbury MA: Jones and Bartlett Publishers, pp. 129-131.

Helen McGough (2002). Waiver of Consent in Emergency Medicine Research. In Amdur, R. & Bankert, E. *Institutional Review Board: Management and Function*. Sudbury MA: Jones and Bartlett Publishers, pp. 132-139.

OHRP Guidance Document; Emergency Research Informed Consent Requirements (OPRR 96-01)

45 CFR 46 Waiver Of Informed Consent Requirements in Certain Emergency Research (Federal Register, Vol. 61, No. 192, pp. 51531-51533, October 2, 1996)

21 CFR 56

45 CFR 46

Procedure documents in M:\LSz\Procedures

G. Monitoring the consent process in ongoing research

RU ORSP has developed procedures for on-site monitoring, to review records and observe a study's informed consent process. In May of 2004, Rutgers University initiated the Human Subjects Assessment Initiative Program.

Protecting the people who participate in the many human subjects research activities at Rutgers is of the utmost importance to researchers and the University. The Office of Research and Sponsored Programs (ORSP), in conjunction with the Institutional Review Board for the Protection of Human Subjects (IRB), established the Assessment Initiative. As part of the IRB Quality Assurance Program, the Assessment Initiative, is meant to serve as an educational as well as an assessment tool for both researchers and administrators and gives researchers an opportunity to review their on-going protocols. During the process, administrators learn first hand of the concerns researchers encounter when conducting human subjects research, and take them into account as policies and procedures are refined and developed. Through an open dialogue regarding the federal requirements, researchers will continue to improve their understanding of the expectations for human subjects research. It will improve the human subjects program at Rutgers for researchers, administration and most importantly, the people who participate in the research.

The Assessment Initiative helps fulfill Rutgers' obligation to self-monitor the human subjects program in accord with our Federalwide Assurance agreement with OHRP.

There are two key elements of the program:

1. **Self-assessment.** All investigators will participate in this aspect.
2. **Face-to-face assessment.** A small percentage of investigators will be selected to participate in this aspect.

An overview of the Assessment Initiative is as follows:

1. All researchers complete the self-assessment portion for each of their non-exempt protocols. The first step is to organize the protocol related documents. *Documentation for the Human Subjects Assurance Initiative* describes the information that is necessary for researchers to organize. It can be found on-line at: <<http://orsp.rutgers.edu/Humans/assessmentdoc.asp>>.
2. Researchers will also complete a Self-Assessment Checklist. The easy to use form can be found on-line at <https://www.rci.rutgers.edu/~orsp/selfassess/selfassess.php>. This checklist was refined as the result of a pilot project conducted with IRB members and Liaisons to the IRB.
3. Protocols in which participation has been determined to be at greater than minimal risk by the IRB will be given priority for participating in the **face-to-face assessment**. In most cases the selection will be done at random.

In addition to the program above, the RU IRB approval letter sent to investigators includes the following sentence: “Please note that the IRB has the authority to observe, or to have a third party observe, the consent process or the research itself.”

The Rutgers University IRB procedures for requiring a continuing review of periods less than the one-year duration of approval for a research protocol is outlined in Standard II-2D. The RU IRB will be guided by this standard when considering if the consent process of ongoing research should be monitored. The two reasons the IRB may decide to monitor ongoing consent procedures are as follows:

1. In an instance of previous noncompliance with federal or university regulations for the protection of human participants in research the IRB will grant less than an annual review in order to verify prospective compliance.
2. Elements of risk, coercion, unconventional study design, conflict of interest on the part of the PI or the characteristics of the participant population as described in the protocol may, in the IRB’s judgment, warrant monitoring the consent process.

The RU IRB will appoint a member of the IRB or an independent agent with no ties or affiliations to the research or investigator to act as the monitor.

REFERENCES:

AAHRPP II-7.G. The RRU has procedures for monitoring of the informed consent process in ongoing research, when appropriate.

Sample NOTICE OF REVIEW AND APPROVAL: IRB Policies and Procedures XV, Attachment 2.

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